Washington Township Health Care District
2000 Mowry Avenue, Fremont, California 94538-1716 | 510.797.1111
Kimberly Hartz, Chief Executive Officer

BOARD OF DIRECTORS MEETING

Wednesday, April 14, 2021 – 6:00 P.M.
Meeting Conducted by Zoom
https://us02web.zoom.us/j/89213605448?pwd=MnZqSFAyUHFTTEtDR3JLeVpLM0poUT09
Password: 549676

AGENDA

		PRESENTED BY:
I.	**CALL TO ORDER & PLEDGE OF ALLEGIANCE**	William Nicholson, M.D. Board President
II.	**ROLL CALL**	Dee Antonio District Clerk
III.	**COMMUNICATIONS**	
	A. Oral *This opportunity is provided for persons in the audience to make a brief statement, not to exceed three (3) minutes on issues or concerns not on the agenda and within the subject matter of jurisdiction of the Board.. "Request to Speak" cards should be filled out in advance and presented to the District Clerk. For the record, please state your name.*	
	B. Written	
IV.	**CONSENT CALENDAR** *Items listed under the Consent Calendar include reviewed reports and recommendations and are acted upon by one motion of the Board. Any Board Member or member of the public may remove an item for discussion before a motion is made.*	William Nicholson, M.D. Board President *Motion Required*
	A. Consideration of Minutes of the Regular Meetings of the District Board: March 10, 15, 22, and 24, 2021	
	B. Consideration of Cepheid Diagnostics c360 and GeneXpert Xpress (POC) PCR Instruments	
	C. Consideration of Institutional Review Board (IRB) Policies:	

D. Consideration of Medical Staff: Revisions to the Moderate Sedation Privileges Form

E. Consideration of Center for Joint Replacement Garden Level Clinic X-ray Machine

V.	**PRESENTATION** A. COVID-19: Vaccine Rollout and Current State of the Pandemic	Stephen Catalya, M.D. Infectious Disease Specialist and Jeffrey Stuart, M.D. Chief Medical Officer
VI.	**REPORTS**	**PRESENTED BY:**
	A. Medical Staff Report	Prasad Kilaru, M.D. Chief of Medical Staff
	B. Service League Report	Debbie Feary Service League President
	C. Lean Presentation: Reducing Hospital Acquired Pressure Injuries in the Intensive Care Unit	Erin Brooks, RN, MSN Nurse Manager, Critical Care and Intermediate Care Units
	D. Quality Report: 2021 Antimicrobial Stewardship / C. difficile	Dianne Martin, M.D. Infectious Diseases
	E. Finance Report	Chris Henry Vice President & Chief Financial Officer
	F. Hospital Operations Report	Kimberly Hartz Chief Executive Officer
VII.	**ANNOUNCEMENTS**	Kimberly Hartz Chief Executive Officer
VIII.	**ADJOURN TO CLOSED SESSION** *In accordance with Section 32106 and 32155 of the California Health & Safety Code, portions of this meeting may be held in closed session.*	

A. Report of Medical Staff and Quality Assurance Committee, Health & Safety Code section 32155

IX.	**RECONVENE TO OPEN SESSION & REPORT ON PERMISSIBLE ACTIONS TAKEN DURING CLOSED SESSION**	William Nicholson, M.D. Board President
X.	**ADJOURNMENT**	William Nicholson, M.D. Board President

In compliance with the Americans with Disabilities Act, if you need assistance to participate in this meeting, please contact the District Clerk at (510) 818-6500. Notification two working days prior to the meeting will enable the District to make reasonable arrangements to ensure accessibility to this meeting.

CALL TO ORDER

PLEDGE OF ALLEGIANCE

A meeting of the Board of Directors of the Washington Township Health Care District was held on Wednesday, March 10, 2021 via Zoom in order to comply with California Governor Gavin Newsom's and Alameda County's mandatory orders as revised on January 25, 2021 to comply with social distancing measures and other restrictions necessary to control the spread of COVID-19. Director Nicholson called the meeting to order at 6:04 pm and led those in attendance of the meeting in the Pledge of Allegiance.

ROLL CALL

Roll call was taken: Directors present: William Nicholson, MD; Jeannie Yee; Bernard Stewart, DDS; Jacob Eapen, MD; Michael Wallace
Absent:

Also present: Kimberly Hartz, Chief Executive Officer; Dee Antonio, District Clerk

Guests: Ed Fayen, Chris Henry, Tina Nunez, Stephanie Williams, Paul Kozachenko, Prasad Kilaru MD, Emi Yoshida MD Mary Bowron, John Lee, Angus Cochran, Jeff Stuart MD, Gisela Hernandez, Debbie Feary, Kel Kanady, Walter Choto, Kranthi Achanta MD, and Sri Boddu.

OPENING REMARKS

Director Nicholson welcomed any members of the general public to the meeting. He stated that Governor's Newsom's Executive Order N-29-20 explicitly waives The Brown Act provision that requires physical presence of members, the clerk or other personnel of the body, or of the public as a condition of participation in, or quorum for, a public meeting. He noted that Washington Township Health Care District continues to comply with the Brown Act in providing appropriate connection information in order to provide the public the opportunity to participate in the meeting and that Public Notice for this meeting, including connection information, was posted appropriately on our website.

Director Nicholson announced that this meeting, conducted via Zoom, will be recorded for broadcast at a later date. When asked if any members of the general public were in attendance and/or interested in speaking, there was no response.

CONSENT CALENDAR

Director Nicholson presented the Consent Calendar for consideration:

A. Minutes of the Regular Meetings of the District Board: February 10, February 22, and February 24, 2021
B. Special Care Nursery Digital Detector
C. Depuy Mini Fragment LCP System

In accordance with District law, policies, and procedures, Director Eapen moved that the Board of Directors approve the Consent Calendar, items A through C. Director Wallace seconded the motion.

Roll call was taken:

William Nicholson, MD – aye
Jeannie Yee – aye
Bernard Stewart, DDS – aye
Jacob Eapen, MD – aye
Michael Wallace – aye

The motion unanimously carried.

COMMUNICATIONS: ORAL

There were no Oral communications.

COMMUNICATIONS: WRITTEN

There were no Written communications.

PRESENTATION: WASHINGTON RADIATION ONCOLOGY: THE STATE OF THE ART IN OUR COMMUNITY

Kimberly Hartz, CEO, introduced Dr. Emi Yoshida, Medical Director of the UCSF-Washington Hospital Radiation Oncology Center. She specializes in the treatment of gynecologic and breast malignancies with expertise in HDR brachytherapy. Dr. Yoshida began her presentations with updates on the Washington Radiation Oncology Center (WROC) and gave a brief history of radiation therapy. She talked about Radiation Oncology and explained how radiation treats cancer. She demonstrated the new capabilities at the WROC such as Image Guided Radiation Therapy (IGRT), Stereotactic Body Radiotherapy (SBRT), and Stereotastic Ablative Body Radiation (SABR).

MEDICAL STAFF REPORT

Dr. Prasad Kilaru reported there are 584 Medical Staff members including 355 active members and 97 ambulatory members. Dr. Kilaru reported the Quarterly Medical Staff meeting recently took place and the medical staff is beginning its election process. Mark Salah MD has been nominated as Chief of Staff-Elect and Tim Tsoi MD has been nominated as Medical Staff Liaison. Plans are underway for some type of "dinner/dance" at the end of May.

SERVICE LEAGUE REPORT

Ms. Debbie Feary, Service League President reported that the Service League members elected a new slate of officers for 2021-22. During the pandemic, the Service League has suspended a majority of volunteering activities, but have been supporting a few special projects including: building COVID-19 test kits for the laboratory; labeling empty syringes for the pharmacy; assisting community members in the vaccination clinic; filing documents in human resources; and limited Gift Shop operations.

QUALITY REPORT: QUALITY DASHBOARD QUARTER ENDING DECEMBER 31, 2020

Mary Bowron, Chief of Quality and Resource Management presented the Quality Dashboard for the quarter ending December 30, 2020 comparing WHHS statistics to State and National benchmarks. We had Zero MRSA Bloodstream Infections, zero VRE Infections, and zero Central Line Associated Bloodstream Infections this past quarter and this past quarter. Catheter Associated Urinary Tract Infection: Our infection rate was higher than predicted at 1.418 (2 CAUTI). C-Difficile: We were lower than predicted this past quarter with 8 infections. We had no infections following colon surgery which was below the predicted number of infections. We had no infections following abdominal hysterectomy which was below the predicted number of infections. Hand Hygiene was at 85%.

Our moderate fall with injury rate was lower than the national rate for the quarter at 2.94. Hospital Acquired Pressure Ulcer rate was below the national rate this past quarter.

We had a higher percent of 30-day medicare pneumonia readmissions compared to the CMS national benchmark (31.7% versus 16.6%). Our 30-day readmission rate

for AMI discharges was below the CMS benchmark (13.2% versus 16.1%). 30-day Medicare Heart Failure readmissions were higher (22.8% versus 21.9%) than the CMS benchmark. Our 30-day Medicare CABG readmission rate was lower (0.0% versus 12.7%) than the CMS benchmark. Our 30-day Medicare Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) was lower than the CMS benchmark (2.7% versus 4.0%). Our 30-day Medicare Chronic Obstructive Pulmonary Disease (COPD) readmission rate was higher than the CMS benchmark (23.5% versus 19.6%).

FINANCE REPORT

Chris Henry, Vice President & Chief Financial Officer, presented the Finance Report for January 2021. The average daily census was 181.3 with admissions of 789 resulting in 5,620 patient days. Outpatient observation equivalent days were 179. The average length of stay was 7.49 days; note that there were a few patients who were discharged in January following very long lengths of stay. The case mix index was 1.743. Deliveries were 91. Surgical cases were 286. Joint Replacement cases were 117. Neurosurgical cases were 18. Cardiac Surgical cases were 6. The Outpatient visits were 6,571; Emergency visits were 3,712. Total productive FTEs were 1,381.2. FTEs per adjusted occupied bed were 6.09.

HOSPITAL OPERATIONS REPORT

Kimberly Hartz, Chief Executive Officer, presented the Hospital Operations Report for February 2021. Preliminary information for the month indicated total gross revenue at approximately $167,409,000. The Average Length of Stay was 6.83. The Average Daily Census was 154.1. It was noted that COVID-19 patients have a significantly higher than average acuity and length of stay. Of the 107 discharges in the month, there were three outliers with lengths of stays at 85, 111, and 247 days. Excluding these, the ALOS was 5.6. There were 4,315 patient days. There were 316 Surgical Cases and 332 Cath Lab procedures at the Hospital. Deliveries were 92. Non-Emergency Outpatient visits were 6,539. Emergency Room visits were 3,077. Total Government Sponsored Preliminary Payor Mix was 71.7%, against the budget of 71.5%. Total FTEs per Adjusted Occupied Bed were 6.59. The Washington Outpatient Surgery Center had 383 cases and the clinics had approximately 15,490 visits.

ANNOUNCEMENTS

- Anthony Baldosano, Certified Nursing Assistant, 6 West, is the March Employee of the Month.
- Kimberly Hartz gave an update on the Community Vaccination Clinic: 17,645 vaccinations in total (11,549 people vaccinated).

ADJOURNMENT

There being no further business, Director Nicholson adjourned the meeting at 8:00 pm.

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William F. Nicholson, M.D. Michael J. Wallace
President Secretary

CALL TO ORDER

A regular meeting of the Board of Directors of the Washington Township Health Care District was held on Monday, March 15, 2021 via Teleconference in order to comply with California Governor Gavin Newsom's and Alameda County's mandatory orders as revised on January 25, 2021 to comply with social distancing measures and other restrictions necessary to control the spread of COVID-19. Director Nicholson called the meeting to order at 6:00 p.m. and led those present in the Pledge of Allegiance.

ROLL CALL

Roll call was taken. Directors present: William Nicholson, MD; Jeannie Yee; Bernard Stewart, DDS; Jacob Eapen, MD; Michael Wallace

Absent:

Also present: Kimberly Hartz, Chief Executive Officer; Ed Fayen, Chief Operating Officer; Chris Henry, Chief Financial Officer; Tina Nunez, Vice President; Stephanie Williams, Vice President; Paul Kozachenko, Legal Counsel; Dee Antonio, District Clerk

COMMUNICATIONS

There were no oral communications.

There were no written communications.

ADJOURN TO CLOSED SESSION

In accordance with Health & Safety Code Sections 32106 and 32155 and California Government Code 54956.9(d)(2), Director Nicholson adjourned the meeting to closed session at 6:04 p.m., as the discussion pertained to a trade secret pursuant to Health & Safety Code section 32106: Strategic Considerations pursuant to Investments and a Report of Medical Staff and Quality Assurance pursuant to Health & Safety Code Section 32155. Director Nicholson stated that the public has a right to know what, if any, reportable action takes place during closed session. Since this is a Teleconference call and we have no way of knowing when the closed session will end, the public was informed they could contact the District Clerk for the Board's report beginning March 16, 2021. He indicated that the minutes of this meeting will reflect any reportable actions.

RECONVENE TO OPEN SESSION & REPORT ON CLOSED SESSION

Director Nicholson reconvened the meeting to open session at 7:08 pm and reported that no permissible action was taken in closed session.

ADJOURNMENT

There being no further business, Director Nicholson adjourned the meeting at 7:08 pm.

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William Nicholson, M.D.
President

Michael J. Wallace
Secretary

CALL TO ORDER

A meeting of the Board of Directors of the Washington Township Health Care District was held on Monday, March 22, 2021 via Zoom in order to comply with Alameda County's orders as issued on January 25, 2021to slow the spread of COVID-19 and reduce the rate of transmission by sheltering at home and continued social distancing. Director Nicholson called the meeting to order at 7:30 a.m.

ROLL CALL

Roll call was taken. Directors present: William Nicholson, MD; Bernard Stewart DDS; Jeannie Yee
Excused: Jacob Eapen; Michael Wallace

Also present: Shakir Hyder, MD; Tim Tsoi, MD; Jeff Stuart, MD; Prasad Kilaru, MD; Jan Henstorf, MD; Kranthi Achanta, MD; Kimberly Hartz, Chief Executive Officer; Stephanie Williams, Vice President & Chief Nursing Officer

COMMUNICATIONS

There were no oral or written communications.

ADJOURN TO CLOSED SESSION

Director Nicholson adjourned the meeting to closed session at 7:30 a.m. as the discussion pertained to Medical Audit and Quality Assurance Matters pursuant to Health & Safety Code Sections 1461 and 32155.

RECONVENE TO OPEN SESSION & REPORT ON CLOSED SESSION

Director Nicholson reconvened the meeting to open session at 8:20 a.m. and reported no reportable action taken in closed session.

ADJOURNMENT

There being no further business, the meeting adjourned at 8:20 a.m.

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William Nicholson, M.D.
President

Michael Wallace
Secretary

CALL TO ORDER

A regular meeting of the Board of Directors of the Washington Township Health Care District was held on Wednesday, March 24, 2021 via Teleconference in order to comply with Alameda County's orders as issued on January 25, 2021 to slow the spread of COVID-19 and to maintain restrictions on movement and public gathering. Director Nicholson called the meeting to order at 6:01 p.m. and led those present in the Pledge of Allegiance.

ROLL CALL

Roll call was taken. Directors present: William Nicholson, MD; Jeannie Yee; Bernard Stewart, DDS; Jacob Eapen, MD; Michael Wallace

Absent:

Also present: Kimberly Hartz, Chief Executive Officer; Ed Fayen, Executive Vice President & COO; Chris Henry, Vice President & CFO; Tina Nunez, Vice President; Stephanie Williams, Vice President; Paul Kozachenko, Legal Counsel; Nicholas Kozachenko, Legal Counsel; Dee Antonio, District Clerk; Sri Boddu

COMMUNICATIONS

There were no oral communications.

There were no written communications.

CONSENT CALENDAR

Director Nicholson presented the Consent Calendar for consideration:

A. Preliminary Report Interface from our After-Hour Advanced Tele-Radiology Services to EPIC

B. PowerPath and Blood Bank System Upgrades

C. Copier Equipment Funding

In accordance with District law, policies, and procedures, Director Stewart moved that the Board of Directors approve the Consent Calendar, items A through C.

Director Yee seconded the motion.

Roll call was taken:

William Nicholson, MD – aye
Jeannie Yee – aye
Bernard Stewart, DDS – aye
Jacob Eapen, MD – aye
Michael Wallace – aye

The motion unanimously carried.

CONSIDERATION OF RESOLUTION No. 1221: RESOLUTION OF THE BOARD OF DIRECTORS OF WASHINGTON TOWNSHIP HEALTH CARE DISTRICT TO APPROVE AMENDED AND RESTATED

In accordance with District Law, Policies, and Procedures, Director Eapen moved that the Board of Directors approve Resolution No. 1221 the Amended and Restated Bylaws and authorize the President and Secretary to execute these Bylaws.

Director Yee seconded the motion.

Paul Kozachenko informed the Board of two additions that he recommended incorporating into the Bylaws based on his further review of the Medical Staff

BYLAWS FOR THE BOARD OF DIRECTORS

Bylaws which are referenced in the Amended and Restated Bylaws. The additions are specifically related to the Medical Staff Membership:

- Article 6, Section 2 Membership: Membership in the Medical Staff shall be comprised of all physicians, dentists and podiatrists who are duly licensed, competent in their respective fields, worthy in character and in professional ethics and privileged to attend to patients in the Hospital and shall include all categories identified in the Medical Staff Bylaws (described below in Section 3).
- Article, Section 6 Allied Health Professionals: The categories of allied health professionals eligible to hold specific practice privileges to perform services within the scope of their licensure, certification or other legal authorization, and the corresponding privileges, prerogatives, terms and conditions for each such allied health professional category or practitioner shall be determined by the Board of Directors upon recommendations received from the Medical Staff executive committee. The Medical Staff shall have the responsibility and authority to investigate and evaluate each application by an allied health professional for satisfaction of relevant eligibility requirements in accordance with the Medical Staff Bylaws, rules and regulations.

Following discussion, the motion was amended by Director Wallace that the Board of Directors approve Resolution No. 1221 the Amended and Restated Bylaws with the incorporation of the additions as discussed and authorize the President and Secretary to execute these Bylaws.

Director Yee seconded the amended motion.

Roll call was taken:

William Nicholson, MD – aye
Jeannie Yee – aye
Bernard Stewart, DDS – aye
Jacob Eapen, MD – aye
Michael Wallace – aye

The motion unanimously carried.

CONSIDERATION OF RESOLUTION No. 1222: RESOLUTION OF THE BOARD OF DIRECTORS OF WASHINGTON TOWNSHIP HEALTH CARE DISTRICT TO APPROVE THE DELEGATION OF THE SECRETARY'S DUTIES

In accordance with District Law, Policies, and Procedures, Director Eapen moved that the Board of Directors approve Resolution No. 1222 to approve the delegation of the Secretary's duties in accordance with Section 54957.2 of the Government Code.

Director Yee seconded the motion.

Roll call was taken:

William Nicholson, MD – aye
Jeannie Yee – aye
Bernard Stewart, DDS – aye

Jacob Eapen, MD – aye
Michael Wallace – aye

The motion unanimously carried.

CONSIDERATION OF RESOLUTION No. 1223: RESOLUTION OF THE BOARD OF DIRECTORS OF WASHINGTON TOWNSHIP HEALTH CARE DISTRICT TO APPROVE THE DELEGATION OF THE TREASURER'S DUTIES

In accordance with District Law, Policies, and Procedures, Director Eapen moved that the Board of Directors approve Resolution No. 1223 to approve the delegation of the Treasurer's duties in accordance with Section 54957.2 of the Government Code.

Director Yee seconded the motion.

Roll call was taken:

William Nicholson, MD – aye
Jeannie Yee – aye
Bernard Stewart, DDS – aye
Jacob Eapen, MD – aye
Michael Wallace – aye

The motion unanimously carried.

CONSIDERATION OF BLUE SHIELD THIRD PARTY ADMINISTRATOR AGREEMENT

In accordance with District Law, Policies, and Procedures, Director Eapen moved that the Board of Directors authorize the Chief Executive Officer to proceed with entering into the COVID-19 Vaccination Program Vaccine Provider Participation Agreement with Blue Shield of California and to take all actions, including entering into any amendments or modifications to the Agreement, which are consistent with the District's intent to continue to serve as a provider of the vaccines to our community.

Director Wallace seconded the motion.

Roll call was taken:

William Nicholson, MD – aye
Jeannie Yee – aye
Bernard Stewart, DDS – aye
Jacob Eapen, MD – aye
Michael Wallace – aye

The motion unanimously carried.

ADJOURN TO CLOSED SESSION

In accordance with Health & Safety Code Sections 32106 and 32155 and California Government Code 54956.9(d)(2), Director Nicholson adjourned the meeting to closed session at 6:33 p.m., as the discussion pertained to a trade secret pursuant to Health & Safety Code section 32106: New Service or Program and Strategic Plan Update; and a Report of Medical Staff and Quality Assurance pursuant to Health & Safety Code Section 32155: Medical Staff Credentials Report. Director Nicholson stated that the public has a right to know what, if any, reportable action takes place

during closed session. Since this is a Teleconference call and we have no way of knowing when the closed session will end, the public was informed they could contact the District Clerk for the Board's report beginning March 25, 2021. He indicated that the minutes of this meeting will reflect any reportable actions.

RECONVENE TO OPEN SESSION & REPORT ON CLOSED SESSION

Director Nicholson reconvened the meeting to open session at 8:46 pm. The District Clerk reported that the Board approved the Medical Staff Credentials Report in closed session by unanimous vote of all Directors present:

William Nicholson, MD – aye
Jeannie Yee – aye
Bernard Stewart, DDS – aye
Jacob Eapen, MD – aye
Michael Wallace – aye

ADJOURNMENT

There being no further business, Director Nicholson adjourned the meeting at 8:47 pm.

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William Nicholson, M.D.
President

Michael J. Wallace
Secretary

Washington Hospital Healthcare System
SINCE 1948

Memorandum

DATE: March 31, 2021

TO: Kimberly Hartz, Chief Executive Officer

FROM: Tina Nunez, VP Ambulatory and Administrative Services

SUBJECT: Cepheid Diagnostics c360 and GeneXpert Xpress (POC) PCR Instruments

The laboratory at WHHS has been working with Cepheid to purchase their GeneXpert Xpress analytical systems, which has received EUA approval to run a COVID-19 assay. These contracts are being offered to only 20 hospitals in the country and WHHS is being included since we helped with customer feedback this summer on one of their point-of-care devices. The sensitivity of the test is similar to the other Covid PCR tests that WHHS laboratory runs. We would like to purchase these as a way to decrease our monthly send out testing expense and reduce the time that we are asking patients to get tested and quarantine prior to a procedure. By bringing the testing in-house, overall cost is less and revenue is increased. In addition, the turnaround time on the machine is hours, whereas now it takes days to get the results from the reference lab. The intent is to do all of the pre-procedure testing on these devices.

We currently do approximately 1,500 COVID PCR pre-procedure tests per month. Cepheid will allocate 250 tests per month for a device. The request is for seven POC devices in order to bring all pre-procedure testing in-house. We are recommending moving forward with this purchase in the amount of $79,275.

In accordance with District Law, Policies and Procedures, it is requested that the Board of Directors authorize the Chief Executive Officer to proceed with entering into the necessary agreement and to move forward with the purchase of the equipment in the amount not to exceed $79,275. This expense is being covered by the Washington Hospital Healthcare Foundation through the Covid Relief Fund. It was not included in the Fiscal Year 2020/21 Fixed Asset Capital Budget.

Washington Hospital Healthcare System

SINCE 1948

Memorandum

DATE: March 30, 2021

TO: Kimberly Hartz, Chief Executive Officer

FROM: Kristin Ferguson, R.N., IRB Administrator/Chief of Compliance

SUBJECT: Revision of the Policies and Procedures of the Institutional Review Board (IRB)

Attached are the revised IRB Policies and Procedures. The revisions have been approved by the members. The IRB requests approval by the Board of Directors.

In addition to minor language and formatting corrections, the following changes are included in the revised document:

- Addition of a section entitled "Exempt Research." This clarifies that the Final Common Rule includes a list of exempt research. Exempt research includes human subjects studies that present no greater than minimal risk to subjects and fit into one or more exempt categories. Exempt research must be initially reviewed by the IRB, but is then exempt from further review. The IRB Administrator or designee will review proposed research to determine if an exemption applies.

- Addition of a section entitled "Review by the Pre-IRB." This clarifies all research proposals and all correspondence directed to the IRB are reviewed by a group called the Pre-IRB, composed of the IRB Chairperson, the IRB Administrator, and a support person assigned by the IRB Administrator.

- Revision of the section entitled "Length of Appointment." This clarifies members shall serve on the IRB for a four-year term, with the option of reappointment for three additional four-year terms. This term limit becomes effective January 1, 2022.

- Addition of a member "Conflict of Interest" section. This clarifies possible conflicts of interest for IRB members, and includes a process where members will be asked to declare any potential or actual conflicts at the start of each meeting. A member with a conflicting interest may provide information and answer questions but cannot be present for the review, discussion or the vote on the research.

- Addition of a section entitled "Disclosure of Financial Interest by Researcher/Investigator Policy." This clarifies the financial disclosure obligations of researchers/investigators involved in sponsored research, and the establishment of a hospital Conflict of Interest Advisory Committee to oversee the disclosure and management of financial interests. The COIAC is comprised of:
    - The IRB Chairperson
    - The IRB Administrator
    - The Hospital legal counsel

    - The Hospital internal auditor
    - An additional member of the IRB from the same discipline as the researcher/investigator
    - At the IRB Chairperson's discretion, other persons from within or outside the IRB as appropriate to the specific situation

- Revisions to the section entitled "Expedited Review" to clarify the criteria for and the process to perform expedited review.
    - Only for minimal risk research

- Addition of a section entitled "Limited Review." This clarifies that limited review is an exemption to Regular Review. Limited Review may be used when there is broad consent in place for the storage, maintenance and secondary research use of identifiable information or identifiable specimens. The IRB may perform a Limited Review to ensure that broad consent was obtained for the use of stored identifiable data or biospecimen, and that the identifiable private information or biospecimen collected have adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

- Revision of section entitled "Intermediate Size Patient Populations and Treatment Protocol for Widespread Treatment Use." This section provides guidance on expanded access (sometimes referred to as compassionate use) for widespread treatment use. Expanded access is the use of an investigational drug or a device outside a clinical trial for the diagnosis, monitoring, or treatment of a serious disease or condition.

- Revision of the Glossary of Terms, Abbreviations, and Acronyms to reflect current research terminology.

Thank you for your assistance in forwarding the revised IRB Policies and Procedures to the Board of Directors for approval.

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Kristin Ferguson, R.N.
IRB Administrator
Chief of Compliance

Washington Hospital Healthcare System (WHHS)
Institutional Review Board (IRB)
Policies and Procedures

Revision 1-16-2021

Table of Contents

I. PREAMBLE

Federal and California law requires the establishment of an Institutional Review Board (IRB) for the protection of human subjects. Federal regulations establish standards for the functions, membership and organization of the IRB, and criteria for IRB review and approval of research.

References:

- Federal Policy- 45 CFR Part 46- Protection of Human Subjects (this was restated as the Final Common Rule effective January 21, 2019)
- Federal Policy- 42 CFR Part 50- Promoting Objectivity in Research
- Federal Policy- 21 CFR Part 50- Protection of Human Subjects
- Federal Policy- 21 CFR Part 56- Institutional Review Boards
- Federal Policy- 21 CFR Part 312- Investigational New Drug Application
- Federal Policy- 21 CFR Part 812- Investigational Device Exemption
- California Health & Safety Code Sections 24170-24179.5 and 111515-111545

Heretofore all reference to medical/clinical research, trials, studies or investigations shall be called "research." Research includes both interventions and inactions.

I. GLOSSARY OF TERMS, ABBREVIATIONS AND ACRONYMS

A glossary of terms, abbreviations and acronyms is included in this Policy as Appendix G.

II. STATEMENT OF PRINCIPLES AND ASSURANCES

The Washington Hospital Healthcare System (WHHS) IRB adopts the Belmont Report as its Statement of Principles and maintains a Federal Wide Assurance (FWA) for the Protection of Human Subjects for Domestic Institutions. The Belmont Report is attached as Appendix A.

III. AUTHORITY AND RESPONSIBILITY

The WHHS IRB is established by authority of the Washington Township Health Care District Board of Directors. The Board is responsible for reviewing and approving IRB Policies and Procedures. The Board of Directors may disapprove research that is approved by the IRB, but may not approve research that has not been approved by the IRB.

The Chief Executive Officer (CEO) is the Authorized Institutional Official, but delegates the administration of the IRB to the Chief of Compliance.

The IRB via the CEO will provide an annual status report to the Board of Directors.

IV. FUNCTION OF THE IRB

It is the responsibility of the IRB to assure the protection of human subjects of research, and to assure compliance with all state and federal laws pertaining to such research.

The IRB will ascertain the acceptability of proposed research in terms of institutional capability and mission and standards of professional conduct and practice.

A. IRB Function:

The IRB shall:

1. Establish policies and procedures to assure the protection of rights of human subjects of research.

2. Review, evaluate, approve or disapprove, suspend or restrict submitted research involving subjects in the Washington Hospital Healthcare System or conducted by an individual affiliated with the Healthcare System. Note: There must be a local researcher/investigator for research to be presented to the WHHS IRB.

3. Accept or reject research for local use that will be overseen by a Central IRB (CIRB).

4. Ensure that the Statement of Researcher/Investigator and Statement of Financial Interest are completed for all proposed research.

5. Notify the investigator(s) and the institution of its decision to approve or disapprove proposed research activity.

6. Require that information given to subjects as part of informed consent meets the criteria outlined in Section XXXI and XXXII of this Policy. Require that informed consent be documented. (Unless the informed consent requirement is waived or altered).

7. Ensure that appropriate personnel in departments impacted by the research understand their role in the research and have access to research documents.

8. Conduct continuing review of research at intervals appropriate to the risk, as described in Section XXVI of these Policies and Procedures.

9. Determine if the research requires evaluation from sources other than the researcher/investigator.

10. Require prompt reporting to the IRB by the researcher/investigator of serious adverse events, unanticipated problems and protocol deviations.

11. Require that changes in approved research are not initiated without IRB review and approval except when necessary to eliminate apparent, immediate hazards to the subject.

12. Suspend or terminate approval of research that is not conducted in accordance with the IRB's requirements or is associated with unanticipated serious harm to subjects and notify the appropriate authority accordingly.

Concern for the interests of subjects must prevail over the interests of science or society.

B. Research Requiring IRB Approval

Any research that involves a human subject about whom an investigator obtains data that:

1. Is designed to contribute to generalizable knowledge.

2. Involves human subjects and a test article subject to regulation by the Food and Drug Administration (FDA) and yields data which either is required to be submitted to or is otherwise intended to be submitted to or held for inspection by the FDA.

3. Is funded, conducted or supported directly or indirectly, by the Department of Health and Human Services (DHHS).

C. Exempt Research

The Final Common Rule includes a list of federally funded research that is exempt from the requirements of that regulation, including review by an IRB. The IRB Administrator or her designee will review proposed research to determine if an exemption applies. The Chairperson of the IRB retains the right to bring proposed research to the full IRB even if there is an applicable exemption.

D. Review by the Pre-IRB

In order to ensure timely and effective functioning of the IRB, all research proposals and all correspondence directed to the IRB are reviewed by a group called the Pre-IRB. This review occurs before the item is placed on the IRB agenda. Membership on the Pre-IRB includes, but is not limited to, the IRB Chairperson, the IRB Administrator and a support person assigned by the IRB Administrator. Others may be included at the discretion of the IRB Chairperson and/or the IRB Administrator.

The Pre-IRB may conduct Expedited Review, Facilitated Review and Limited Review.

V. MEMBERSHIP

A. Composition

The IRB shall have no fewer than five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted in the Washington Hospital community. At least one member shall be a licensed physician, at least one member shall be a scientist and at least one shall have primary concerns in a non-scientific area. In addition, the IRB shall have a least one member whose only affiliation with the Hospital is his or her membership on the IRB (a member of the immediate family of a person who is affiliated with the Hospital does not qualify). The membership should be diverse in race, gender, cultural background and sensitivity to such issues as community attitudes, and shall be sufficiently qualified through maturity, experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects of research. There are no alternate members. Refer to Appendix B for the current membership roster. The roster may be changed by the IRB in response to approved membership changes.

B. Selection

IRB members shall be appointed by the CEO with the concurrence of the Board of Directors. If the IRB is reviewing research that involves a vulnerable category of subjects, consideration will be given to including one or more individuals that are knowledgeable about and experienced in working with such subjects or are members of the vulnerable group.

C. Length of Appointment

Members shall serve on the IRB for a four-year term with the option of reappointment for three additional four-year terms. Such term limit does not apply to the IRB Administrator or to support staff so designated by the IRB Administrator. (Note: This term limit policy becomes effective January 01, 2022. To ensure continuity on the IRB, term limits will be phased in by the CEO with the concurrence of the IRB Chairperson and the IRB Administrator. Once the transition to term limits is complete, this "Note" will be removed from these Policies and Procedures).

D. Chairperson

The members shall recommend a Chairperson to the Board of Directors via the CEO. This will occur at the first meeting of the IRB in odd calendar years. The Chairperson shall serve a term of two years and may be elected to successive terms. The CEO will appoint someone to fill a vacancy of the Chairperson. The Board of Directors will be informed of the appointment. The Chairperson may vote.

E. Removal

It shall be the responsibility of the IRB Chairperson to recommend termination of any members from the IRB. A majority of the members may recommend termination of the Chairperson. The final decision regarding termination will be made by the Board of Directors.

F. Orientation and Education

All members of the IRB shall receive an orientation to the purpose, policies and procedures of the IRB. All members are required to take and pass the NIH web-based training course, "Protecting Human Research Participants." The IRB shall seek continuing education opportunities for its members.

G. Use of Non-Member Experts

The IRB may, at its discretion, invite individuals or Hospital and/or Medical Staff Departments or Committees with competence in special areas to assist in the review of issues that require expertise beyond that available on the IRB. These individuals cannot vote.

VI. MEETINGS

A. General Rule

Convened meetings of the IRB may be virtual, telephone conference or in person.

B. Frequency

The IRB shall meet as often as required, but not less than quarterly.

C. Member Attendance

Members are required to attend regularly at least 50% of scheduled meetings in a year. The year is July through June. Members can request a leave of absence for up to 12 months. Leaves will be granted by a vote of the majority of the members of the IRB.

D. Quorum

A quorum must be present in order to conduct business. A quorum is a majority of members of the Board that must include one physician, one non-scientist and one non-physician scientist or administrative representative.

E. Voting

1. Requirement

   A vote is required for initial approval/disapproval, continuing approval, protocol modifications/amendments/revisions, consent documents and changes to consent documents, letters to subjects, advertisements for subjects and changes to such items and any surveys or questionnaires provided to subjects, except as defined by Expedited Review, see Section XVI. All votes shall be documented in the meeting minutes.

2. Passing Vote

   A majority of the quorum present is required for a passing vote.

3. Voting Rights

   All IRB members have voting rights.

F. Conflict of Interest

1. General Rule- No member shall participate in initial or continuing review of research in which the member has a conflicting interest. Reference to a "member" includes the individual, their spouse or registered domestic partner and dependent children.

2. Examples of Possible Conflicts for IRB members;
   - Participation in the research project including the design, conduct or reporting of the research;

   - Supervision of any aspect of the research project including quality and safety monitoring;

- Financial interest in the project or research sponsor;
- Involvement in research utilizing a competing technology;
- Personal relationship with the investigator or members of the research team;
- Proprietary or personal interest related to the research;
- Fiduciary relationship to the sponsor, i.e. board member or executive, even if un-paid;
- Competitive relationship with the investigator or member of the research team;
- Any other reason making the member unable to render an independent, unbiased review.

3. Process- "Conflict of Interest" will appear as an item on the IRB agenda. At the start of each meeting, members will be asked to declare any potential or actual conflict of interest. At the discretion of the IRB Chairperson, a member with a conflicting interest may provide information and answer questions to the IRB but cannot be present for the review, discussion or the vote on the research.

VII. IRB RECORDS

A. Description of Records

1. Copies of the following documentation of IRB activities:
   - All research proposals reviewed.
   - Scientific evaluations, if any, that accompany research proposals.
   - Approved consent documents and any other information that goes to subjects.
   - Progress reports and records of continuing review activities including the rationale for conducting continuing review of research that otherwise would not require continuing review. Refer to Section XXVI of these Policies and Procedures.
   - Reports of unanticipated problems/adverse events/injuries to subjects.
   - Reports of protocol deviations.
   - Reports from Safety Monitoring activities.
   - Annual and interim research reports.
   - All correspondence between the IRB and investigators.
   - Statements of significant new findings provided to subjects by the investigator, as required by law.

- The rationale for an Expedited Reviewers' determination that research appearing on the Expedited Review list provided by the Secretary of DHHS is more than minimal risk

- Final research reports.

2. Minutes of the IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

3. A roster of IRB members (included in these Policies and Procedures as Appendix B) identified by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, and so forth, sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution. A curriculum vitae (CV) may be provided.

4. Written Policies and Procedures of the IRB.

5. Documentation of the activities undertaken by Washington Hospital and the IRB to ensure compliance with federal and state regulations regarding research and the protection of human subjects.

B. Retention of and Access to Records

1. The required records described in Section VIII. A, shall be maintained for at least three years after completion of the research.

2. Records may be maintained in printed form or electronically.

3. Records pertaining to research subject to DHHS or FDA jurisdiction shall be accessible for inspection and copying by authorized representatives of these agencies at reasonable times and in a reasonable manner.

C. Confidentiality

Except as provided in Section VIII.B, the records of the IRB shall remain confidential pursuant to Washington Hospital policy, Numbered Memorandum 1-116.

VIII. DETERMINATION OF EXPERIMENTAL USE

Consideration of Experimental Use vs Off Label Use

In an attempt to provide the Hospital, and the treating physician, with protection from risks of liability associated with the dispensing and utilization of approved drugs and devices for non-approved uses, as well as consideration for subject rights, the IRB may be asked to determine whether a physician's proposed use of such drug or device should be considered experimental.

To make that determination, the IRB may use literature review or may seek input from Hospital Medical Staff Departments or Committees. If the use is considered experimental, the IRB shall evaluate the protocol in the same manner as it does for other experimental and investigational drugs, devices and procedures. If it is determined that the use is not experimental, the development of guidelines for off-label use shall be the responsibility of the appropriate Hospital and/or Medical Staff Department or Committee.

IX. IRB ASSISTANCE TO INVESTIGATORS

The IRB maintains the following approved templates to assist investigators:

- Research Application
- Application for Low Risk Biomedical Research and Evidence Based Practice Projects

The IRB maintains sample Informed Consent Forms (ICFs) that investigators may use for reference. In order to avoid the appearance of a Conflict of Interest, the IRB cannot write research protocols, research applications or ICFs on behalf of investigators. Selected members of the IRB may however, meet with investigators to discuss and answer questions regarding IRB Policies and Procedures and the IRB's review of submitted information.

X. DISCLOSURE OF FINANCIAL INTEREST BY RESEARCHER/INVESTIGATOR POLICY

1. It is the policy of the WHHS IRB that all potential conflicts of interest in research be recognized and identified, then managed, reduced or eliminated.

2. Disclosure must reflect the interests of the researcher/investigator, their spouse, registered domestic partner and any dependent children.
3. All researchers/investigators, involved in sponsored research, are required to complete and submit the form Statement of Financial Interest for Researchers (hereafter referred to as "Statement" or "Statement of Financial Interest") with the initial request for IRB review of research. This includes research for which the WHHS IRB is the IRB of record and research that is overseen by a Central IRB (CIRB).

4. All researchers/investigators, involved in sponsored research, are expected to submit a revised Statement within 30 days of discovering or acquiring a new financial interest, during the conduct of the research.

5. If the WHHS IRB is the IRB of record, a new Statement of Financial Interest is required as part of all requests for continuing review/renewal.

6. If a CIRB is the IRB of record, a new Statement of Financial Interest must be submitted to the WHHS IRB with the copy of the annual report that the researcher submitted to the CIRB.

7. All completed Statements of Financial Interest are reviewed by the Chief of Compliance. For federally funded research, this position is referred to as the "Designated Official."

8. If a Statement of Financial Interest reflects a real or potential conflict of interest, the issue is referred to the Conflict of Interest Advisory Committee (COIAC). See Section XII of these Policies and Procedures.

XI. DEFINITION AND MANAGEMENT OF CONFLICTS OF INTEREST

Refer to Appendix C for policies and procedures regarding the definition and management of conflicts of interest in research.

Any report of a possible conflict of interest in research, brought to the attention of the IRB, will be investigated and as appropriate forwarded to the COIAC for review and action.

XII. RESPONSIBILITIES OF INVESTIGATORS

A. New Investigators

New investigators are individuals that have not had a research study approved by the WHHS IRB within the past 5 years.

New investigators must complete a course on research that has been approved for such purpose by the IRB. Proof of completion must be provided to the IRB by the date that the research application will be reviewed by the IRB.

B. All Investigators

1. Receive a current copy of the applicable IRB Policies and Procedures.

2. Prior to submission of a research application, discuss the proposed research with the management of Impacted Hospital or affiliated departments/services. For the purpose of these Policies and Procedures "Impacted Hospital or affiliated departments/services" means any area of Washington Hospital or its affiliates that will have a role in, or care for, patients that are subjects in the research. This will include, but is not limited to, departments such as the Operating Room and the Interventional Radiology Service where study devices are inserted and Pharmacy, that may store or dispense study drugs. Hereafter, such areas are simply called "Impacted Departments." Investigators must comply with any other requirements for research imposed by Impacted Departments. Refer to Section XVII of these Policies and Procedures for other requirements related to Impacted Departments.

3. Submit to the IRB the documents described in Section XVI.B of these Policies and Procedures.

4. Submit to the IRB a signed Statement of Financial Interest for Researchers specific to the proposed research.

5. Submit to the IRB a signed Statement of the Researcher/Investigator which attests to the following:

- I agree that informed consent will be obtained for all study subjects and all subjects will be given the "Experimental Subject's Bill of Rights" as required by California Law (Health & Safety Code section 24172). (If the study does not require an ICF, the researcher/investigator will cross-through and initial the paragraph). I understand that the Institutional Review Board (IRB) has a right to observe or have a third party observe the consent process.

- I agree that no significant change in the approved protocol or the subject's informed consent (if applicable) will be initiated without IRB review and written approval. All changes will be submitted to the IRB in writing according to the timeline designated in the IRB Policies and Procedures.

- I agree to adhere to all IRB designated reporting timelines for unanticipated problems, adverse events and protocol deviations. Reports will be in writing. If an adverse event or protocol deviation results in suspension of the research at this site, I agree to also immediately verbally notify the Chairperson of the IRB. For research subject to HHS regulations, I understand that reporting of unanticipated problems must be filed to the Office for Human Research Protection (OHRP) and that the FDA imposes a similar requirement on the sponsor to report adverse effects to the FDA.

- I agree to keep sufficient records so as to describe clearly the conduct and results of the research. I agree to follow record retention requirements that govern this research. I understand that the IRB has the right to review these records upon request.

- I agree to comply with all federal and state regulations regarding medical research which include, but are not limited to, drugs and biologicals, medical devices, human cloning, stem cell, embryonic and oocyte research and research using umbilical cord blood.

- I agree to comply with the Policies and Procedures of the WHHS IRB.

- I agree to conduct this research in accordance with accepted ethical principles of medical research.

- I agree that it is my responsibility as the researcher/investigator to ensure that all submissions for approval of new research and/or renewal of existing research are complete and submitted timely to the IRB.

- I agree to comply with the requirements of the research protocol for this study including strict adherence to the inclusion and exclusion criteria.

- I agree to comply with HIPAA regulations regarding research and to protect the confidentiality of research subject information as outlined in the research protocol.

- I agree that I have adequate resources to safely conduct this research.

- I agree to provide Impacted Departments with a copy of the current research protocol and ICF and to provide or arrange for necessary training for Hospital /affiliate staff regarding their role in the research.

- I agree to identify research or potential research subjects in the Admitting History and Physical if the subject is admitted to the Hospital as an inpatient and/or outpatient and to provide the Hospital with a copy of the subject's signed research ICF.

- I agree to provide the IRB a copy of the report of any audit conducted in my office/clinic by the sponsor or by any regulatory agency regarding this research.

6. Attend the IRB meeting at which the research application will be presented or be available by phone during the meeting. This requirement may be waived by the Chairperson of the IRB if a suitable designee, able to answer about the research questions, can attend in lieu of the researcher/investigator.

7. Respond promptly to any request by the IRB for information regarding proposed or approved research and attend a meeting of the IRB if requested.

XIII. DETERMINATION OF APPLICABLE REGULATIONS

Revisions to the Common Rule (45 CFR 46), known as the Final Common Rule, become effective January 21, 2019. One result of the revision is that there is less consistency between the two federal regulations that govern research (45 CFR and 21 CFR). With the assistance of the researcher, all research proposals will be evaluated by the IRB to determine which federal regulation applies.

In addition, California Health and Safety Code sections 24170-24179.5 and 111515- 111545 and these Policies and Procedures apply to all research reviewed by the WHHS IRB.

Evaluation Criteria:

1. Federal Funding – If the research is funded, partially or in full, by the federal government, and the research does not meet one of the exceptions stated in the regulation, the Final Common Rule (45 CFR 46) applies.

2. Involvement of the FDA – If the research involves FDA regulated products or supports applications to the FDA for research or marketing permits, 21 CFR applies. In addition, the IRB retains the right to apply elements of the Final Common Rule to the review of the research.

3. Federally Funded and Involvement of the FDA – For research that falls under the purview of both regulations, where the regulations differ, the regulation that offers the greatest protection to human subjects will be followed.

4. Other – If the research is not federally funded and the FDA is not involved, the IRB retains the right to apply elements of the Final Common Rule to the review of the research.

XIV. APPLICATION OF THESE POLICIES & PROCEDURES

These Policies and Procedures govern the actions of the WHHS IRB at all times. If another IRB is the IRB of record, some of these Policies and Procedures will not apply to that

particular research. If another IRB is the IRB of record, refer to Section XIX of these Policies and Procedures.

XV. REVIEW OF RESEARCH BY THE IRB

In order for research to be considered by the WHHS IRB, there must be a researcher that is affiliated with WHHS.

All new research protocols and modifications/amendments/revisions to approved research (except when the modification is necessary to eliminate apparent immediate hazards to the subject) must be prospectively reviewed by the WHHS IRB. No previously approved research may be continued beyond the expiration date without prospective continuing review/renewal unless the research is exempt from Continuing Review. Refer to Section XXVI of these Policies and Procedures. If a modification is necessary to eliminate immediate hazards, the modification must be submitted to the next regularly scheduled meeting of the IRB.

A. Review Types

Review will be by Regular Review, Expedited Review, Facilitated Review, or Limited Review.

B. Regular Review

All protocols that do not qualify for Expedited Review, Facilitated Review or Limited review are subject to Regular Review at a convened IRB meeting.

1. Copies of Research Protocols – A sufficient number of copies to provide a set for each member and a set for the file, must be provided to the IRB Chairperson no later than 13 business days before a scheduled meeting of the IRB.

2. Required Materials to be Submitted to the IRB – In order for the IRB to consider a research protocol, the following material must be submitted:

   - A full description of the proposed research, including the Investigators' Brochure if applicable.

   - A consent form which meets the requirements stated in Section XXI.E with a completed Informed Consent Checklist.

   - If applicable, any written materials including surveys, questionnaires and advertisements that will be provided to research subjects.

   - A signed Statement of the Researcher/Investigator. Refer to Section XIII.B of these Policies and Procedures for the contents of that Statement.

   - A signed Statement of Financial Interest for Researchers/Investigators.

C. Expedited Review

Protocols submitted for Expedited Review must meet the requirements set forth in 45 CFR 46.110 and 21 CFR 56.110. Per the regulations, Expedited Review may be used in the following circumstances:

1. Expedited Review for Initial Review may be used only for minimal risk research that appear on the OHRP Expedited Review Categories list, published in the Federal Register and is attached to these Policies and Procedures as Appendix D for informational purposes. The current list is published on the OHRP website. These Policies and Procedures automatically incorporate the most recently published list

2. Expedited Review may be used for Continuing Review/Renewal if some or all of the research appears on the list noted above, unless the reviewer determines that the study involves more than minimal risk, and in research previously approved by the convened IRB when one or more of the following conditions are met:

    - The protocol is permanently closed to enrollment of new subjects AND all subjects have completed all protocol related interventions AND the protocol remains active only for long-term follow-up of subjects.

    - The protocol in which no subjects have been enrolled and no additional risks have been identified.

    - The protocol for which the remaining research activities are limited to data analysis.

3. Expedited Review may be used for minor modifications/amendments during the IRB approval period in the following situations:

    - The changes are administrative only.

    - The changes do not alter the research design.

    - Any increment in risk is less than minimal risk.

4. Expedited Review may be used to validate compliance with IRB requested changes/additions to submitted research documents. In such circumstances, the approval date of the research will be the date that contingent/conditional approval was granted by the convened IRB.

5. Expedited Review is conducted in the following manner:

    - Expedited Review is conducted by the Chairperson or two members of the IRB and documented on the IRB approved Expedited Review Checklist form.

    - In reviewing the protocol, the reviewers may exercise all of the authority of the IRB except they may not disapprove the research. Research may be disapproved only by the full IRB.

- The IRB will be informed of all Expedited Reviews at the next regular meeting.

D. Facilitated Review

Facilitated Review is performed by a sub-set of the IRB. A report from the Facilitated Review is provided to the full IRB.

E. Limited Review

Limited Review is an exemption to Regular Review by the IRB allowed by the Final Common Rule, 45 CFR 46.104. Limited Review may be used for federally funded research when there is broad consent in place for the storage, maintenance and secondary research use of identifiable private information or identifiable biospecimans collected for either research studies other than the proposed research or non-research purposes.

1. When conducting Limited Review, the reviewers will make the following determinations;

   - that broad consent was obtained and that the research to be conducted is within the scope of the broad consent, and

   - that the broad consent was appropriately documented or there was a waiver of documentation, and

   - if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimans are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidently of data.

2. Limited Review will be conducted using the same process as that described above for Expedited Review, XVI C. 5.

XVI. REQUIREMENT TO INVOLVE IMPACTED HOSPITAL/AFFILIATED DEPARTMENTS AND SERVICES (IMPACTED DEPARTMENTS)

The researcher/investigator and the IRB have a joint responsibility to ensure that appropriate personnel in Impacted Departments are aware of the potentially approved research, understand their role in the research and, if requested, have access to the current research protocol and the ICF.

A. The researcher/investigator is required to:

1. Discuss the proposed research with management staff of the Impacted Department.

2. Provide management of the Impacted Department with a copy of the current protocol and ICF upon request.

3. Provide or arrange for any necessary training for Hospital staff regarding their role in the research.

B. The IRB will:

1. Ensure that the management of Impacted Departments is invited to attend the IRB meetings for initial review and continuing review and review of modifications/amendments to applicable research.

2. Ensure that designated staff of Impacted Departments have, if requested, access to the current research protocol and ICF for applicable research.

XVII. COOPERATIVE RESEARCH

Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all applicable regulations. For research without a sponsor or coordinating body, as part of the approval process, but without causing delay in the start of the research, a copy of the protocol that was approved at other institutions and the approval letter should be reviewed by the IRB. As described in the revision to 45 CFR 46 and effective January 19, 2020, all federally funded research conducted in institutions located in the United States that are engaged in Cooperative Research must rely on approval by a single IRB for the portion of the research conducted in the US, unless certain criteria exist. Refer to 45 CFR 46.114 The reviewing IRB will be identified by the federal department or agency supporting or conducting the research or proposed by the lead institution subject to acceptance by the federal department or agency supporting the research.

XVIII. USE OF A CENTRAL IRB

A. General Rule

Washington Hospital encourages the use of the WHHS IRB for all medical research involving subjects in the Washington Hospital Healthcare System, or conducted by individuals/researchers affiliated with the Healthcare System. However, Washington Hospital will consider reliance on a Central IRB (CIRB) on a case-by-case basis if the proposed research is acceptable to the organization. The IRB is aware that the revision of federal regulation 45 CFR 46 (The Final Common Rule) requires the use of a single/CIRB for all federally funded cooperative research effective January 19, 2020. When a CIRB is used, each entity is responsible for safeguarding the rights and welfare of human subjects and for complying with federal regulations.

If a CIRB is used, the CIRB may be the IRB of record if the following requirements are fulfilled:

1. The WHHS IRB, after review of the protocol and the ICF, if applicable, for local involvement, agrees to rely on the CIRB for oversight of the research.

2. There is a written agreement between Washington Hospital and the CIRB that clearly defines the role of each entity and delegates responsibility of oversight to the CIRB. These are usually called “Reliance Agreements.” The written agreement may be study

specific. Washington Hospital may also consider a global agreement with a specific CIRB. The CEO signs the agreement on behalf of the Hospital.

3. The researcher provides written evidence that the research has been approved by the CIRB.

B. Responsibilities of the Researcher/Investigator

When a CIRB will be the IRB of record, the researcher/investigator is expected to:

1. Fulfill the requirement to inform Impacted Departments of the research, provide a copy of the research protocol and ensure that any required training of staff occurs.

2. Submit a completed Statement of the Researcher/Investigator and Statement of Financial Interest to the IRB.

3. Provide the required number of copies of the research protocol to the IRB.

4. Provide copies of the ICF, the California Research Participants Bill of Rights and any other documents that will be provided to subjects, to the IRB for the purpose of local review. Minor changes and/or additions may be required to the consent form to incorporate local issues/requirements.

5. Provide a copy of the final approval by the CIRB of the research at the local site.

6. Agree to provide to the WHHS IRB, a copy of their annual status report submitted to the CIRB.

7. Agree to provide to the WHHS IRB, copies of reports of unanticipated problems and adverse events on local subjects that were sent to the CIRB.

8. Agree to provide the WHHS IRB with copies of any major changes to the approved protocol and/or ICF that may affect the safety of local subjects.

9. Agree to provide evidence to the WHHS IRB that the CIRB has conducted continuing review, including the outcome of that review.

Note: The researcher/investigator remains responsible to ensure that all necessary approvals and documents are in place before the research proceeds.

C. Responsibilities of the CIRB

1. Perform initial review of the research protocol and the ICF and make a final decision to approve or disapprove the research.

2. Carry out continuing review, review of adverse events, unanticipated problems and protocol deviations, review of protocol amendments, review of Data Safety Monitoring reports and review of any other documents related to the research.

3. Notify the WHHS IRB of serious or continuing noncompliance determinations, unanticipated problems with the research and/or suspension or termination of CIRB approval of the research protocol or the local researcher.

4. Notify the WHHS IRB immediately if there is a suspension or restriction of the CIRB's authorization to review research protocols.

D. Responsibilities of the WHHS IRB

1. Accept or reject the research protocol and the ICF for local use. This decision is based on ensuring that the rights of subjects are adequately safeguarded, that the research is scientifically sound and that all documents and information given to subjects are appropriate given the characteristics of local subjects. Minor changes and/or additions may be required to the consent form to incorporate local issues/requirements. Deletion of CIRB approved requirements in the protocol and the ICF or substantive changes that affect the meaning of CIRB requirements are not allowed.

2. Inform the researcher/investigator of the decision of the WHHS IRB.

3. Report to the CIRB any serious or continuing noncompliance issues at the local site that potentially impact human subject protections.

4. Notify the CIRB immediately if there is a suspension or restriction of the WHHS IRB's authorization to review research protocols.

E. Possible Actions by the WHHS IRB

1. The WHHS IRB agrees to rely on the CIRB, pursuant to the reliance or other agreement with the CIRB, without requiring modification of the research protocol, ICF, or other information provided to local research subjects.

2. The WHHS IRB agrees to rely on the CIRB, pursuant to the reliance or other agreement with the CIRB, but will require modification of the protocol, ICF, and/or other information provided to local research subjects.

3. The WHHS IRB does not agree to rely on the CIRB. The research study may not be conducted at WHHS until the study is approved by the WHHS IRB.

XIX. POSSIBLE ACTIONS BY THE IRB

The IRB systematically and thoroughly evaluates each research protocol to ensure the protection of research subjects. Possible decisions of the IRB are:

A. Approved with No Changes – Approval requires an affirmative vote of the majority of the convened quorum. The research may proceed.

B. Contingent/Conditional Approval – Approval at a convened IRB meeting contingent on the investigator making minor changes. Such minor changes must be clearly delineated by the IRB at the meeting and must be outlined in writing to the requestor. Approval is contingent/conditional on the investigator simply concurring, accepting the IRB

stipulations or making any verbatim changes to documents requested by the IRB. The research may proceed after the required changes are verified by the IRB Chairperson or by two voting IRB members designated by the Chairperson (this review and confirmation that the contingency has been satisfied is by an Expedited Review). If during the meeting the members decide major changes are required, the protocol is tabled.

C. Tabled – No vote is taken because changes and/or additional information will be reviewed at a later date by the convened IRB. The research may proceed only after the IRB has reviewed and approved the required changes to the research at a convened IRB meeting. A protocol will remain tabled until it is approved or not approved by the voting members at a convened meeting.

Not Approved – Denial of approval requires a majority vote of the convened quorum. The researcher/investigator and the Hospital Administration are informed.

XX. CRITERIA FOR APPROVAL BY THE IRB

In order to approve research, the IRB shall determine that all of the following requirements are satisfied:

A. Identification of Risk

Research protocols submitted to the IRB must include the identification of potential risks to study subjects. The level of risk must be described as low, medium or high as quantified by the researcher/investigator. Also refer to Section XLI for additional information on risk assessment in research involving medical devices.

B. Minimization of Risk to Subjects

The IRB shall determine that the investigators have minimized the risks to the subjects by:

1. Using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes, rather than performing additional or different procedures as part of the research.

C. Risk Benefit Analysis

The IRB shall determine if the risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of the IRB's responsibility.

D. Equitable Selection of Subjects

In determining whether the selection of subjects is equitable, the IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners and individuals with impaired decision-making capacity, or the educationally or economically disadvantaged.

E. Informed Consent

The IRB shall determine that informed consent will:

1. Be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by federal regulations, California law and these Policies and Procedures.

2. Be appropriately documented, or appropriately waived, in accordance with, and to the extent required by regulations pertaining to informed consent. Refer to Section XXXI of these Policies and Procedures.

3. Include a signed copy of the Experimental Subject's Bill of Rights.

Exceptions to Informed Consent – Refer to Section XXXIV for requirements.

Refer to Section XXXII of these Policies and Procedures for additional guidance on Informed Consent.

F. Monitoring the Research

Where appropriate, the research plan adequately provides for monitoring the data which are collected to insure the safety of subjects. A Data Monitoring Plan is required for research considered more than low risk, research where there is a NIH or FDA requirement for a plan and other research when requested by the IRB.

G. Privacy and Confidentiality

The investigator must include adequate provisions for the protection of the subject's privacy and for the maintenance of confidentiality of patient data. Under federal and state privacy regulations, use or disclosure of a subject's protected health information for research purposes may occur only with written authorization from the subject or in limited situations, with a waiver of authorization from the IRB. The subject's authorization should be a separate signature on the ICF or may be an attachment to the ICF. Conditions under which protected health information may be disclosed without authorization, includes use of de-identified data sets and limited data sets. Refer to 45 CRF 164- Security and Privacy.

Note: As required by the Final Common Rule, the Secretary of DHHS will issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

H. Special Precautions for Vulnerable Subjects

Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or persons that are economically or educationally disadvantaged, the IRB shall require appropriate safeguards to be included in the study, to protect the rights and welfare of these subjects. Refer to 45 CFR 46 A, B, C and D and 21 CFR 50 D.

In addition, WHHS IRB recognizes the following situations as possibly involving vulnerable subjects:

1. Non-English Speaking Individuals – Non-English speaking individuals should not be excluded from participation in research. The preferred method for obtaining consent from such subjects or their representative is providing current forms written in a language that is understandable to the subject/representative. The Experimental Subject's Bill of Rights must be provided in the language that is understandable to the subject/representative.

2. Short Form - For the occasional and unanticipated non-English speaking subject, a Short Form alternative method is allowed. The Short Form must state that the required elements of informed consent have been presented orally to the subject/representative in understandable language. This occurs by reading the complete ICF to the subject/representative in their language. This occurs in lieu of providing an approved written summary of the research. The Short Form must be approved by the IRB.

   The subject/representative must sign the Short Form. The English language document must be signed by the person obtaining the consent.

   A witness, who may be the translator, must be present for the oral presentation. The witness must sign the Short Form and the English language document.

   If the Short Form method is used and the interpreter is on the phone or video call, in lieu of the interpreter's signature, the interpreter's name and license number may be written on the consent form and in the patient's medical record to document an interpreter was used.

3. Employees and Students at WHHS and WHHS affiliates– Employees and students at WHHS may be considered vulnerable participants because of the risk of coercion or undue influence, except in situations where the employee or student has a medical condition or other characteristic that makes them appropriate research subjects.

   When the IRB reviews research that involves a vulnerable category of subjects, consideration will be given to including one or more individuals who are knowledgeable about and experienced in working with these subjects or are members of the vulnerable group.

XXI. APPROVAL DURATION

Duration of initial approval of research and continuing review/renewal research is based on the degree of risk to subjects and may not exceed one year. During the Continuing Review

process, in addition to determining the duration of approval, the IRB will determine which projects need verification from sources other than the principal investigator that no material changes have occurred since previous IRB review. Criteria for granting approval for a period less than one year include, but are not limited to, risks to subjects, vulnerability of subjects, complexity of the research and concern with the conduct of research by the researcher/investigator in the past.

XXII. APPROVAL NOTICE

The IRB Chairperson shall notify the researcher/investigator in writing of the IRB's decision to approve the proposed research and the interval at which the study must be submitted to the IRB for continuing review, if continuing review and renewal are necessary.

XXIII. CRITERIA FOR DENYING APPROVAL

Any proposed research protocol will be denied if any of the following conditions apply:

- The research protocol violates federal or state laws or regulations.
- In the judgment of the IRB, the risk created to the subjects outweighs the benefits to be obtained.
- In the process of conducting research, unnecessary risks are imposed.
- There is reason to believe, based on reliable information presented to the IRB, that the investigational procedure, drug or device may be unsafe or ineffective when used as intended by the research.
- Unless specifically waived by the IRB, informed consent by experimental subjects has not been obtained and documented.
- The information submitted to the IRB is incomplete, inconsistent or contains false statements.
- It does not appear there is adequate scientific basis for the research.
- It does not appear there are adequate resources available to safely conduct the research.

XXIV. DISAPPROVAL NOTICE

The IRB Chairperson shall notify in writing the researcher/investigator and CEO of its decision to disapprove the proposed research activity. The notification shall include the reason for this decision and give the researcher/investigator an opportunity to respond in person or in writing.

XXV. CONTINUING REVIEW/RENEWAL OF APPROVAL OF RESEARCH

A. Continuing Review/Renewal of Federally Funded Research Subject to the Final Common Rule.

1. Continuing review/renewal is not required in the following circumstances. Should the IRB elect to conduct continuing review in the following circumstances, the reason for the review will be documented.

   - Research eligible for Expedited Review.
   - Research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 104.
   - Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB approved research: a) data analysis, including analysis of identifiable private information or identifiable biospecimen, or b) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

2. If the research does not meet the criteria listed above, continuing review/renewal will be conducted as described in B. below.

B. Continuing Review/Renewal of Non-Federally Funded Research

1. The IRB will conduct continuing review by the convened IRB at intervals appropriate to the degree of risk, but not less than once a year except: continuing review is not required for non-FDA research, for which a waiver of consent was granted and the research involves data collection and analysis only. Two months prior to the end of the IRB approval period, a Continuing Review/Renewal Reminder Letter will be sent to the investigator by the IRB Chairperson.

2. In order for continuing review/renewal to occur, the investigator must submit a status report that includes the following information.

   - The number of subjects enrolled in the research, at the local site and for the entire project.
   - A description of the subject's experience, including benefits, adverse events, unanticipated problems and subject complaints about the research.
   - Any withdrawals from the research, including the reason for withdrawal.
   - Results of the research to date, including multi-site results.
   - A current risk-benefit assessment any new information.
   - Any recent literature relevant to the research.
   - Any new information or changes since the last IRB review.

3. In addition to the status report, the following documents must be submitted for continuing review of research open to subject accrual:

   - The current ICF.

- All translated ICFs.
- For FDA approved research, a copy of the Investigators Brochure.
- All surveys, questionnaires, information brochures and advertising that may be provided to subjects or potential subjects, including any translations.
- Any other documents for which the sponsor requests IRB approval.
- A current signed copy of the form Statement of Financial Interest for Researchers.

Note: A copy of an ICF, signed by a subject, may be requested by the IRB.

C. Action by the IRB

The actions that may be taken by the IRB following continuing review are the same of those described in Section XVIII of these Policies and Procedures.

XXVI. REPORTING OF UNANTICIPATED PROBLEMS/ADVERSE EVENTS

Pursuant to federal regulations, investigators are required to submit to the IRB reports of Unanticipated Problems and/or Adverse Events related to the research within the time-frame specified in the research protocol or within seven days of discovery of the event, whichever is shorter. The IRB reserves the right to request additional information/explanation regarding the Unanticipated Problem /Adverse Event from the investigator. Only Internal Events, not events from other research sites or other research studies, need to be reported to the IRB. Refer to Appendix E - Internal Adverse Event Reporting Flowchart.

XXVII. REPORTING OF PROTOCOL DEVIATIONS

Investigators are required to submit to the IRB a report of all deviations to the research protocol immediately upon discovery. If an investigator deviates from an approved protocol in order to protect the life or physical well-being of a subject in an emergency, the report to the IRB must be submitted as soon as possible, but no later than five working days after the emergency. If a protocol deviation results in suspension or termination of the research at the local site, the researcher/investigator or designee must verbally inform the IRB Chairperson immediately.

XXVIII. MODIFICATIONS/AMENDMENTS/REVISIONS

Modifications/amendments/revisions to research protocols and ICFs must be approved in advance by the IRB except as described in Section XIV of this policy.

XXIX. SUSPENSION OR WITHDRAWAL OF APPROVAL

The IRB may suspend or terminate approval of research that is not being conducted in accordance with regulations, the IRB's requirements or that has been associated with unanticipated serious harm to subjects. This includes failure to submit required progress reports, or reports of serious adverse events or unanticipated problems and protocol deviations, and/or failure to seek approval of modifications/amendments/revisions prior to

implementation as required by federal regulations. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall promptly be reported to the investigator, Hospital Administration, and for research subject to federal regulations, to the appropriate department or agency.

XXX. REQUIREMENTS FOR INFORMED CONSENT

The requirements listed below are a combination of the federal requirements, California law and WHHS IRB Policy. The informed consent requirements outlined in the these Policies and Procedures are not intended the pre-empt any applicable federal state or local regulations that require additional information to be disclosed in order for informed consent to be legally effective.

A. General Rule

Both federal and California law establish the general rule that no investigator may involve a human being as a subject in medical research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

1. An investigator must seek such consent only under circumstances that provide the prospective subject or their representative sufficient opportunity to discuss and consider whether or not to participate, and that minimize the possibility of coercion or undue influence.

2. The information that is given to the subject or their representative, verbally and in writing, must be in non-technical terms and in language understandable to the person giving consent. California law states that the information must be given in a language in which the prospective subject or their representative is fluent [Health and Safety Code Section 24173(c)]. Refer to Section XXI.H.

3. The subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate and an opportunity to discuss that information.[1]

4. No informed consent, whether oral or written, may include any exculpatory language through which the prospective subject or their representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

5. The ICF must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why to participate or not participate in the research. This information must be organized and presented in a way that facilitates comprehension.[1]

6. The ICF as a whole must present information in sufficient detail relating to the research and must be organized and presented in way that does not merely provide lists of isolated facts but rather facilitates the prospective subject's or legalized authorized representative's understanding of the reason why one might or might not want to participate.[1]

7. The WHHS IRB requires that each page of the ICF document shall be numbered, with the page number and total number of pages, dated and include a space for the subject's

initial. If subject is unable to initial each page due to physical limitations, there must be documentation by the researcher/investigator to this effect on the final signature page. The subject must initial this documentation as evidence of acknowledgement.

B. Basic Elements of the Informed Consent

1. A statement that the procedure or treatment involves research.

2. An explanation of the purposes of the research and the expected duration of the subject's participation.

3. An estimate of the subject's expected recovery time after the research (if applicable).

4. An explanation of the procedures to be followed and any drug or device to be utilized, including the purposes of such procedures, drugs or devices, and identification of any procedures, drugs, or devices that are experimental. If a placebo will be given to a portion of the subjects involved in a medical experiment, all subjects of the experiment must be informed of this fact; however, they need not be informed as to whether they will actually receive a placebo.

5. A description of any reasonable foreseeable risks or discomforts to the subjects. Ideally, the risks should be quantified (e.g., 2%) and cite the source of the information.

6. A description of any benefits to the subject or to others, which may reasonably be expected from the research.

7. A disclosure of appropriate alternative procedures or sources of treatment, if any, that might be advantageous to the subjects and their relative risks and benefits.

8. A statement describing the extent, if any, to which confidentiality of records that identify the subject will be maintained. For research subject to the FDA regulations, this statement must also specify that the FDA may inspect the records of subjects participating in studies involving a drug or device subject to FDA regulation.

9. A statement that the subject will or will not receive compensation for participation in the research and who is responsible for all costs of the hospitalization, physician visits, lab, etc. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of and where further information may be obtained.

10. A statement regarding compensation, if the investigator is compensated for enrolling subjects in the research. A material ($10,000 or more) financial interest or compensation in the outcome of the medical experiment must also be disclosed regardless of when it is earned or expected to be earned.

11. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

12. The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for conducting the research.

13. The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general authority the research is being conducted.

14. Economic or other interest(s) that benefit the Hospital or researcher/investigator.

15. The name, address and telephone number of an impartial third party not associated with the research to whom the subject may address complaints about the experiment. This may be the IRB Chairperson or the IRB Administrator.

16. An offer to answer any inquiries concerning the research or procedures involved, and explanation of who to contact for answers to pertinent questions about the research and the research subject's rights, and who to contact in the event of a research-related injury.

17. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimen: [1]

    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimen and that, after such removal, the information or biospecimen could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

    - A statement that a subject's information or biospecimen collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

XXXI. ADDITIONAL ELEMENTS OF INFORMED CONSENT

When appropriate, in connection with a specific research project, federal law requires that one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

6. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects and if so, under what conditions. [1]

7. The approximate number of subjects involved in the study.

8. A statement that the subject's biospecimen (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.[1]

9. For research involving biospecimen, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).[1]

10. The name and title of the person providing information for consent, if other than the investigator.

11. Disclosure of any conflict of interest associated with the investigator's involvement in the study.

12. The statement: "A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify subjects. At most, the website will include a summary of the results." This requirement applies to research involving drugs and biological and devices. Phase I drug trials, small trials to determine feasibility and non-interventional research trials are exempt from this requirement.

Note: Nothing in these required elements is meant to limit the authority of a physician to provide emergency medical care to the extent permitted by law.

XXXII. PROCEDURES FOR OBTAINING INFORMED CONSENT

A. Elements of the Consent Process / Documentation of Informed Consent

1. A written consent form must be initialed on each page and signed by each subject or his/her legally authorized representative. Electronic signature is acceptable.

2. Signing of the consent form should take place only after the subject has read and had an opportunity to ask questions about the study.

3. The ICF must be in understandable, non-technical terms, in language that is understandable to the subject/representative. Refer to Section XXI.H for additional guidance for consenting non-English speaking and educationally disadvantaged individuals, including the use of a short form consent.

4. The ICF must be approved by the IRB. The actual ICF used must bear the current stamp of the IRB.

5. The ICF must also be signed and dated by a person other than the subject who can attest that the requirements of informed consent have been satisfied.

6. A copy of the ICF shall be given to the subject or the subject's legally authorized representative.

B. Exceptions to Requiring Signed ICF

The IRB may waive the requirement for a researcher/investigator to obtain written informed consent in the following circumstances. In these circumstances, the IRB may require the researcher/investigator to provide subjects with a written statement regarding the research.

1. When the only record linking the subject and the research would be the ICF and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern:

2. When the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context: or

3. When the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

C. Role of the IRB

1. The IRB shall make reasonable attempts to ensure that the ICF to be utilized for a particular research contains all of the elements required in Section XXXI.B of these Policies and Procedures.

2. The IRB has the authority to observe or have a third party observe the consent process, or to ask for documentation that the informed consent process has occurred.

XXXIII. EXCEPTIONS TO INFORMED CONSENT PROCESS: WAIVER AND/OR ALTERATION

The IRB may waive or alter the requirements for informed consent in certain circumstances:

A. Waiver in Research Involving Public Benefit

The research is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under the programs, possible changes in or alternatives to programs or procedures or possible changes in methods or levels of payment for benefits or services under the programs.

B. General Waiver or Alteration of Consent

The IRB may waive or alter the requirement for informed consent described in these Policies and Procedures only if all of the following conditions are met:

1. The research involves no more than minimal risk to the subjects.

2. The research could not practicably be carried out without the requested waiver or alteration.

3. If the research involves using identifiable private information or identifiable biospecimen, the research could not practicably be carried out without using such information or biospecimen in an identifiable format.

4. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

5. Whenever appropriate, the subjects or legally authorized representative will be provided with additional pertinent information after participation.

C. Other Circumstances

There are other circumstances, including the provision of emergency medical care and the screening, recruiting and determining eligibility for research in which regulations allow a waiver or alteration of the informed consent process. As necessary, the IRB will refer to 45 CFR 46.116, 21 CFR 50, 23 and 24 and California Health and Safety Code Section 24177.5 for additional guidance.

XXXIV. POSTING OF RESEARCH INFORMED CONSENT FORM

The Final Common Rule requires that for each clinical trial conducted or supported by a federal department or agency, one IRB approved ICF must be posted by the awardee or the federal department or agency conducting the research on a publicly available federal website that will be established as a repository of such ICFs. WHHS IRB will not be responsible for posting ICFs unless specifically requested to do so.[1]

XXXV. EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In addition to the elements of Informed Consent listed in sections XXXI and XXXII the California Protections of Human Subjects in Medical Experimentation Act requires that all subjects be given a copy of the "Experimental Subject's Bill of Rights" before consent to participate in any medical research is obtained (Health and Safety Code section 24173(a)). The Bill of Rights must be written in language that is understandable to the subject and/or representative (the WHHS IRB maintains copies of translated versions) and must be signed and dated by the subject. The list of the rights of a subject in medical research must include, but need not be limited to, the subject's right to:

- Be informed of the nature and purpose of the research.

- Be given an explanation of the procedures to be followed in the medical research and any drug or device to be utilized.
- Be given a description of any discomforts and risks reasonably to be expected from the research, if applicable.
- Be given a description of any benefits to the subject reasonably to be expected from the research, if applicable.
- Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- Be informed of the avenues of medical treatment, if any, available to the subject after the research if complications arise.
- Be given an opportunity to ask any questions concerning the research or the procedures involved.
- Be instructed that consent to participate in the medical research may be withdrawn at any time, and the subject may discontinue participation in the medical research without prejudice.
- Be given a copy of the signed and dated written consent form and the Experimental Subject's Bill of Rights form.
- Be given the opportunity to decide to consent or not to consent to a medical research without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

XXXVI. WHO MAY CONSENT

In most circumstances, the subject must sign the ICF in order to participate in research studies. In circumstances in which the potential subject is unable to sign, the IRB relies on the current version of the California Hospital Association (CHA) Consent Manual for guidance.

XXXVII. BROAD CONSENT

A. Definition and General Rule [1]

Broad consent is permission by a subject or legally authorized representative for the storage, maintenance and secondary research use of identifiable private information or identifiable biospecimen collected for either research studies other than the proposed research or non-research purposes. It is permitted as an alternative to the informed consent requirements described in these Policies and Procedures. If the subject or the legally authorized representative is asked to provide broad consent, they must be provided with the following:

1. A description of the risks and benefits of participation, the extent to which confidentiality will be maintained and a statement that there will be no penalty or loss of benefits for failure to participate.

2. When appropriate, a statement regarding the possible commercial use of biospecimen and whether the research will or might include whole genome sequencing.

3. A general description of the types of research that may be conducted with the identifiable private information or the identifiable biospecimen. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research.

4. A description of the identifiable private information or identifiable biospecimen that might be used in research, whether sharing that that information/biospecimen may occur and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimen.

5. A description of the period of time that the identifiable private information or identifiable biospecimen may be stored and maintained and a description of the period of time that such information/biospecimen may be used. These times may be indefinite.

6. Unless the subject or the legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of specific research studies that might be conducted using their identifiable information/biospecimen/including the purpose of the research and that they might have chosen not to consent to some of the specific research studies.

7. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results will not be disclosed.

8. An explanation of who to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimen and whom to contact in the event of a research-related harm.

B. Use of Broad Consent

Broad consent may be used in connection with a specific research study for which informed consent was obtained, if the researcher believes that identifiable private information and/or identifiable biospecimen may be stored, maintained and used for secondary research.

Broad consent may be used in circumstances in which identifiable private information and/or identifiable biospecimen are collected for non-research purposes but will be stored, maintained and possibly used for future research.

XXXVIII. ASSURING COMPLIANCE WITH REGULATIONS

A. Internal Methods

The WHHS IRB adopts internal audit and self-assessment practices to assure compliance with federal and state regulation and with these Policies and Procedures. These practices include, but are not limited to, use of an expiration stamp on informed consent documents, informed consent, timeliness and other internal audits. Audits may also be conducted based on need. The IRB maintains the right to observe the informed consent process. The IRB

also maintains the right to request from the investigator, copies of audits performed by the research sponsor or by the FDA in the office/clinic of the investigator regarding research approved by the WHHS IRB.

B. Penalties for Failure to Comply with Federal and State Regulations

Several types of penalties may be imposed if the investigator and/or the institution in which the research is conducted fails to appropriately secure the subject's informed consent and/or fails to ensure that an IRB which complies with the regulations reviews and approves the research as required by the regulations. Pursuant to federal law, the FDA may withhold approval of new research and terminate an ongoing research study. "When the apparent non-compliance creates a significant threat to the rights and welfare of human subjects, the FDA may notify relevant state and federal regulatory agencies and other parties with a direct interest in the agency's action on the deficiencies in the operation of the IRB." 21 CFR 56.120

The FDA may also disqualify the IRB and/or the institution. A determination that the FDA has disqualified an IRB is disclosable to the public (21 CFR sections 56.121 and 56.122). A failure to comply with the regulations also creates the risk that civil liability will be imposed upon the investigator and/or the institution on the basis that a subject suffered damages as a result of the investigator's and/or the institution's failure to comply with the FDA regulations.

In addition, penalties under California law may be imposed on the investigator and/or the institution for failure to obtain informed consent.

In addition, injured subjects may seek to recover damages under any other applicable law. Providing an adequate consent process does not, of course, preclude a subject from seeking damages based on other theories of professional or institutional liability.

XXXIX. RESEARCH INVOLVING NON FEDERALLY FUNDED EXISTING DATA

Research involving existing data/retrospective research is the use of data that are existing at the time that a research proposal is submitted. Such research is usually determined to be low risk. In many situations where research involves use of existing data, the researcher/investigator will request a waiver of informed consent. Refer to Section XXXIV of this Policy. Based on the probability that subject's information could be individually identifiable, the IRB may request a generic consent form which informs a subset of patients that their information may be used in research involving existing data, i.e., retrospective research.

XL. DETERMINATION OF RISK IN RESEARCH INVOLVING MEDICAL DEVICES

If the article being studied is a medical device, the materials to be submitted to the IRB by the investigator shall include either a valid investigational device exemption (IDE) number issued by the FDA, or a written statement by the sponsor reflecting its determination that the device is of non-significant risk (NSR) and does not require an IDE under FDA regulations. In the latter case, the investigator shall also submit documentation of the sponsor's risk assessment and the rationale used in making its NSR determination.

A "**significant risk device**" means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety or welfare of a subject.

If the study is presented without an IDE number based on the sponsor's assessment that the device is NSR, the IRB shall make an independent assessment of the risk status of the device, taking into account information such as reports of prior investigations conducted with the device, the proposed investigational plan, the proposed subject selection criteria, and the proposed monitoring procedures. The IRB should also consider such guidance and examples as may be provided in "Information Sheets" or other such materials published by the FDA.

If the study is covered by an IDE, or the sponsor and the investigator have determined that the device is NSR and the IRB agrees with that determination, the study may commence upon notice of final approval by the IRB. If the IRB disagrees with a sponsor's assessment that a device is NSR, the IRB shall notify the sponsor and the investigator of its determination. The sponsor must then notify the FDA of the IRB's determination, and the FDA will make a final decision regarding SR/NSR status.

XLI. HUMANITARIAN USE DEVICES

Federal regulations (21 CFR 814) authorize the FDA, under certain circumstances, to grant special marketing approval for devices which are to be used in the diagnosis or treatment of rare diseases or conditions. Rare is defined as affecting or being manifested in less than 4,000 individuals in the United States per year. Use of the device, as specified in the exemption, must be approved by an IRB that operates in accordance with FDA's regulations and has agreed to oversee such use. Initial and continuing IRB approval is required. The IRB, with input from the physician, will determine if informed consent is required for humanitarian use. For additional guidance on Humanitarian Use Devices and Humanitarian Use Exemption, refer to 21 CFR 814.H.

XLII. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS AND DEVICES

Refer to Appendix F for guidance on Expanded Access.

XLIII. PROHIBITION OF HUMAN CLONING

California Health and Safety Code section 24185 prohibits the cloning of a human being and the purchase or sale of an ovum, zygote, embryo, or fetus for the purpose of cloning a human being.

XLIV. RESEARCH INVOLVING PREGNANT WOMEN, HUMAN FETUSES, NEONATES AND CHILDREN

There are specific federal regulations governing research on groups listed above. If the IRB receives a research application involving such groups, the applicable regulations will be reviewed and followed.

XLV. STEM CELL, EMBRYONIC AND OOCYTE RESEARCH

A. Stem Cell Research

California has enacted legislation stating that it is the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and must be reviewed by a stem cell research oversight committee. The WHHS IRB cannot approve stem cell research (Health and Safety Code Section 125300).

B. Embryonic Research

Embryonic or cadaveric fetal tissue may be donated for research purposes. However, no embryonic or cadaveric fetal issue may be purchased or sold for research purposes. It is permissible to exchange reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation or implantation of a part. The WHHS IRB will not accept, review or approve embryonic research applications.

C. Procuring Oocytes for Research

California law requires that certain procedures occur prior to consent for assisted oocyte production or any alternative method of ovarian retrieval for research. Health and Safety Code 125341 – 125346. The WHHS IRB will not accept, review or approve oocyte research applications.

XLVI. RESEARCH USING UMBILICAL CORD BLOOD

California law requires that when umbilical cord blood is used for research, the research protocols must be approved by the IRB for California State Health and Human Services Agency. The WHHS IRB cannot approve research using umbilical cord blood.

XLVII. FUTURE GENETIC RESEARCH

During the course of some research, blood and/or tissue samples are collected and stored for use in future genetic research. The WHHS IRB will approve such collection and storage if it is clearly described in the ICF.

Note: This applies to non-federally funded research.

XLVIII. FORMS

A variety of forms and standard letters are developed to facilitate the work of the IRB. All forms are approved by the IRB prior to use.

[1] This element is required by the Final Common Rule (45 CFR 46) for research that is federally funded. The WHHS IRB reserves the right to require this element for other, non-federally funded, research.

XLIX. REVIEW OF POLICIES AND PROCEDURESOF THE WHHS IRB

The Policies and Procedures of the IRB will be reviewed at least every three years and revised as necessary. Any proposed changes must be approved by the Board of Directors prior to implementation.

Signature: _____ Date: _____
Jack Rose, M.D.
Chairperson

Signature: _____ Date: _____
Kristin Ferguson, R.N.
Chief of Compliance

Signature: _____ Date: _____
Kimberly Hartz
Chief Executive Officer

Reviewed: Revisions to WHHS Institutional Review Board Policies and Procedures

Appendix A
Belmont Report

THE BELMONT REPORT

Office of the Secretary

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Members of the Commission

Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.

Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.

Robert E. Cooke, M.D., President, Medical College of Pennsylvania.

Dorothy I. Height, President, National Council of Negro Women, Inc.

Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco.

Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.

Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion.

**** David W. Louisell, J.D., Professor of Law, University of California at Berkeley.*

Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas.

**** Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.*

**** Robert H. Turtle, LL.B., Attorney, VomBaur, Coburn, Simmons & Turtle, Washington, D.C.*

*** Deceased.

Table of Contents

Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes [1] intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

Part A: Boundaries Between Practice & Research

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals [2]. By contrast, the term "research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is “experimental,” in the sense of new, untested or different, does not automatically place it in the category of reseach. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project [3].

Research and practice may be carried on together when research is designed to evaluate the safety and

efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Part B: Basic Ethical Principles

B. Basic Ethical Principles

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. — Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. — Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude

Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. — Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons

confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Part C: Applications

C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent. — Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that **(1)** incomplete disclosure is truly necessary to accomplish the goals of the research, **(2)** there are no undisclosed risks to subjects that are more than minimal, and **(3)** there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustified pressures usually occur when persons in positions of authority or commanding influence – especially whre possible sanctions are involved – urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

2. Assessment of Risks and Benefits. — The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or

welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: **(i)**Brutal or inhumane treatment of human subjects is never morally justified. **(ii)** Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. **(iii)** When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation). **(iv)** When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. **(v)** Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects. — Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already

burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted.

[1] Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

[2] Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

[3] Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

Appendix B
IRB Roster

Name	Licensure Degree	Affiliated with WHHS	Scientist Non-Scientist	Relationship	Gender	Date IRB Member	Background Qualification
Jack Rose Chairperson	MD Neurology	Yes	Scientist	Member Washington Hospital Medical Staff	Male	January 2016	• Experience as an investigator in research • Experience with statistical analysis of study results
Desmond Erasmus	MD Neurosurgery	Yes	Scientist	Member Washington Hospital Medical Staff	Male	June 2008	• Former Chairperson of the IRB • Former Chairperson of Physicians Advisory Committee • Chairperson of the Bioethics Committee • Wide exposure to different faiths • Exposure to life & death in neurosurgery
Ronald Adamson	PhD Metallurgy	No	Scientist	Community Member	Male	April 2003	• Extensive experience as research scientist • Supports animal research worldwide • Objective concern for rights of individuals • Member of Bioethics Committee
Minh-Thu Dennen	PharmD	Yes	Scientist	Employee	Female	January 2000	• Director of Pharmacy • Active participant in clinical studies in the past
Kristin Ferguson	RN, MS Nursing MS-Healthcare Administration	Yes	Scientist	Employee	Female	June 2013	• Chief of Compliance • Risk Manager • Patient Safety Officer • Member of Bioethics Committee • Healthcare Compliance Certified
Marina Bigongiari	AA	Yes	Non-Scientist	Service League Volunteer	Female	July 2007	• Former President Washington Hospital Service League • Involved in non-profit project for patient advocacy • Dedicated to the protection of humans and animals
Britt Hermansson-Firstman	CHC	Yes	Non-scientist	Employee	Female	July 2015	• Internal Auditor • Certified in Healthcare Compliance • Big Five Public Accounting Experience
Kristine LaVoy Perry	RN, MS Health Services Administration	Yes	Scientist	Retired Employee Paid Consultant	Female	February 2015	• Previous Member of WHHS IRB • Formerly Certified in Healthcare Compliance • Experience in Quality Assessment & Risk Management with a focus on patients' rights & patient safety

Dianne Martin	MD Internal Medicine, Infectious Disease	Yes	Scientist	Member Washington Hospital Medical Staff	Female	November 2009	• Experience as an investigator in research
June Mastrocola	MA Education Counseling	Yes	Non-Scientist	Retired Employee	Female	July 2007	• Kaiser Hospice Volunteer • Fremont City Life Eldercare Volunteer
James Schoon	D Ministry	No	Non-Scientist	Community Member	Male	October 2009	• Retired, Founding Pastor, New Hope Community Church
Kathy Weinberg	RN	Yes	Scientist	Employee	Female	July 2015	• Member of IRB at prior facility • Experience as an investigator in research • Research coordinator for several research studies

Appendix C
Financial Conflict of Interest Policy

A. Purpose- To promote objectivity in research by establishing standards to ensure that the design, conduct or reporting of research will be free from bias resulting from investigator financial conflict of interest.

B. Applicability- This policy applies to sponsored research regardless of the funding source, including any study in which the investigator receives funding outside of the clinical trial agreement/budget. The Washington Hospital Healthcare System (WHHS) IRB also reserves the right to apply this policy to any non-sponsored research presented to the IRB.

This policy applies to any investigator who participates or plans to participate in research within WHHS.

C. Definitions

PHS means the Public Health Service, an operating division of the US Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an investigator's professional responsibilities on behalf of the institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

Investigator/researcher means the principal investigator and any other person who is responsible for the design, conduct and reporting of research, including co-investigators, consultants and any other person who has responsibility for designing, conducting or reporting the proposed research. For research funded by the PHS, the term investigator includes, but is not limited to, all key personnel identified in the grant application, progress report, or other reports submitted to the PHS. As used herein, the term “researcher” is synonymous with the term “investigator.”

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest Report means an institution's report of a FCOI to a PHS Awarding Component (the organizational unit within the PHS which funds the investigators research).

Designated Official means the person authorized by WHHS to solicit and conduct review of Statements of Financial Interest in Research. At WHHS the Designated Official is the Compliance Officer.

Conflict of Interest Advisory Committee (COIAC) means the group charged with determining whether Significant Financial Interests are related to proposed research and whether they constitute FCOIs. The COIAC is comprised of the Chairperson of the IRB, the Designated Official, the WHHS Internal Auditor, Hospital legal counsel and an additional member of the IRB from the same discipline as the researcher/investigator involved in the possible conflict. The IRB Chairperson, who shall chair the COIAC, has the discretion to include other persons, from within or outside of the IRB, as appropriate to the specific situation.

Management Plan (MP) means a written agreement between WHHS and an investigator for the purpose of reducing, mitigating or eliminating an actual or potential FCOI held by the investigator.

Significant Financial Interest (SFI) means:

1. A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse, registered domestic partner, and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:
    - For any publicly-traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. "Remuneration" includes salary and any payments for services not otherwise identified as salary (other than salary described in #3), for example, consulting fees, honoraria, paid authorship and equity interest, including stock, stock options or other ownership interest at the date of disclosure as determined by public prices or other reasonable measure of fair market value.
    - For any non-publicly-traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when the investigator (or the investigator's spouse, registered domestic partner, or dependent children) holds any equity interest including stocks, stock options, or other ownership interest.
    - Receipt of income from intellectual property rights and interests (for example, patents and copyrights).

2. Travel reimbursement made to or on behalf of the investigator, regardless of the amount, by a for-profit or non-profit entity, related the investigator's institutional responsibilities. The investigator must disclose the following information

regarding travel reimbursement: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. With respect to such disclosures, the IRB reserves the right to request additional information if needed to ascertain the value of such travel for purposes of making a determination under this Policy.

3. SFI does not include the following types of financial interests:
   - Income from investment vehicles, such as mutual funds and retirement funds, as long as the investigator does not directly control the investment decisions made for these investment vehicles;
   - Salaries, stipends, royalties, honoraria, reimbursement of expenses, or any other payment made by WHHS.
   - Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state or local government agency, a US institution of higher education or a research institute, academic medical center or hospital affiliated with an institution of higher education.
   - Travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education.

D. Policy

1. ***Regulatory Compliance*** – WHHS follows all federal, state, and local regulations to detect, disclose, and resolve conflicts of interest in research. This policy is intended to conform to the requirements of the PHS regarding actual and potential conflicts of interest set forth at 42 C.F.R. Part 50, Subpart F, commencing with § 50.601 (the "PHS Regulations"). In the event of a conflict between this Policy and the PHS Regulations or an ambiguity in this Policy, this Policy shall be interpreted in a manner that requires compliance with the PHS Regulations.

2. ***Significant Financial Interests –*** Investigators must disclose all SFIs as follows:
   - PHS-funded investigators are required to disclose all SFIs that are related to their institutional responsibilities.
   - Non-PHS-funded investigators must disclose all SFIs that are related to their research.

3. ***Disclosure*** **-** Investigators are required to disclose SFIs to the WHHS IRB using the Statement of Financial Interest for Researchers. In all cases, disclosure is required for the individual investigator, his/her spouse, registered domestic partner and any dependent children.

4. ***Final Decisions*** – The final determination regarding the management of SFIs and/or FCOIs are made by the WHHS Chief Executive Officer (CEO), after initial review by the COIAC with input from the Chairperson of the WHHS IRB, and as appropriate, from the WHHS Chief Medical Officer. Final decisions must be made within sixty (60) days of disclosure of the SFI.

5. ***Monitoring*** - Whenever the WHHS institutes a MP under this Policy, the COIAC shall monitor the investigator's compliance with such plan on an ongoing basis until completion of the research project.

6. ***Actions for Non-Compliance*** – Failure to comply with timely, accurate, and complete reporting or with appropriately addressing conflicts may result in: loss or suspension of an individual's participation in research projects, cancellation of the research project, and/or other actions as allowed by WHHS or Medical Staff Bylaws.

7. ***Retrospective Review for Untimely Management*** - In the event a FCOI was not identified or managed in a timely manner, the Designated Official or COIAC (as selected by the IRB Chairperson) shall, within one hundred twenty (120) days of the determination of non-compliance, complete a retrospective review of the investigator's activities to determine whether the research was biased in the design, conduct, or reporting of such research. This retrospective review shall be documented as required by 42 C.F.R § 50.605(a)(2) and action taken as required by 42 C.F.R. § 50.605(a)(3).

8. ***Reporting to PHS*** - For PHS funded research, FCOIs are reported to PHS by the Designated Official (or designee) prior to expenditure of PHS funds, upon subsequent disclosure or discovery of a conflict, on an on-going basis, and in the event of a failure to comply as required by 42 C.F.R. § 50.605(b) and 42 C.F.R. § 50.606.

9. ***Review by Outside Agency*** - WHHS will cooperate with PHS or other regulatory agencies regarding financial conflicts of interest in research.

10. ***Public Access to COI Information*** - WHHS shall post this Policy on its publicly accessible website https://www.whhs.com/. For PHS funded research, WHHS shall insure public accessibility via a written response to any requestor, within 5 business days, of information concerning any SFI disclosed to the institution, as required by 42 C.F.R. § 50.605(a)(5).

E. Procedures

1. Investigator Responsibilities

A. ***Disclosure*** - Regardless of the source of funding, investigators conducting or planning to conduct research at WHHS shall disclose all SFIs in accordance with this policy on the Statement of Financial Interest for Researchers. Investigators shall certify on the Statement of Financial Interest for Researchers that they have read the WHHS IRB Conflict of Interest in Research Policy and shall conduct their research in a manner that promotes objectivity in research. The Statement of Financial Interest for Researchers must be submitted or updated to reflect all current activities at the following times:

- At the time of application for approval/acceptance of the research at WHHS;
- Annually during the life of the research study; and
- Within 30 days when a new financial interest is acquired or discovered.

B. ***Training*** – For PHS funded research, investigators must complete conflict of interest training, including the responsibility to disclose and the PHS regulations, at the following times:
   - Prior to engaging in the research;
   - Every four years thereafter; and
   - Upon recommendation of the COIAC when an investigator is not in compliance with this policy.

C. ***Compliance with MPs and Other Requirements*** – Investigators are expected to comply with the requirements of an approved FCOI MP and/or with other imposed requirements or sanctions. Refer to section D of this Policy for possible actions for non-compliance.

2. **Institutional Responsibilities**

A. ***Policy –*** WHHS maintains a current, written and enforced policy regarding FCOI in research. WHHS ensures that all investigators are informed of this Policy, including Policy revisions.

B. ***Review and Referral*** - The Designated Official will review all Statements of Financial Interest for Researchers. Disclosure forms that include a potential SFI are forwarded to the COIAC for review and possible action.

C. ***Role of COIAC*** –
   - Reviewing and assessing FCOIs;
   - Recommending a MP;
   - Monitoring the elements of a MP to ensure compliance;
   - Reviewing and making recommendations in the event of a breach of this policy; and
   - As assigned, conduct review of research that was initiated prior to FCOI review.

D. ***Initial Review*** – After review of Statement of Financial Interest for Researchers, the COIAC recommendations may include, but are not limited to, the following options that the disclosed financial interest is:
   - Acceptable without any need for management;
   - Acceptable with some form of MP (such as disclosure or restrictions on the activities of the investigator, or such other form as determined appropriate); or
   - Not acceptable – in which case the financial interest must be divested or other action taken.

E. ***Management Plan*** – Upon determination that a FCOI exists, WHHS may impose a MP in order to reduce, mitigate or eliminate an actual or potential FCOI. Requirements may include, but are not limited to:
   - Public disclosure of significant financial interests in presentations and publications;
   - Requesting an addendum to previously published research;

- For research involving human subjects, disclosure of FCOI directly to participants;
- Monitoring of the research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the research;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflict; and
- Any other action deemed appropriate by the COIAC based on the individual situation.

F. ***Institutional Response to Failure to Comply –***
- The Designated Official, or designee, shall report any failures to comply with this Policy or related regulations or laws to the CEO, the Chairperson of the IRB, the Chief of Medical Staff Services, and WHHS legal counsel as appropriate.
- Failure to comply with this Policy may result in an investigator no longer being able to conduct further research at WHHS and being removed from all currently approved research studies. When an investigator's failure to comply with this Policy biases the design, conduct, or reporting of the research, the Designated Official, or designee, shall promptly report the corrective action taken to the appropriate funding agency, if required.
- The COIAC will address all breaches of this Policy, including:
  - Failure to comply with the disclosure requirement, whether by virtue of a refusal, late response, or by responding with incomplete or inaccurate information;
  - Failure to remedy conflicts; and
  - Failure to comply with conditions in a prescribed conflict MP

G. ***Records***- Records of all financial disclosures and all actions taken by WHHS with respect to financial interests will be maintained by the IRB for at least three years from the completion of the research.

Appendix D
OHRP Expedited Review Categories

OHRP Expedited Review Categories (1998)
Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS

regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).
Source: 63 FR 60364-60367, November 9, 1998.
Content created by Office for Human Research Protections
Content last reviewed on March 21, 2016

Appendix E
Internal Adverse Event Reporting Flowchart

The flow chart below provides an algorithm for determining whether an adverse event represents an unanticipated problem that needs to be reported to the IRB under regulations at 45 CFR part 46. Only Internal Adverse Events, those experienced by a subject enrolled by an investigator at the Washington Hospital site, need to be reported.

An unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unanticipated (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and ICF, or the Investigator Brochure; and (b) the characteristics of the subject population being studied, i.e., that the event is not part of the expected natural progression of any underlying disease, disorder or condition of the subject.

- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research).

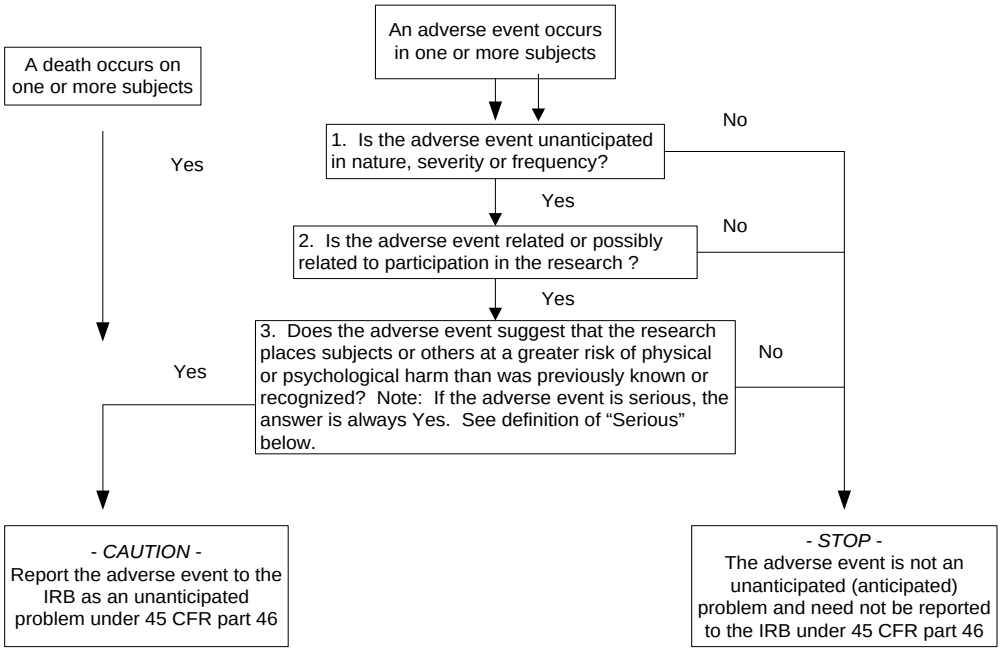
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

Definition of "Serious" – Any adverse event that results in death, is life threatening, results in hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, results in a congenital anomaly or birth defect, based on appropriate medical judgment, may jeopardize the subject's health and requires intervention.

Reference: OHRP "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events."

Appendix E

Internal Adverse Events Reporting Flowchart



Appendix F
Expanded Access to Investigational Drugs and Devices

A. Summary and Definitions

The FDA recognizes that there are circumstances in which investigational drugs and/or devices are the only option available for a patient with a life-threatening disease or condition. The purpose of the regulations regarding expanded access is to facilitate the availability of such drugs and devices when there is no comparable or satisfactory alternative therapy to diagnose, monitor or treat the patient's disease or condition. A Central IRB may be the IRB of record for Expanded Access Use.

All Expanded Access Use requires the involvement of the IRB, either IRB approval or the concurrence of the IRB Chairperson.

Prior approval of the FDA is required for all expanded access use except emergency use of medical devices.

Informed consent of the patient or their legally authorized representative must be obtained except where an emergency exception applies. Because Expanded Access is not considered research, all the requirements for informed consent outlined in these Policies and Procedures may not apply.

The regulations include the following definitions:

- Immediate life-threatening disease or condition: A stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

- Serious disease or condition: A disease or condition associated with morbidity that has substantial impact on day-to-day functioning.

- Expanded Access Programs: The FDA term for the various types of allowable Expanded Access Use. For drugs this includes: Single Patient, Emergency Use for Single Patient, Intermediate Size Patient Population and Treatment Protocol for Widespread Treatment Use. For devices this includes: Emergency Use, Compassionate Use and Treatment Use.

Refer to Section XLII of these Policies and Procedures for Humanitarian Use Devices.

B. Criteria for All Expanded Access Programs

The FDA may allow Expanded Access if the following conditions are met:

- The patient and a licensed physician are both willing to participate.

- The patient's physician documents that there is no comparable or satisfactory therapy available to diagnose, monitor or treat the patient's disease or condition.

- The probable risk to the patient from the investigational product is not greater than the probable risk from the disease/condition.

- The FDA determines that there is sufficient evidence of the safety and effectiveness of the investigational product to support the use in the particular situation.

- The FDA determines that providing the investigational product will not interfere with the initiation, conduct or completion of clinical investigations to support market approval.

- The sponsor (usually the company developing the investigational product) or the investigator or the patient's physician (in case of a single patient expanded access request) submits a clinical protocol and patient treatment plan that is consistent with FDA regulations for IND or IDE applications, describing the proposed use of the investigational product.

- The patient is unable to obtain the investigational product under another IND or IDE or to participate in a clinical trial.

C. Expanded Access to Drugs

The FDA provides forms to be used by the physician to request Expanded Access. The forms are available on the FDA website. For additional guidance on Expanded Use of investigational drugs refer to 21 CFR 312. 1.

1. Single Patient Use
   - Criteria – In addition to the criteria described above in B., the FDA may permit an investigational drug to be used for the treatment of an individual patient by a licensed physician if the following determinations are made:
     – The physician determines and documents that in this situation, the probable risk from the investigational drug is not greater than the probable risk from the disease or condition.
     – The FDA determines that the patient cannot obtain the drug under another IND or protocol.

   - Monitoring and Reporting
     – Treatment is generally limited to a single course of therapy for a specified duration unless the FDA expressly authorizes multiple courses or chronic therapy.
     – At the conclusion of treatment, the licensed physician or sponsor must provide the FDA with a written summary of the results of the Expanded Access Use including adverse effects.

   - Role of the IRB
     – Review and approve the ICF. If there is no ICF, obtain assurance from the requesting physician that informed consent will be obtained from the patient or legally authorized representative.
     – Ensure that FDA approval for the Expanded Access has been obtained.
     – Approve or disapprove the Expanded Access Use.
     – Request that the requesting physician provide a copy to the IRB of the summary report described above that is provided to the FDA.

2. Emergency Use for Single Patient
   - Criteria – If there is an emergency that requires the patient to be treated before a written submission can be made, the FDA may authorize the Expanded Access Use to begin

without a written submission. The request may be submitted by a licensed physician or sponsor by telephone, fax or other means or electronic communication. The FDA reviewing official may authorize the emergency use by telephone. The licensed physician or sponsor must explain how the Expanded Access Use will meet the requirements outlined in B and C1 of this section of these Policies and Procedures and must agree to submit an Expanded Access submission within 15 working days of the FDA's authorization of the use.

- Role of the IRB
  - Unless the emergency exception to informed consent applies, review and approve the ICF. If there is no form, obtain assurance from the requesting physician that informed consent will be obtained from the patient or legally authorized representative.
  - Ensure that request for Expanded Access has been submitted to the FDA and that emergency use has been verbally authorized.
  - Approve or disapprove the Expanded Access Use. In the interest of time in an emergency situation, the IRB Chairperson may approve the Expanded Access Use.
  - Request that the requesting physician provide copies to the IRB of any subsequent reports required by the FDA regarding the Expanded Access Use.

3. Intermediate Size Patient Populations
   - Criteria- In addition to the criteria described in B above, the FDA may permit an investigational drug to be used for treatment of a patient population smaller than that typical of a treatment IND or treatment protocol in the following situations:
     - The drug is not being developed because, for example the disease or condition is so rare that recruiting patients for a clinical trial is not possible.
     - The drug is being studied but the patients needing the drug are unable to participate in the clinical trial because of failure to meet inclusion criteria, enrollment is closed or because the trial site is inaccessible.
     - The drug is approved but is no longer available because of safety concerns or drug shortages.

   - Additional Criteria
     - There is evidence that the drug is safe enough to justify a clinical trial in the approximate number of patients expected to receive the drug under expanded access.
     - There is at least preliminary clinical evidence of the effectiveness of the drug.
     - The sponsor provides information adequate to satisfy the FDA that the requirements for Expanded Access for Intermediate Size Patient Population have been met.

   - Monitoring and Reporting
     - The sponsor is responsible for monitoring the Expanded Access Protocol to ensure that physicians comply with the protocol.
     - The sponsor must submit an IND annual report to the FDA.

   - Role of the IRB

- Review and approve the ICF. If there is no ICF, obtain assurance from the requesting physician that informed consent will be obtained from the patient or legally authorized representative.
- Ensure that FDA approval for the Expanded Access has been obtained.
- Approve or disapprove the Expanded Access Use.
- Request that the requesting physician provide copies to the IRB of any subsequent reports required by the sponsor and/or the FDA regarding the Expanded Access Use.

4. Treatment IND or Treatment Protocol for Widespread Treatment Use

- Criteria- In addition to the criteria described in B above, the FDA may permit an investigational drug to be used for widespread treatment use in the following situations:
  - The drug is being investigated in a controlled clinical trial.
  - All clinical trials of the drug have been completed and the sponsor is pursuing marketing approval of the drug for the expanded access use.

- Additional Criteria
  - The expanded access use is for a serious disease or condition and there is sufficient clinical evidence of safety and effectiveness to support the expanded use.
  - The expanded access use is for an immediately life threatening disease or condition, the available scientific evidence provides a reasonable basis to conclude that the drug may be effective and would not expose patients to unreasonable and significant risk of illness or injury.
  - The sponsor provides information adequate to satisfy the FDA that the requirements for Expanded Access for Widespread Treatment Use have been met.

- Monitoring and Reporting
  - The sponsor is responsible for monitoring the treatment protocol to ensure that licensed physicians comply with the protocol and the regulations applicable to investigators.

- Role of the IRB
  - Review and approve the ICF. If there is no ICF, obtain assurance from the requesting physician that informed consent will be obtained from the patient or legally authorized representative.
  - Ensure that FDA approval for the Expanded Access has been obtained.
  - Approve or disapprove the Expanded Access Use.
  - Request that the requesting physician provide copies to the IRB of any subsequent reports required by the sponsor and/or the FDA regarding the Expanded Access Use.

D. Expanded Access to Medical Devices

For additional guidance on Expanded Access to investigational devices refer to 21 CFR 812.

1. Emergency Use

Emergency use is intended to provide patients and physicians with access to devices intended to treat life-threatening or serious diseases when there is no available alternative and no time to obtain FDA approval. Emergency use may apply even if the investigational device is being studied in a clinical trial under an IDE if a physician needs to use the device

in a manner inconsistent with the approved investigational plan or a physician who is not part of the clinical study wishes to use the device to treat a patient with a life-threatening or serious condition. Emergency use of an investigational device may occur before an IDE is approved and when a device is not being studies under an IDE.

- Criteria - All of the following criteria must be met:
  - The patient has a life-threatening or serious condition that needs immediate treatment.
  - No generally acceptable alternative treatment for the condition exists.
  - Because of the immediate need to use the device, there is no time to use existing procedures to obtain FDA approval for the use.

  The FDA expects the physician to make the determination that the patient's circumstances meet the above criteria, to assess the potential for benefit from the use of the device and have reason to believe that benefit exists.

- Patient Protection Procedure – The physician should follow as many of the following patient protection procedures as time and patient circumstances allow:
  - Informed consent from the patient or legally authorized representative.
  - Clearance from the organization.
  - Concurrence from the IRB Chairperson.
  - An independent assessment from an uninvolved physician.
  - Authorization from the device manufacturer.

- Monitoring and Reporting
  - If there is an IDE for the device, the IDE sponsor must notify the FDA of the emergency use within 5 days through submission of an IDE report. The report should include a summary of the conditions constituting the emergency, the patient protection procedures that were followed and patient outcome information.
  - If no IDE exists, the physician should submit a follow-up report to the FDA on the use of the device including a description of the device used, the details of the case and the patient protection procedures followed.

- Role of the IRB
  - Unless the emergency exception to informed consent applies, review and approve the ICF. If there is no ICF, obtain assurance from the requesting physician that informed consent will be obtained from the patient or legally authorized representative.
  - Ensure that the hospital (or other affiliated entity) agrees with the Expanded Access Use.
  - Ensure that if time allows that there has been an independent assessment of the patient and the use of the device from an uninvolved physician.
  - Ensure that if time allows, the device manufacturer has authorized the use of the device.
  - If the above four requirements are met or waived due to time, the IRB Chairperson can approve the Expanded Access Use by documenting concurrence with the use.

2. Compassionate Use

The compassionate use provision provides a path to accessing investigational devices that have not received FDA approval for patients for whom the treating physician believes the device may benefit. Compassionate use can be for devices that are being studied in a clinical trial but the patient does not meet the criteria for inclusion, but for whom the physician believes the device may provide benefit. Compassionate use can also be used for devices that are not part of a clinical trial. This provision is typically approved for a single patient but may be approved to treat a small group. FDA approval is required before compassionate use occurs.

- Criteria – Both of the following criteria must apply:
  - The patient has a life-threatening or serious disease or condition.
  - No generally acceptable alternative treatment for the condition exists.

- Request for FDA Approval
  - If there is an IDE for the device, the IDE sponsor should submit an IDE supplement to the FDA requesting approval for compassionate use including: a description of the patient's condition and the circumstances necessitating treatment, a discussion of why alternative therapies are unsatisfactory, why the risk of using the device is no greater than the probable risk of the condition and identification of any deviations from the approved clinical protocol that may be needed and the patient protection measures that will be followed.
  - If there is no IDE for the device, the physician or manufacturer must submit to the FDA all of the information described in the above paragraph and a description of the device provided by the manufacturer. The device may not be used until the FDA approves the use in the specific situation.

- Patient Protection Procedures – The following patient protection procedures must be followed:
  - Informed consent from the patient or legally authorized representative.
  - Clearance from the organization.
  - An independent assessment from an uninvolved physician.
  - Approval of the expanded access use by the FDA.
  - Authorization from the device manufacturer for the expanded access use.

- Role of the IRB
  - Ensure that all the patient protection procedures listed above have been followed. If so, the IRB Chairperson can approve the expanded access use by documenting concurrence. The IRB Chairperson may elect to take the compassionate use request to the full IRB.

3. Treatment Use

An approved IDE specifies the maximum number of clinical sites and the maximum number of human subjects that may be enrolled in the research study. During the course of the clinical trial, if the data suggests that the device is effective, the trial may be expanded to include additional patients with life-threatening or serious diseases or conditions. This is called treatment use.

- Criteria – All of the following criteria must be met:
  - The device is intended to treat or diagnose a serious or life-threatening disease or condition.
  - There is no comparable or satisfactory alternative device available to treat or diagnose the disease or condition in the intended patient population.
  - The device is under investigation in a controlled clinical trial for the same use under an approved IDE or all clinical trials have been completed.
  - The sponsor of the approved clinical trial is pursuing marketing approval/clearance of the device with due diligence.

- Request for FDA Approval – A treatment IDE application must be submitted to the FDA by the sponsor.

- Monitoring and Reporting
  - The sponsor of a treatment IDE must submit semi-annual progress reports to all reviewing IRBs and the FDA. Progress reports must contain the elements described in the regulations and include the number of patients treated with the device, the names of the investigator's participating in the treatment use and a description of the sponsor's efforts to pursue marketing approval/clearance of the device.

Note: In treatment use, the involved physician is considered an "investigator" and as such, must comply with all applicable FDA regulations.

- Role of the IRB – The IRB must review and approve the treatment use and the ICF.

Appendix G
Glossary of Terms, Abbreviations and Acronyms

21 CFR – Department of Health and Human Services, Code of Federal Regulations – Title 21, Parts 50, 56, 312 and 812, Food and Drug Administration. The FDA's regulations apply to the investigational use of "new drugs", "new devices" and "test articles."

42 CFR – Department of Health and Human Services, Code of Federal Regulations, Title 42, Part 50, Subject F, Promoting Objectivity in Research – These regulations apply to federally funded research.

45 CFR – Department of Health and Human Services, Code of Federal Regulations, Title 45,Part 46,Protection of Human Subjects – These regulations apply to federally funded research.

Adverse Event, External – Those adverse events experienced by subjects enrolled by investigators at other institutions involved in the research. External Adverse Events do not need to be reported to the WHHS IRB.

Adverse Event, Internal – Those adverse events experienced by subjects enrolled by an investigator at the Washington Hospital site. Internal Adverse Events need to be reported to the WHHS IRB.

Adverse Event (AE), Anticipated – An event that may be reasonably anticipated to occur as a result of the study procedures or study participation and should thus be described in the research proposal, the ICF and investigator's brochure (when applicable), or is part of the normal disease process or progression.

Adverse Event (AE), Unanticipated – An event that exceeds the nature, severity, or frequency described in the current protocol, ICF and investigator brochure (when applicable). An unanticipated AE also includes any AE that meets any of the following criteria:

- Results in subject withdrawal from study application,
- An overdose of study medication, or
- A deviation from the approved study protocol.

Affiliated – Associated with an institution, organization, or project typically in a dependent position (i.e., an employee of the institution, a paid consultant to a research project).

Assent – A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. 21 CFR 50.3

Authorized Institutional Individual (or Official) – An officer or appointed representative of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research. (At WHHS the Authorized Institutional Individual is the CEO).

Blinded Study Designs – Study designs comparing two or more interventions in which either the investigators, the subjects, or some combination thereof do not know the treatment group assignments of individual subjects. These are sometimes called "masked" study designs.

Broad Consent - Consent that may be obtained in lieu of informed consent obtained in accordance with regulations and these Policies and Procedures only with respect to the storage, maintenance and secondary research uses of identifiable private information and identifiable biospecimens**.** 45 CFR 46.116

California Health & Safety Code Sections 24170 – 24179 and 111515 – The California law that applies to all medical experiments involving human subjects.

Children – Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. 21 CFR 50, Subpart D and 45 CFR 4b, Subpart D

CIRB - Central Institutional Review Board – A group designated to monitor research involving human subjects for all sites involved in a research study (IRB of record). This group could be an institution's IRB; a federal IRB; or a private, independent IRB.

Clinical Investigation – Any experiment that involves a test article and one or more human subjects and either meets the requirement for prior submission to the FDA or does not meet the requirements for prior submission, but the results of which are intended to be submitted to, inspected by the FDA as part of an application for a research or marketing permit. 21 CFR 50.3

Co-Investigator – A person that may share some of the duties of the Principal Investigator, such as enrolling subjects, but does not have overall responsibility for the research. May be called a sub-investigator. Such persons are required to disclose financial interests.

Compassionate Use – A term commonly used to describe some of the ways of making unapproved products (drugs and/or devices) available to patients. In fact "Compassionate Use" is only one mechanism for Expanded Access to drugs or devices. Refer to Appendix F.

Cooperative Research – Projects which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of the human subjects and for complying with applicable federal and state regulations. 45 CFR 46.114

Clinical Trial – A research study in which one or more human subjects are prospectively assigned to one or more interventions (including placebo or control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. 45 CFR 46.102

Data Monitoring Plan – A written plan for the collection and analysis of data during the course of a research project which monitors adverse effects and other trends that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue the trial.

De-identified – Health information that neither identifies nor provides a reasonable basis to identify an individual. The HIPAA Privacy Rule provides two ways to de-identify information: (1) A formal determination by a qualified statistician; or (2) the removal of 18 specified identifiers of the individual and of the individual's relatives, household members, and employers, and the covered entity has no actual knowledge that the remaining information could be used to identify the individual. 45 CFR 164.514

Delivery – Complete separation of the fetus from the woman by expulsion or extraction or any other means.

Drug – Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

Emancipated Minor – A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation.

Embryo – Early stages of a developing organism, broadly used to refer to states immediately following fertilization of an egg through implantation and very early pregnancy (i.e., from conception to the eighth week of pregnancy).

Equitable – Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed. 45 CFR 46 .111

Expanded Access – A policy and procedure which permits individuals who have serious or life-threatening diseases for which there are no alternative therapies to have access to investigational drugs and/or devices that may be beneficial to them. Refer to Appendix F.

Expedited Review – Review of proposed research by the IRB Chairperson or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. 45 CFR 46.110

Facilitated Review – The review is performed by a sub-set of the IRB. A report from the Facilitated Review is provided to the full IRB.

Fetus – The product of conception from implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant45 CFR 46.203. The term “fetus” generally refers to later phases of development; the term “embryo” is usually used for earlier phases of development.

FWA – Federal Wide Assurance – A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved. 45 CFR 46 .103

Grant – Financial support provided for research designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by the grant.

Guardian – An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. 45 CFR Part 46.402

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Information or biospecimen through intervention or interaction with the individual and uses, studies, or analysis of the information or biospecimens or (2) Obtains, uses,

studies, analyzes or generates identifiable private information or identifiable biospecimen. A human subject may be the recipient of a test article or as a control. 45 CFR 46.102

Humanitarian Use – A Humanitarian Use Medical Device (HUD) is a medical device that has been granted (by the FDA) a special exemption from some of the requirements for approval before marketing, because its expected market is so small that the studies needed for licensure would simply never be able to be carried out. The general criteria are:

- Expected to benefit fewer than 4,000 people in the US per year.
- No comparable device already available.
- No exposure to "unreasonable or significant risk of illness or injury."
- Potential benefits of the device outweigh its risks.

Identifiable Private Information – Information for which the identity of the subject is or may be readily ascertained by the researcher/investigator or associated with the information.

Identifiable Biospecimen – A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

Note: Within one year after implementation of the Final Common Rule and at least every four years thereafter, federal departments or agencies, with input from appropriate experts will re-examine the meaning of identifiable private information and identifiable biospecimen and whether there are analytic technologies or techniques that should be considered by investigators to generate such information or biospecimen. Such technologies and techniques will be included in a list that will be published in the Federal Register. This definition is contained in the Final Common Rule, 45 CFR 46.102

Impacted Department – Any area, service or department within Washington Hospital or within an affiliated entity, that has a role in or care for patients that are subjects in a research at the Washington Hospital site.

Implant – A device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for 30 days or more. 21 CFR 812.3

Informed Consent – A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventative procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence. 45 CFR 46. 116 and 21 CFR 50. B

Institution – For the purposes of these Policies and Procedures institution refers to Washington Hospital.

Interaction – Communication or interpersonal contact between investigator and subject. 45 CFR 46.102

Intervention – Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for

research purposes. Interaction includes communication or interpersonal contact between investigator and subject. 45 CFR 46.102

Investigational Device Exemptions (IDE) – Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations. 21 CFR 812

Investigational New Drug (IND) – A drug or biological product permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing. 21 CFR 312

Investigator – An individual who actually conducts a clinical investigation. For purpose of these Policies and Procedures, "investigator" means the same as "researcher." 21 CFR 50.3

Investigator's Brochure – A comprehensive document summarizing the body of information about an investigational product.

IRB Administrator – At WHHS the Chief of Compliance is the IRB Administrator.

IRB Approval – The determination by the IRB that the research has been reviewed and may be conducted at the institution within the constraints set forth by the IRB and by other institutional and federal requirements. 45 CFR 46.102

Lactation – The period of time during which a woman is providing her breast milk to an infant or child.

Legally Authorized Representative – An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. 45 CFR 46.102

Limited IRB Review – An exemption to full IRB review that can be utilized for federally funded research when there is a broad consent in place. 45 CFR 46.104

Longitudinal Study – A study designed to follow subjects forward through time.

Medical Device – Any healthcare product that does not achieve its principal intended purpose by chemical action or being metabolized. Such devices included diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102, 21 CFR 50.3 For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

NCI – National Cancer Institute – A large national cancer organization which conducts oncology related clinical trials using a network of cooperative research sites.

Neonate – A newborn.

NIH - National Institutes of Health – A federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.

Non-Affiliated Member – A member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (i.e., minister, business person, attorney, teacher, homemaker).

Non-Scientist – A person who by trade, training, and/or education is not a specialist in any scientific field.

Non-Significant Risk Device – An investigational medical device that does not present significant risk to the patient.

Nonviable Fetus – An expelled or delivered fetus which although it is living cannot possibly survive to the point of sustaining life independently, even with the support of available medical therapy. 45 CFR 46.203. Although it may be presumed that an expelled or delivered fetus is nonviable at a gestational age or less than 20 weeks and weight less than 500 grams, a specific determination as to viability must be made by a physician in each instance.

Nonviable Neonate – A neonate after delivery that, although living, is not viable.
(See nonviable fetus).

Null Hypothesis – The proposition, to be tested statistically, that the experimental intervention has "no effect," meaning that the treatment and control groups will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thereby allowing the investigator to reject the null hypothesis.

OHRP - Office for Human Research Protections – The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (DHHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and behavioral research.

Parent – A child's biological or adoptive parent. 21 CFR 50.3

Paternalism – Making decisions for others against or apart from their wishes with the intent of doing them good.

Permission – The agreement of parent(s) or guardian to the participation of their child or ward in research. 45 CFR 46.402

Phased Drug Trials – Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phase 3), to post-marketing studies (Phase 4).

Phase 1 Drug Trial – Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the

drug is intended for use in patients with a particular disease, however, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects involved in Phase 1 investigations is generally in the range of 20-80.

Phase 2 Drug Trial – Phase 2 trials include controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well-controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred subjects.

Phase 3 Drug Trial – Phase 3 trials involve the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide an adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects.

Phase 4 Drug Trial – Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain post marketing (Phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time. 21 CFR 312.85

Pregnancy – Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. 45 CFR 46.203

Principal Investigator – The scientist or scholar with primary responsibility for the design and conduct of a research project.

Prisoner – Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes, or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing. 45 CFR 46.303

Privacy – Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Private Information – Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for the information to constitute research involving human subjects.

Prospective Studies – Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

Protocol – The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for the prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data

Random, Random Assignment, Randomization, Randomized – Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

Research – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102 Activities which meet this definition constitute research where or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Researcher – An individual who actually conducts research. For the purpose of these Policies and Procedures, “researcher” means the same as “investigator.”

Retrospective Studies – Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

Risk – The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.”

Scientist – A person learned in science and especially natural science, whose primary concerns are in scientific areas.

Serious Adverse Event (SAE) – A Serious Adverse Event (SAE) is defined as an Adverse Event that:

a) Led to a death

b) Led to a serious deterioration in the health of the subject that either resulted in:
    1) A life-threatening illness or injury, or
    2) A permanent impairment of a body structure or a body function, or
    3) In-patient hospitalization or prolongation of an existing hospitalization, or
    4) Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.
c) Led to fetal distress, fetal death or a congenital abnormality or birth defect.

Significant Risk Device – An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the subject.

Sponsor – A person who takes responsibility for and initiates a clinical investigation. A sponsor may be an individual, a company (such as a pharmaceutical or medical device company), governmental agency, academic institution, private or other organization. The sponsor does not actually conduct the research unless the sponsor is a sponsor- investigator. 21 CFR 50.3

Sponsor-Investigator – An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

Statistical Significance – A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. [*See McLarty (1987), p. 2.*] If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).

Subject – A human who participates in an investigation either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease. 21 CFR 812.3

Test Article – Any drug, including a biological product for human use, medical device for human use, human food additive, electronic product or other article subject to regulation under the Federal Food, Drug and Cosmetic Act. 21 CFR 50.3

Unanticipated Problem – Any incident, experience or outcome that meets all of the following criteria:

- The adverse event is unanticipated in nature, severity or frequency.
- The adverse event related or possibly related to participation in the research.
- The adverse event suggests that the research places subjects or others are at a greater risk of physical or psychological harm than was previously known or recognized.

Viable – As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Written (or in Writing) – Writing on a tangible medium (e.g. paper) or in an electronic format. 45 CFR 46.102

Appendix H
Table of Abbreviations and Acronyms

Abbreviation	Full Text
21 CFR	Title 21 of the Code of Federal Regulations
42 CFR	Title 42 of the Code of Federal Regulations
45 CFR	Title 45 of the Code of Federal Regulations
AE	Adverse Event
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CIRB	Central Institution Review Board
COIAC	Conflict of Interest Advisory Committee
CTSU	Cancer Trials Support Unit
CV	Curriculum Vitae
DHHS	Department of Health and Human Services
FDA	(Federal) Food and Drug Administration
FWA	Federal Wide Assurance
HUD	Humanitarian Use Device
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
NCI	National Cancer Institute
NIH	National Institutes of Health
NSR	Non-Significant Risk
OHRP	Office for Human Research Protections
SAE	Serious Adverse Event
SR	Significant Risk
UCSF	University of California, San Francisco
WHHS	Washington Hospital Healthcare System

Washington Hospital Healthcare System

SINCE 1948

Memorandum

DATE: March 15, 2021

TO: Kimberly Hartz, Chief Executive Officer

FROM: Prasad Kilaru, MD, Chief of Staff

SUBJECT: MEC for Board Approval:

The Medical Executive Committee, at its meeting of March 15, 2021, approved the revisions to the Moderate Sedation privilege form.

Please accept this memorandum as a formal request for presentation to the Board of Directors for final approval of the attached revisions to the Moderate Sedation privilege form.

Moderate Sedation Pathways

The physician must demonstrate that they have 1) the requisite knowledge to administer pharmacologic agents to predictably achieve and maintain desired levels of sedation, and 2) have the training and experience to recognize and rescue patients from the cardiovascular and respiratory depressive effects of unavoidably or unintentionally obtaining a deeper-than-desired level of sedation.

Applicants applying for privileges may fulfill these requirements via 1 of 4 pathways.

PATHWAY 1: Administration of sedation and airway management were integral components of the applicant's training. This applies to the specialties of Anesthesia, Critical Care, Pulmonary Medicine, and Emergency Medicine. The applicant must provide documentation that they have provided moderate sedation, deep sedation, or endotracheal intubation for at least 12 patients in the last 24 months.

PATHWAY 2: Applicants must possess current ACLS certification (or PALS for pediatricians), and pass a course developed by the Department of Anesthesiology. This course will include components on sedation and airway management.

PATHWAY 3: Cardiologists routinely provide advanced cardiac care and may be exempted from the ACLS requirement. They must pass a course developed by the Department of Anesthesiology. This course will include components on sedation and airway management.

PATHWAY 4: Applicants must possess current ACLS certification (or PALS for pediatricians), and provide proof of moderate sedation privileges at another facility. These physicians may be granted moderate sedation privileges if the training and testing requirements at that facility are deemed equivalent by the Chair of Anesthesiology.

Reappointment: The applicant must provide documentation of administration of moderate sedation services (at least 12 cases that can be a combination of moderate sedation, deep sedation, or endotracheal intubation) representative of the scope and complexity of the privileges requested over the last 24 months. Applicants granted privileges outside of Pathway 1 and 3 must maintain current ACLS certification (or PALS for pediatricians).

If the applicant cannot provide this documentation for reappointment, they must re-apply for moderate sedation privileges.

Washington Hospital Medical Staff

2000 Mowry Avenue ◆ Fremont, CA 94538
(510) 791-3446◆ Fax (510) 792-0795
Washington Township Hospital District

Specialty: Moderate Sedation Rev March 2021

Delineation of Privileges

Applicant's Name:

Instructions:

1. Click the **Request** checkbox to request a group of privileges such as *Core Privileges* or *Special Privileges*.
2. Uncheck any privileges you do not want to request in that group.
3. When requesting your privileges, please remember you must be able to demonstrate current competency to be granted or to have a privilege renewed.
4. Please pay close attention to make sure you submit all required forms (i.e., activity, case logs), as incomplete files cannot be processed.
5. Electronically Sign/Date form.

Notes:

- Applicants are not required to apply for all specialty-specific Core Privileges. If requirements exist for a particular specialty, the criteria will be outlined under the required qualifications section of each privilege form.
- Applicants may request privileges that apply to multiple specialties if they qualify.
- **IMPORTANT - If you have not met the minimum activity requirements for any privileges, do not check the boxes for those privileges.**

Required Qualifications	
Qualifications	Licensed M.D. or D.O. **AND** Qualified practitioners within any of the Departments of the Medical Staff may apply for privileges contained in this document. The Anesthesia Chair or designee is responsible for reviewing the qualifications and making recommendation(s) for this privilege.
Membership	Meet all requirements for medical staff membership if applicable.
Education/Training	The physician must demonstrate that they have 1) the requisite knowledge to administer pharmacologic agents to predictably achieve and maintain desired levels of sedation, and 2) have the training and experience to recognize and rescue patients from the cardiovascular and respiratory depressive effects of unavoidably or unintentionally obtaining a deeper-than-desired level of sedation. Applicants applying for privileges may fulfill these requirements via 1 of 4 pathways. Pathway 1 - Administration of sedation and airway management were integral components of the

applicant's training. This applies to the specialties of Anesthesia, Critical Care, Pulmonary Medicine, and Emergency Medicine. The applicant must provide documentation that they have provided moderate sedation, deep sedation, or endotracheal intubation for at least 12 patients in the last 24 months.

OR

Pathway 2 - Applicants must possess current ACLS certification (or PALS for pediatricians), and pass a course developed by the Department of Anesthesiology. This course will include components on sedation and airway management.

OR

Pathway 3 - Cardiologists routinely provide advanced cardiac care and may be exempted from the ACLS requirement. They must pass a course developed by the Department of Anesthesiology. This course will include components on sedation and airway management.

OR

Pathway 4 - Applicants must possess current ACLS certification (or PALS for pediatricians), and provide proof of moderate sedation privileges at another facility. These physicians may be granted moderate sedation privileges if the training and testing requirements at that facility are deemed equivalent by the Chair of Anesthesiology.

Clinical Experience (Initial)

When requested, the applicant must be able to demonstrate that s/he has administered moderate sedation, deep sedation or endotracheal intubation for at least 12 patients within the past 24 months.

OR

Practitioners without the requisite prior experience may demonstrate instead successful completion of a CME course on moderate sedation approved in advance by the Chair of Anesthesiology, which includes procedural airway skills and/or simulation.

Clinical Experience (Reappointment)

The applicant must provide documentation of administration of moderate sedation services (at least 12 cases that can be a combination of moderate sedation, deep sedation, or endotracheal intubation) representative of the scope and complexity of the privileges requested over the last 24 months. Applicants granted privileges outside of Pathway 1 and 3 must maintain current ACLS certification (or PALS for pediatricians).

If the applicant cannot provide this documentation for reappointment, they must re-apply for moderate sedation privileges.

Special Privilege: Moderate (Procedural) Sedation

Request ☐	***Request all privileges listed below.*** *Uncheck any privileges that you do not want to request.*	Dept Chair Rec ☐
☐	Moderate Sedation	☐

☐ Review of the first 3 cases of administration of moderate sedation by a physician who has unrestricted moderate sedation privileges. The proctor does not need to be from the same specialty. Proctorship of the procedure requiring the sedation must be documented separate from the primary procedure.

☐ Review of OPPE data collected related to moderate sedation

Acknowledgment of Applicant

I have requested only those privileges for which I am qualified by education, training, current experience, and demonstrated current competency I am entitled to perform and that I wish to exercise at Washington Hospital and I understand that:

A. In exercising any clinical privileges granted, I am constrained by Hospital and Medical Staff Bylaws, policies and rules applicable generally and any applicable to the particular situation.

B. Any restriction on the clinical privileges granted to me is waived in an emergency situation and in such situation my actions are governed by the applicable section of the Medical Staff Bylaws or related documents.

C. I certify that I have no emotion or physical condition that would affect my ability to perform these privileges.

D. Furthermore, I attest that the information I have provided about my clinical activity is accurate and true.

Practitioner's Signature _____ Date _____

Anesthesiology Department Chair/Designee Recommendation - Privileges

I have reviewed the requested clinical privileges and supporting documentation and make the following recommendation(s):

☐	Recommend all requested privileges
☐	Do not recommend any of the requested privileges
☐	Recommend privileges with the following conditions/modifications/deletions (listed below)

Privilege	Condition/Modification/Deletion/Explanation

Anesthesiology Department Chair/Designee Recommendation - FPPE Requirements

Signature of Anesthesia Department Chair/Designee

Date

Submit

Washington Hospital Healthcare System

SINCE 1948

Memorandum

DATE: April 9, 2021

TO: Kimberly Hartz, Chief Executive Officer

FROM: Ed Fayen, Executive Vice President and Chief Operating Officer
John Lee, Chief Information Officer

SUBJECT: CJR Garden Level Clinic X-Ray

As covered in the most recent Capital Improvement Priorities update shared with the Board on January 27, 2021, we are moving forward with the design of the second clinic in the CJR building to accommodate clinic growth. We have completed the programming and schematic design portion of the plans and need to move into design development.

This clinic will include x-ray capabilities (just like the clinic on the upper floor). To complete the design documents, the architects have to have the design specifications for the x-ray equipment. No x-ray vendor will provide that information until they have received a PO for the purchase of the equipment. We would like to move forward with this purchase now so that we can complete the design drawings.

Our intention is to hold on delivery and payment of this equipment until we are in the late construction phases of this project. Nonetheless, we need the approval of $228,255.71 now for GE Definium646 High Definition System. Participating physicians have agreed with the selection of the equipment. The project is included in the FY21 capital budget.

In accordance with District Law, Policies and Procedures, it is requested that the Board of Directors authorize the Chief Executive Officer to proceed with the purchase of the GE Definium646 High Definition System for a total amount not to exceed **$228,255.71**.

Washington Hospital Healthcare System

WASHINGTON HOSPITAL

MONTHLY OPERATING REPORT

February 2021

Washington Hospital Healthcare System

WASHINGTON HOSPITAL
INDEX TO BOARD FINANCIAL STATEMENTS
February 2021

Washington Hospital Healthcare System

SINCE 1948

Memorandum

DATE: April 8, 2021

TO: Board of Directors

FROM: Kimberly Hartz, Chief Executive Officer

SUBJECT: Washington Hospital – February 2020
Operating & Financial Activity

SUMMARY OF OPERATIONS – (Blue Schedules)

1. **Utilization – Schedule Board 3**

	February Actual	February Budget	Current 12 Month Avg.
ACUTE INPATIENT:			
Average Daily Census	154.1	146.4	146.1
# of Admissions	683	837	769
Patient Days	4,315	4,098	4,447
Discharge ALOS	6.83	4.90	5.65
OUTPATIENT:			
OP Visits	6,556	6,809	6,215
ER Visits	3,077	5,756	4,622
Observation Equivalent Days – OP	189	149	172

Comparison of February acute inpatient statistics to those of the budget showed a lower level of admissions and a higher level of patient days. The average length of stay (ALOS) based on discharged days was above budget. Outpatient visits were lower than budget. Emergency Room visits were below budget for the month.

2. **Staffing – Schedule Board 3**

Total paid FTEs were 64.2 above budget. Total productive FTEs for February were 1,346.6, 65.0 above the budgeted level of 1,281.6. Nonproductive FTEs were 0.8 below budget. Productive FTEs per adjusted occupied bed were 5.84, 0.19 above the budgeted level of 5.65. Total FTEs per adjusted occupied bed were 6.59, 0.18 above the budgeted level of 6.41.

3. **Income - Schedule Board 1**

For the month of February the Hospital realized a loss of $1,407,000 from operations.

Total Gross Patient Service Revenue of $167,409,000 for February was 6.2% above budget.

Deductions from Revenue of $130,355,000 represented 77.87% of Total Gross Patient Service Revenue. This percentage is above the budgeted amount of 77.79%, primarily due to payor mix.

Total Operating Revenue of $37,329,000 was $134,000 (0.4%) above the budget.

Total Operating Expense of $38,736,000 was $584,000 (1.5%) above the budgeted amount.

The Total Non-Operating Income of $807,000 for the month includes an unrealized loss on investments of $930,000 and property tax revenue of $1,447,000.

The Total Net Loss for February was $600,000, which was $747,000 better than the budgeted loss of $1,347,000.

The Total Net Income for February using FASB accounting principles, in which the unrealized loss or income on investments, net interest expense on GO bonds and property tax revenues are removed from the non-operating income and expense, was $26,000 compared to a budgeted loss of $1,618,000.

4. **Balance Sheet – Schedule Board 2**

There were no noteworthy changes in assets and liabilities when compared to January 2020.

KIMBERLY HARTZ
Chief Executive Officer

KH/CH

Washington Hospital Healthcare System

WASHINGTON HOSPITAL
STATEMENT OF REVENUES AND EXPENSES
February 2021
GASB FORMAT
(In thousands)

February ACTUAL	February BUDGET	February FAV (UNFAV) VAR	February % VAR.			YEAR TO DATE ACTUAL	YEAR TO DATE BUDGET	YEAR TO DATE FAV (UNFAV) VAR	YEAR TO DATE % VAR.
					OPERATING REVENUE				
$ 111,841	$ 101,630	$ 10,211	10.0%	1	INPATIENT REVENUE	$ 925,465	$ 840,813	$ 84,652	10.1%
55,568	55,958	(390)	-0.7%	2	OUTPATIENT REVENUE	472,180	485,154	(12,974)	-2.7%
167,409	**157,588**	**9,821**	6.2%	3	**TOTAL PATIENT REVENUE**	**1,397,645**	**1,325,967**	**71,678**	5.4%
(127,214)	(119,354)	(7,860)	-6.6%	4	CONTRACTUAL ALLOWANCES	(1,063,976)	(1,000,749)	(63,227)	-6.3%
(3,141)	(3,228)	87	2.7%	5	PROVISION FOR DOUBTFUL ACCOUNTS	(27,946)	(27,161)	(785)	-2.9%
(130,355)	**(122,582)**	**(7,773)**	-6.3%	6	**DEDUCTIONS FROM REVENUE**	**(1,091,922)**	**(1,027,910)**	**(64,012)**	-6.2%
77.87%	**77.79%**			7	**DEDUCTIONS AS % OF REVENUE**	**78.13%**	**77.52%**		
37,054	**35,006**	**2,048**	5.9%	8	**NET PATIENT REVENUE**	**305,723**	**298,057**	**7,666**	2.6%
275	2,189	(1,914)	-87.4%	9	OTHER OPERATING INCOME	2,893	4,543	(1,650)	-36.3%
37,329	**37,195**	**134**	0.4%	10	**TOTAL OPERATING REVENUE**	**308,616**	**302,600**	**6,016**	2.0%
					OPERATING EXPENSES				
17,556	16,195	(1,361)	-8.4%	11	SALARIES & WAGES	150,611	135,561	(15,050)	-11.1%
5,931	6,612	681	10.3%	12	EMPLOYEE BENEFITS	52,795	51,774	(1,021)	-2.0%
5,046	4,949	(97)	-2.0%	13	SUPPLIES	42,227	40,810	(1,417)	-3.5%
4,438	4,617	179	3.9%	14	PURCHASED SERVICES & PROF FEES	38,047	38,334	287	0.7%
1,842	1,695	(147)	-8.7%	15	INSURANCE, UTILITIES & OTHER	14,321	13,331	(990)	-7.4%
3,923	4,084	161	3.9%	16	DEPRECIATION	31,926	32,231	305	0.9%
38,736	**38,152**	**(584)**	-1.5%	17	**TOTAL OPERATING EXPENSE**	**329,927**	**312,041**	**(17,886)**	-5.7%
(1,407)	**(957)**	**(450)**	-47.0%	18	**OPERATING INCOME (LOSS)**	**(21,311)**	**(9,441)**	**(11,870)**	-125.7%
-3.77%	**-2.57%**			19	**OPERATING INCOME MARGIN %**	**-6.91%**	**-3.12%**		
					NON-OPERATING INCOME & (EXPENSE)				
219	316	(97)	-30.7%	20	INVESTMENT INCOME	2,239	2,530	(291)	-11.5%
62	-	62	0.0%	21	REALIZED GAIN/(LOSS) ON INVESTMENTS	254	-	254	0.0%
(1,674)	(2,360)	686	29.1%	22	INTEREST EXPENSE	(14,510)	(16,252)	1,742	10.7%
24	250	(226)	-90.4%	23	RENTAL INCOME, NET	1,360	2,153	(793)	-36.8%
1,658	-	1,658	0.0%	24	FOUNDATION DONATION	1,658	-	1,658	0.0%
1	(39)	40	102.6%	25	BOND ISSUANCE COSTS	(718)	(310)	(408)	-131.6%
-	-	-	0.0%	26	FEDERAL GRANT REVENUE	1,069	-	1,069	0.0%
1,447	1,443	4	0.3%	27	PROPERTY TAX REVENUE	11,529	11,545	(16)	-0.1%
(930)	-	(930)	0.0%	28	UNREALIZED GAIN/(LOSS) ON INVESTMENTS	(1,723)	-	(1,723)	0.0%
807	**(390)**	**1,197**	306.9%	29	**TOTAL NON-OPERATING INCOME & EXPENSE**	**1,158**	**(334)**	**1,492**	446.7%
$ (600)	**$ (1,347)**	**$ 747**	55.5%	30	**NET INCOME (LOSS)**	**$ (20,153)**	**$ (9,775)**	**$ (10,378)**	-106.2%
-1.61%	**-3.62%**			31	**NET INCOME MARGIN %**	**-6.53%**	**-3.23%**		
$ 26	**$ (1,618)**	**$ 1,644**	101.6%	32	**NET INCOME (LOSS) USING FASB PRINCIPLES****	**$ (20,808)**	**$ (11,954)**	**$ (8,854)**	-74.1%
0.07%	**-4.35%**				**NET INCOME MARGIN %**	**-6.74%**	**-3.95%**		

******NET INCOME (FASB FORMAT) EXCLUDES PROPERTY TAX INCOME, NET INTEREST EXPENSE ON GO BONDS AND UNREALIZED GAIN(LOSS) ON INVESTMENTS

SCHEDULE BOARD 2

Washington Hospital Healthcare System

WASHINGTON HOSPITAL
BALANCE SHEET
February 2021
(In thousands)

	ASSETS AND DEFERRED OUTFLOWS	February 2021	Audited June 2020
	CURRENT ASSETS		
1	CASH & CASH EQUIVALENTS	$ 28,639	$ 68,355
2	ACCOUNTS REC NET OF ALLOWANCES	76,585	61,017
3	OTHER CURRENT ASSETS	14,666	12,523
4	TOTAL CURRENT ASSETS	119,890	141,895
	ASSETS LIMITED AS TO USE		
6	BOARD DESIGNATED FOR CAPITAL AND OTHER	215,608	214,744
7	REVENUE BOND FUNDS	6,635	10,923
8	BOND DEBT SERVICE FUNDS	11,515	31,387
9	OTHER ASSETS LIMITED AS TO USE	10,097	10,155
10	**TOTAL ASSETS LIMITED AS TO USE**	243,855	267,209
12	**OTHER ASSETS**	238,275	222,268
13	**OTHER INVESTMENTS**	11,880	11,679
14	**NET PROPERTY, PLANT & EQUIPMENT**	652,584	684,274
15	**TOTAL ASSETS**	**$ 1,266,484**	**$ 1,327,325**
16	**DEFERRED OUTFLOWS**	42,446	62,304
17	**TOTAL ASSETS AND DEFERRED OUTFLOWS**	**$ 1,308,930**	**$ 1,389,629**

	LIABILITIES, NET POSITION AND DEFERRED INFLOWS	February 2021	Audited June 2020
	CURRENT LIABILITIES		
1	CURRENT MATURITIES OF L/T OBLIG	$ 10,930	$ 9,500
2	ACCOUNTS PAYABLE	18,833	18,669
3	OTHER ACCRUED LIABILITIES	107,130	116,193
4	INTEREST	2,723	11,247
5	TOTAL CURRENT LIABILITIES	139,616	155,609
	LONG-TERM DEBT OBLIGATIONS		
6	REVENUE BONDS AND OTHER	212,349	223,881
7	GENERAL OBLIGATION BONDS	328,777	331,992
	OTHER LIABILITIES		
10	NET PENSION LIABILITY	16,199	31,798
11	SUPPLEMENTAL MEDICAL RETIREMENT	40,783	42,578
12	WORKERS' COMP AND OTHER	8,652	8,440
14	**NET POSITION**	511,681	531,834
15	**TOTAL LIABILITIES AND NET POSITION**	**$ 1,258,057**	**$ 1,326,132**
16	**DEFERRED INFLOWS**	50,873	63,497
17	**TOTAL LIABILITIES, NET POSITION AND DEFERRED INFLOWS**	**$ 1,308,930**	**$ 1,389,629**

Washington Hospital Healthcare System

WASHINGTON HOSPITAL
OPERATING INDICATORS
February 2021

12 MONTH AVERAGE	February ACTUAL	February BUDGET	February FAV (UNFAV) VAR	February % VAR.			YEAR TO DATE ACTUAL	YEAR TO DATE BUDGET	YEAR TO DATE FAV (UNFAV) VAR	YEAR TO DATE % VAR.
						PATIENTS IN HOSPITAL				
146.1	154.1	146.4	7.7	5%	**1**	ADULT & PEDS AVERAGE DAILY CENSUS	155.8	139.3	16.5	12%
5.7	6.8	5.3	1.5	28%	**2**	OUTPT OBSERVATION AVERAGE DAILY CENSUS	6.2	5.5	0.7	13%
7.2	6.3	9.1	(2.8)	-31%	**3**	NURSERY AVERAGE DAILY CENSUS	7.1	9.4	(2.3)	-24%
159.0	167.2	160.8	6.4	4%	**4**	TOTAL	169.1	154.2	14.9	10%
2.9	0.4	3.3	(2.9)	-88%	**5**	SPECIAL CARE NURSERY AVERAGE DAILY CENSUS *	2.5	3.5	(1.0)	-29%
4,447	4,315	4,098	217	5%	**6**	ADULT & PEDS PATIENT DAYS	37,854	33,839	4,015	12%
172	189	149	40	27%	**7**	OBSERVATION EQUIVALENT DAYS - OP	1,516	1,341	175	13%
769	683	837	(154)	-18%	**8**	ADMISSIONS-ADULTS & PEDS	6,264	6,904	(640)	-9%
5.65	6.83	4.90	1.93	39%	**9**	AVERAGE LENGTH OF STAY-ADULTS & PEDS	5.93	4.90	1.03	21%
						OTHER KEY UTILIZATION STATISTICS				
1.582	1.547	1.490	0.057	4%	**10**	OVERALL CASE MIX INDEX (CMI)	1.622	1.475	0.147	10%
						SURGICAL CASES				
132	133	149	(16)	-11%	**11**	JOINT REPLACEMENT CASES	1,133	1,268	(135)	-11%
21	22	19	3	16%	**12**	NEUROSURGICAL CASES	186	164	22	13%
8	14	8	6	75%	**13**	CARDIAC SURGICAL CASES	72	84	(12)	-14%
161	147	156	(9)	-6%	**14**	ALL OTHERS	1,352	1,428	(76)	-5%
322	316	332	(16)	-5%	**15**	TOTAL CASES	2,743	2,944	(201)	-7%
326	332	331	1	0%	**16**	TOTAL CATH LAB PROCEDURES	2,791	2,831	(40)	-1%
116	92	123	(31)	-25%	**17**	DELIVERIES	906	1,103	(197)	-18%
6,215	6,556	6,809	(253)	-4%	**18**	OUTPATIENT VISITS	55,636	56,909	(1,273)	-2%
3,330	3,077	3,839	(762)	-20%	**19**	EMERGENCY VISITS, EXCLUDING RSTU VISITS	28,370	31,849	(3,479)	-11%
1,292	0	1,917	(1,917)	-100%	**20**	RSTU VISITS	11,196	16,635	(5,439)	-33%
						LABOR INDICATORS				
1,314.5	1,346.6	1,281.6	(65.0)	-5%	**21**	PRODUCTIVE FTE'S	1,342.5	1,233.6	(108.9)	-9%
173.1	173.7	174.5	0.8	0%	**22**	NON PRODUCTIVE FTE'S	181.0	186.9	5.9	3%
1,487.6	1,520.3	1,456.1	(64.2)	-4%	**23**	TOTAL FTE'S	1,523.5	1,420.5	(103.0)	-7%
6.09	5.84	5.65	(0.19)	-3%	**24**	PRODUCTIVE FTE/ADJ. OCCUPIED BED	5.71	5.62	(0.09)	-2%
6.90	6.59	6.41	(0.18)	-3%	**25**	TOTAL FTE/ADJ. OCCUPIED BED	6.47	6.47	-	0%

* included in Adult and Peds Average Daily Census