I. Policy

A. All IRB written policies and procedures (collectively referred to as policy) will be written based on all available, applicable federal, state and local laws, regulations and policies.
B. All IRB written policies will be written using the attached template for policies and procedures

C. All written policies will be certified as active only after review by the Director and input of all applicable entities, appropriate institutional officials and affiliated institutions when necessary.

D. All new and revised policies and procedures and other IRB guidance will be posted to the OIRB website for use by the research community.

II. Overview

A. This procedure starts upon creation of or modification of a specific IRB policy

B. This procedure ends when the specific IRB policy is activated.

C. Summary of responsibilities

1. IRB Director or Associate Director is responsible for researching, drafting, modifying proposed and existing IRB policies.

2. The Office of the IRB (OIRB) staff is responsible for researching, drafting, modifying proposed and existing IRB policies at the discretion of the IRB Director.

III. Procedure

A. The proposed or existing IRB policy is scheduled for creation or modification by the IRB Director

1. The IRB Director or Associate Director

   a) researches, drafts, modifies the policy, or;

   b) assigns personnel to research, draft, or modify the policy;

   c) determines which policy requires input of which applicable entities, appropriate institutional officials or affiliated institutions;

B. The IRB Director/Associate Director or assigned OIRB Staff use the following references in drafting or modifying policy and procedures relating to:

1. Determination of What Activities are Human Research

   a) 21 CFR 56.102

   b) 38 CFR 16.102

   c) 45 CFR 46.102

2. IRB

   a) Concerning IRB procedures

      (1) Applicable sections of 45 CFR 46 (e.g., 103, 108)
(2) Applicable sections of 21 CFR 56 (e.g., 108(c))

(3) Applicable sections of 38 CFR 16 (e.g., 108) when VA research is involved.

(4) To obtain consultants: applicable sections of 45 CFR §46.107(e), 21 CFR §56.107(f).

b) Concerning IRB review and approval of research

(1) Applicable sections of The Belmont Report, 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, for example:

(a) Page 4, item 3 "An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."

(2) Applicable sections of 21 CFR 50, for example:

(a) 21 CFR 50.25

(3) Applicable sections of 21 CFR 56, for example:

(a) 21 CFR 56.111

(4) Applicable sections of 38 CFR 16 when VA research is involved, for example:

(a) 38 CFR 16.109

(b) 38 CFR 16.111

(5) Applicable sections of 45 CFR 46, for example:

(a) 45 CFR 46.108

(b) 45 CFR 46.109

(c) 45 CFR 46.110

(d) 45 CFR 46.111

(e) 45 CFR 46.116

(f) 45 CFR 46.117

(g) 45 CFR 46 Subparts B

(h) 45 CFR 46 Subparts C

(i) 45 CFR 46 Subparts D & 21 CFR 50 Subpart D
c) Concerning informed consent

(1) Applicable sections of 45 CFR 46, for example:

(a) 45 CFR 46.101(i)
(b) 45 CFR 46.109 (b),(c)
(c) 45 CFR 46.111
(d) 45 CFR 46.116
(e) 45 CFR 46.117

(2) Applicable sections of 21 CFR 50, for example:

(a) 21 CFR 50.20
(b) 21 CFR 50.23-25
(c) 21 CFR 50.27

(3) Applicable sections of 21 CFR 56, for example:

(a) 21 CFR 56.109 (b),(c)

(4) Applicable sections of 38 CFR 16 (e.g., 116, 117) when VA research is involved, for example:

(a) 38 CFR 16.116
(b) 38 CFR 16.117

(5) Applicable sections of Title 38 USC 1710(f) and 1710(g)

(6) Veterans Health Administration Handbook 1200.5 34 CFR 97 [Department of Education Subpart D]

(7) Specifically concerning Waivers of Consent


3. Complaints (Subject Complaints)

a) 45 CFR 46.116(a)
4. Coordination

a) No references for most committee coordination.

b) STVHCS

   (1) 38 CFR 16

   (2) Veterans Health Administration Handbook 1200.5

   (3) UT HSC/VA Memorandum of Understanding

5. Conflict of Interest

a) 38 CFR 16.107(e)

b) 21 CFR 46.103, 107

c) 21 CFR 56.107

d) 21 CFR 54 (as reference)

e) 42 CFR 50 Subpart F


6. Cognitively impaired:

a) Federal regulations at 45 CFR 46.111(a)(3) require that IRBs take into account the special problems of research involving vulnerable populations. There is no other explicit Federal or Texas statute that speaks to the inclusion of cognitively impaired subjects in research.

b) Veterans Health Administration Handbook 1200.5

7. Privacy and Confidentiality (See also HIPAA at III.B.24 below):

a) Federal regulations at:

   (1) Applicable sections of 21 CFR 50 (e.g., 50.25(a)(5) “Elements of Consent” concerning How confidential records will be maintained, FDA may inspect) and 56 e.g., 56.111(a)(7) “Privacy and confidentiality will be protected”)

   (2) Applicable sections of 21 CFR 812 (e.g., 812.38 “Confidentiality of data and information”)

(3) Applicable sections of 21 CFR 312 (e.g., 312.130(c) concerning release of an IND safety report relating to the use in the individual to the individual).

(4) Applicable sections of 45 CFR 46 (e.g., 46.102 Definitions of Human Subject, Identifiable private information and Private information; 46.111(a)(7) under “Criteria for IRB approval of research” concerning “When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data”; 46.116(b)(5) under Basic elements of informed consent “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained” and 46.117(c)(1) under Documentation of Informed Consent “That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.”)

(5) 45 CFR 160 and 164 Privacy Rule (HIPAA)

b) State regulations at:

(1) Texas Health and Safety Code,

(a) Chapter 181 Medical Records Privacy

(b) Chapter 161 Public Health Provisions, 161.0073 Registry Confidentiality (Child immunization registry).

(c) Chapter 241 Hospitals, 241.151 Definitions.

(d) Chapter 241 Hospitals, 241.152. Written Authorization For Disclosure Of Health Care Information.


(f) Chapter 611 Mental Health Records, 611.004. Authorized Disclosure Of Confidential Information

(g) Chapter 611 Mental Health Records, 611.0045. Right To Mental Health Record

(h) Chapter 773 Emergency Medical Services, 773.092. Exceptions

(i) Chapter 773 Emergency Medical Services, 773.093. Consent.

(j) Chapter 47 Hearing Loss In Newborns, 47.008 Confidentiality And General Access To Data

(k) Chapter 81 Communicable Diseases, 81.103 Definitions

(2) Occupations Code, Title 3, Chapter 159, “Physician-Patient Communication” including but not limited to:

(a) Sec. 159.002. Confidential Communications
(b) **Sec. 159.004. Exceptions to Confidentiality in Other Situations.** An exception to the privilege of confidentiality in a situation other than a court or administrative proceeding, allowing disclosure of confidential information by a physician, exists only with respect to the following: (2) medical or law enforcement personnel, if the physician determines that there is a probability of: medical or law enforcement personnel, if the physician determines that there is a probability of: (A) imminent physical injury to the patient, the physician, or another person; or (B) immediate mental or emotional injury to the patient; (3) qualified personnel for research.

(c) **Sec. 159.005. Consent For Release Of Confidential Information.**

c) Applicable sections of “Patient Privacy Policies” in Chapter 11 of the HOP including but not limited to:

   (1) “Patient Health Records” in Section 11.1.5.

   (2) “Confidentiality of Patient Health Information” in Section 11.1.6.

   (3) “Uses and Disclosures of Protected Health Information” in Section 11.2.

      (a) “De-identification of Protected Health Information” in Section 11.2.9.

      (b) “Uses and Disclosures of Protected Health Information for Research” in Section 11.2.12.

8. Data Safety Monitoring

   a) Federal Regulations at

      (1) 45 CFR 46.111(a)(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (DHHS)

      (2) 38 CFR 16.111(a)(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (VA)

      (3) 21 CFR 56.111(a)(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. [Sponsors are required to monitor studies evaluating new drugs, biologics, and devices (see 21 CFR 312.50 and 312.56 for drugs and biologics, as well as 21 CFR 600.80, and 21 CFR 812.40 and 812.46 for devices).] (FDA)

      (4) 32 CFR 219.111(a)(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (DoD)

9. Exempt

   a) 45 CFR §46.104(d)(1)-(8), 45 CFR §46.301(a), 21 CFR §56.104(c)-(d), OHRP Guidance

   b) 45 CFR 46.104(d)(5): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs,

10. Continuation Review

a) 21 CFR 56.108(a)(1)&(2)
b) 21 CFR 56.109(f)
c) 21 CFR 56.110
d) 21 CFR 56.111
e) 21 CFR 56.115(a)(3)&(7)
f) 38 CFR 16.103(b)(4)
g) 38 CFR 16.108(b)
h) 38 CFR 16.109(e)
i) 38 CFR 16.110
j) 38 CFR 16.111
k) 38 CFR 16.115(a)(3)&(7)
l) 45 CFR 46.103
m) 45 CFR 46.108(a)(3)(ii)
n) 45 CFR 46.109(e) & (f)
o) 45 CFR 46.110
p) 45 CFR 46.111
q) 45 CFR 46.115(a)(3)&(7)

11. Modifications and amendments

a) 21 CFR 56.110(b)(2)
b) 38 CFR 16.110(b)(2)
c) 45 CFR 46.110(b)(1)(ii)
d) 38 CFR 16.111
e) 45 CFR 46.111
12. Expedited Review

a) 45 CFR 46.108(a)(3), 45 CFR 46.110(b), 45 CFR 46.110(c)

b) 21 CFR 56.108(a), 21 CFR 56.110(b), 21 CFR 56.110(c)

c) Human Subject Protections (Office for Protection from Research Risks (OPRR) Report) Number 93-01, November 9, 1992, Local IRB Review of Multicenter Clinical Trials: Clarifying procedures for local IRB review of National Institutes of Health (NIH) multicenter Clinical Trials

d) OHRP Compliance Activities: Common Findings and Guidance #14, #15, #20, #26, #71(f),

e) OHRP Guidance on Expedited Review

f) FDA Information Sheets: Frequently Asked Questions: IRB Procedures,

g) FDA Information Sheets: Recruiting Study Subjects


i) Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure – FDA & DHHS

j) IRB policies and procedures, “Modifications and Amendments” Policy

k) IRB policies and procedures, “Continuation Review” Policy

l) IRB policies and procedures, “Informed Consent” Policy

m) 45 CFR 46.110

n) 45 CFR 46.102(j)

o) 38 CFR 102(i)

p) 21 CFR 56.110

q) 21 CFR 56.102(i)

r) 38 CFR 16.110

13. Off Site Research

a) Office for Human Research Protections (OHRP)

(1) Engagement Memo
(2) Terms of the Federalwide Assurance of Protection for Human Subjects

(3) IRB Knowledge of Local Research Context Guidance

(4) Sample Unaffiliated Investigator Agreement

(5) 45 CFR 46.114

b) Food and Drug Administration (FDA)

(1) Cooperative Research Guidance

(2) Non-Local IRB Review Guidance

(3) 21 CFR parts 50 and 56

14. Advertising


c) [http://www.hhs.gov/ohrp/policy/clinicaltrials.html](http://www.hhs.gov/ohrp/policy/clinicaltrials.html)

d) [http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting](http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting)

e) HHS regulations at 45 CFR 46.109(b) require that IRBs ensure that information given to subjects as part of informed consent meets the requirements specified in the regulations at 45 CFR 46.116.

15. Records

a) Federal regulations at

(1) [21 CFR 56.115](http://www.hhs.gov/ohrp/policy/clinicaltrials.html) IRB records

(2) [45 CFR 46.115](http://www.hhs.gov/ohrp/policy/clinicaltrials.html) IRB records.

b) State and Local regulations are discussed in HOP Policies which include:

(1) [HOP 2.2.1 Records and Information Management and Retention](http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting)

(2) [State of Texas Record Retention Schedule](http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting): Medical Services / Research and Development 130 DE. (AC +15 years)

(a) Grants Records - Grants which include clinical trials / drug studies. This records series consists of research data and documentation gathered or created in the course of a clinical trial. May include but is not limited to case history records,
case reports, study protocol and amendments, patient care data, objectives and purpose of the study, selection criteria, clinical procedures, FDA forms, serious adverse events reports, study design and other documentation relating to study protocols, pharmaceutical studies, findings, research papers, and serious adverse events reports.

(b) AC = After completion and upon receipt of notice of new drug application approval or investigational new drug withdrawal (21 CFR 312.57). Includes both federal and non-federal grants and sponsored agreements. Departments may keep text portions of grants and data compiled as long as they are deemed administratively valuable.

c) Record retention considerations include:

(1) Record retention regulations and guidance are dependent on funding source.

(2) Record retention for investigators requires consideration in drafting IRB record retention requirements.

(3) NIH regulations- record retention is 3 years after the final financial report and includes: financial and programmatic records, supporting documents statistical records, and all other records that are required by the terms of a grant or may reasonably be considered pertinent to a grant for a period of 3 years from the date the annual FSR is submitted.

(4) NSF regulations also call for records to be retained for at least 3 years.

(5) FDA regulations:

(a) For IND applications:

(i) for 2 years following date a marketing application is approved for the drug for the indication being investigated;

(ii) OR until 2 years after the investigation is discontinued and FDA is notified that investigator does not plan to file for market application

(b) For non clinical Lab study results for whichever period is shorter:

(i) 2 years following approval by FDA of the application for research or marketing permit which was filed. or

(ii) 5 years following date results of lab study submitted to FDA in support of application for a research or marketing permit or

(iii) 2 years following the date on which the study is completed, terminated, or discontinued if study does not result in submission of application for research or marketing permit

(6) HHS protection of human subject regulations require the institution to retain IRB records for at least 3 years after completion of research and either the institution or the PI designated by the institution should also retain the informed consents signed by the subjects (hard copy or electronic) for at least 3 years after completion of the research.
(7) UCSF Brain Tumor Research Center developed detailed guidelines for research data and manuscripts in 1989 with a revision in 2000. These are recognized as comprehensive guidelines for responsible data management. They suggest PI store and retain records at least 5 years after ending of funding for study.

(8) Other considerations which might warrant longer retention of research data or supporting clinical information:

(a) Data sets which are not easily reproduced and might have significant secondary uses.

(b) Data that is widely recognized as having very unusual significance that is indeed unique.

(c) So in general if special considerations not a factor 3-5 years after study completed is usually sufficient.

(9) If investigators have been designated to retain certain records (e.g., informed consent documents signed by subjects) on behalf of the institution as required by the HHS regulations at 45 CFR 46.115(b), they must retain the records in some form. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (45 CFR 46.115(b)). Retention of multiple copies of each record is not required.

(10) If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated, for the period of time required under HHS regulations at 45 CFR 46.115(b).


(a) The required records, including the investigator’s research records, must be retained for a minimum of 5 years after the completion of the study and in accordance with VHA’s Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors.

(i) All records must be accessible for inspection and copying by authorized representatives of VA, OHRP, FDA and other authorized entities at reasonable times and in a reasonable manner.

(ii) Records are the property and the responsibility of the local research office. The medical center must designate where the records will be maintained and/or stored.

(iii) Complete (non-redacted) minutes, whether from the VA or affiliate IRB reviewing VA research, must be submitted to the R&D Committee and maintained in the facility research office. The R&D Committee must review and act upon all IRB minutes regardless whether the IRB is established at the medical center or at the affiliate university.

(a) Each IRB that uses an expedited review process must adopt a method for keeping all members advised of research proposals that have been approved under this process. The minutes and/or the protocol file must reflect the expedited review eligibility category that the research meets.

d) IRB Minutes

(1) 45 CFR 46.107
(2) 45 CFR 46.108
(3) 45 CFR 46.111
(4) 45 CFR 46.115 (a)(2)
(5) 45 CFR 46.116
(6) 45 CFR 46.117
(7) 45 CFR 46.409
(8) 21 CFR 812.3(m)
(9) 21 CFR 50.23
(10) 21 CFR 50.24
(11) Veterans Health Administration Handbook 1200.5.

16. IRB Membership

a) 21 CFR 56.107
b) 21 CFR 56.115(a)(5)
c) 38 CFR 16.103(b)(3) & 115(a)(5)
d) 38 CFR 16.107
e) 45 CFR 46.108(a)(2) & 115(a)(5)
f) 45 CFR 46.107

17. IRB Meetings

a) 21 CFR 56.108c
b) 21 CFR 56.109
c) 45 CFR 46.103
d) 45 CFR 46.107(e)

e) 45 CFR 46.108

18. IRB Meeting minutes

a) 45 CFR 46.107

b) 45 CFR 46.108

c) 45 CFR 46.111

d) 45 CFR 46.115 (a)(2)

e) 45 CFR 46.116

f) 45 CFR 46.117

g) 45 CFR 46.409

h) 21 CFR 812.3(m)

i) 21 CFR 50.23

j) 21 CFR 50.24

k) Veterans Health Administration Handbook 1200.5

19. Reporting

a) Federal regulations at

   (1) 45 CFR 46 Subparts B - D

   (2) 21 CFR 50 Subpart D

   (3) 38 CFR 16

   (4) Veterans Health Administration Handbook 1200.5

   (5) May 2003 OHRP Guidance on the Involvement of Prisoners in Research


   (7) Under 45 CFR 46 46.108(a) (3)(i) & (ii) and 21 CFR 56.108(a)(1) reporting its findings and actions concerning initial and continuing review to the investigator and the institution;
(8) Under 45 CFR 46.108(a) (4) prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(9) Under 45 CFR 46.113 an IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(10) Under 21 CFR 56.108(b)(1) prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of Any unanticipated problems involving risks to human subjects or others; any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or any suspension or termination of IRB approval. (Note: FDA guidance interprets 108(b)(1) to require investigators to report these “unanticipated problems” to the IRB and sponsors to report serious unexpected events, including analyses of such events, to investigators and to FDA. Therefore, UTHSCSA policy shall include written procedures to confirm these activities occurred to comply with 21 CFR 56.108(b)(1). Serious or continuing noncompliance and suspension or termination are determinations of the IRB and will be reported by the IRB to appropriate institutional officials, and the FDA as per this regulation.)

(11) Under 21 CFR 56.113, an IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration

(12) IRBs are required to function under written procedures. One of these procedural requirements [21 CFR 56.108(a)(3)] requires ensuring “prompt reporting to the IRB of changes in a research activity.” The completion of the study is a change in activity and should be reported to the IRB. Although subjects will no longer be “at risk” under the study, a final report/notice to the IRB allows it to close its files as well as providing information that may be used by the IRB in the evaluation and approval of related studies. Therefore the UTHSCSA IRB will report its findings and actions concerning Final reports (which constitute changes in research activity under the FDA) to the investigator and the institution;

20. Adverse Event reporting (Adverse Events, Unanticipated problems, Unanticipated Adverse Drug Experiences, Unanticipated Adverse Device Effects)

a) For all non-exempt human studies,

(1) OHRP’s published guidance for use by Human Subject Protection Programs U.S. Department of Health and Human Services: Office for Human Research Protections. (January 15, 2007)

(2) Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting — Improving Human Subject Protection (Draft Guidance) U.S. Department of Health and Human Services: Food and Drug Administration April 2007,
(3) For drug studies,

(4) For device studies,

(a) investigators are required to submit a report of a UADE to the sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the event (§ 812.150(a)(1)).

(b) Sponsors must immediately conduct an evaluation of a UADE, and must report the results of the evaluation to FDA, all reviewing IRBs, and participating investigators within 10 working days after the sponsor first receives notice of the effect (§§ 812.46(b), 812.150(b)(1)).

21. Noncompliance

a) 21 CFR 56.123

b) 45 CFR 46.112

22. FDA regulated research

a) For all FDA Regulated research

   (1) 21 CFR 50 and 56

b) For Emergency use - In addition to III.B.22.a) above:

   (1) 21 CFR 56.102(d)

   (2) 21 CFR 56.104(c)

   (3) 21 CFR 50.23

   (4) 21 CFR 312.36

   (5) 21 CFR 812.

   (6) FDA Information Sheet, Drugs and Devices 1998

   (7) FDA Information Sheet, Medical Devices 1998

   (8) May 15, 1991, OPRR statement

(a) an article or substance recognized in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, and the official National Formulary, or any supplement of them;

(b) an article or substance designed or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) an article or substance, other than food, intended to affect the structure or any function of the body of man or other animals; or

(d) an article or substance intended for use as a component of any article or substance specified in this definition.

d) Devices - In addition to III.B.22.a) above:

(1) See 21 CFR 812

(2) See 21 CFR 812.66 concerning significant risk device determinations.

(3) See 21 CFR 812.2(b)


(a) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component; part, or accessory; that is:

(i) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(iii) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

(5) Exemptions

(a) See exemptions at 21 CFR 812.2(C)

(b) For clarification concerning devices previously cleared by the FDA, they are considered exempt from the requirement for prior submission to the FDA for an IDE before a clinical investigation when they are devices:

(i) with an approved PMA(812. (c)(4));

(ii) which have been cleared via a Premarket Notification 510(k)(812.2(c)(2));
(iii) which have been considered exempt under 510(k) (812.2(c)(2) referencing 807.85 which includes pre-1976).

(iv) considered to be a Pre-Amendments device.

(6) Reports to the IRB from the investigator and the sponsor

(a) 21 CFR 812.150.

23. Suspension or Termination

  a) 21 CFR 56.113
  
  b) 45 CFR 46.113
  
  c) 38 CFR 16.113

24. HIPAA (See also Privacy and Confidentiality at III.B.7 above)

  a) 45 CFR 164.512
  
  b) 45 CFR 164.532
  
  c) 45 CFR 164.530
  
  d) 45 CFR 164.508
  
  e) 45 CFR 164.514
  
  f) NIH’s Research Repositories, Databases, and the HIPAA Privacy Rule
  
  g) NIH’s Privacy Boards and the HIPAA Privacy Rule

C. When the proposed or existing IRB Policy and Procedure is turned in to the IRB Director at the Draft Deadline

  1. The IRB Director or Associate Director

     a) Reviews and edits the policy
     
     b) Returns the policy for further research/modification or;
     
     c) Routes the policy to the OIRB Staff to route as necessary.

  2. OIRB Staff

     a) Copy the draft policy and route as necessary to the applicable entities, appropriate institutional officials or affiliated institutions.
D. When the proposed or existing IRB Policy and Procedure is turned in to the IRB Director at the Final Deadline.

1. The IRB Director or Associate Director
   
a) Reviews and edits the policy

b) Returns the policy for further research/modification or;

c) Routes the policy to the OIRB Staff to route as necessary.

2. OIRB Staff
   
a) Copy the Final policy and route as necessary to the applicable entities, appropriate institutional officials or affiliated institutions.

b) The Final Draft of the Policy and Procedure is activated and posted to the IRB website with the paper and electronic copies maintained in accordance with the Record Keeping Policy and Procedure.

IV. References

A. Definitions (see Glossary)