Policy Name: Training Requirements for IRB Members, IRB Office Staff, Research Investigators, and Research Study Staff	
Policy Owner: Research Activities Compliance Committee	**Effective Date: September 10, 2015**
Approved By: System Performance Committee	**Last Reviewed Date: August 13, 2015**
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1.0 **Scope:**
This policy applies to Texas Health Resources and all of its wholly owned or wholly controlled affiliates.

1.1 Applicable Entities:
Any Texas Health wholly owned or controlled entities.

2.0 **Purpose:**
To establish and communicate the training requirements for the Texas Health Resources (THR) Institutional Review Board (IRB) members, IRB office staff, research investigators, research study staff and others engaged in research activities that are subject to oversight by the THR IRB.

3.0 **Policy Statement(s):**
THR IRB members, IRB office staff, research investigators and research study staff engaged in research activities subject to the oversight of the THR IRB must complete initial and periodic refresher training as specified in this policy. The training curriculum and materials are dependent on the individual's role and responsibilities related to research activities. For purposes of this policy, the primary roles include:

- IRB Members
- IRB Office Staff
- Research Investigators and Research Study Staff

4.0 **Policy Guidance:**
IRB approval will not be granted until all required training is complete. All members of the research community are required to maintain and keep current credentials on file in the eIRB system and must be renewed every three years.

5.0 **Definitions:**

5.1 eIRB – The THR electronic information system that must be used by IRB members, IRB office staff, research investigators and research study staff to submit initial and continuing review applications and information necessary for the THR IRB to carry out the Board's review and oversight responsibilities.

5.2 Health Insurance Portability and Accountability Act (HIPAA) – Federal privacy and information security laws and regulations generally designed to protect

personal health information with specific provisions applicable to patient privacy requirements for research activities.

5.3 Human Subject Protection Training- This training consists of online modules that educate the user on how to protect human subjects when conducting research. Topics covered include regulatory framework, HIPAA, informed consent, vulnerable populations, IRBs, conducting clinical research, and conflicts of interest.

5.4 Institutional Review Board (IRB) - The Committee authorized by the Texas Health Board of Trustees to review and monitor research involving human subjects in accordance with ethical standards, laws and regulations.

5.5 Research Community – Research investigators, research staff, IRB members, IRB office staff and any other persons involved in research activities subject to oversight by the THR IRB.

5.6 Humanitarian Use Device (HUD) – A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The IRB must approve the use of the device before it can be used in a Texas Health facility.

6.0 **Responsible Parties:**
This policy covers any THR employee or agent in which THR is engaged, and conducts research within any THR facility or with THR equipment or resources.

6.1 Research Investigators and Research Study Staff

6.1.1 *Human Subject Protection (HSP):* Research investigators and research staff must complete HSP training as specified by the IRB prior to initial IRB approval of research. There are no exceptions to this training requirement. Refresher training is required every three years.

6.1.2 *HIPAA Privacy Training:* Research investigators and research study staff must review this training prior to protocol submission and every three years, thereafter. The completion certificate, which is provided with the policy document, must be signed, dated and returned.

6.1.3 *Texas Health Research Policy Review:* Specific Texas Health policies, which can be found on the Texas Health IRB Website, must be reviewed prior to IRB approval of research. Information of interest include:

a) Federal Regulations Regarding Research
b) Corporate Policies
c) Research Compliance Program: Structures, Monitoring, & Audits
d) Other policies as deemed necessary.

6.1.4 *Current License:* Copies of current licenses are required for all licensed professionals who are not credentialed at a THR facility. All such professionals should keep licenses current in accordance with requirements of the licensing agency.

6.1.6 *HUD Training:* HUD training is only required for investigators and study staff that will be using a HUD. If they are only involved with the HUD they may substitute HUD Training for Human Subject Protection Training.

6.2 IRB Members

6.2.1 *Human Subject Protection (HSP) Training:* IRB Members must complete all required member courses as specified by the IRB.

6.2.2 *Refresher HSP Training:* Refresher member training is required every three years.

6.2.3 All IRB Members must review the IRB Orientation materials that include at least the following. Note: All members of the IRB are expected to remain knowledgeable and current regarding human subject protection and therefore review updates to the materials.

a) Federal Regulations Regarding Research
b) Corporate Policies
c) Research Compliance Program: Structures, Monitoring, & Audits
d) Indemnification Letter to IRB Members from Ithe THR Corporate Counsel
e) FDA Good Clinical Practice (GCP)
f) FDA Guidance for IRBs and Investigators
g) NIH Bioethics Resources
h) Office of Biotechnology Activities
i) Office of Civil Rights (HIPAA Privacy Rule)
j) Office of Human Research Protections (OHRP)
k) The Belmont Report
l) The Declaration of Helsinki
m) The Nuremberg Code

6.2.4 eIRB Training: IRB members must review the following materials prior to becoming a voting IRB member and every three years.

a) eIRB User Manual for IRB Members
b) eIRB Slide Presentation for IRB Members
c) Accessing Meeting Agenda/ Study(s) in eIRB- Preparing for a Full Board Review
d) Reviewing Submissions in eIRB- Preparing for a Full Board Review

6.2.5 a) *IRB Member Handbook*

6.2.6 a) *HIPAA Privacy Training:* IRB Members must review the THR Research Privacy Training Policy every three years thereafter. The completion certificate, which is provided with the policy document, must be signed and returned

6.2.7 Other IRB training as deemed necessary.

6.2.8 IRB Member Verification Form: All IRB Members must complete the member training Verification Form acknowledging that training is complete including:

a) IRB Member Orientation Checklist (for new members only)
b) eIRB Training for IRB Members
c) Contact Information on file

6.2.9 *Educational Opportunities:* IRB members may be invited to attend national conferences on the protection of human research subjects periodically and are encouraged to attend.

6.2.10 *Other Training Materials:* IRB Members are provided with the IRB Member Handbook and the Human Research Report.

6.3 IRB Office Staff

6.3.1 The IRB Staff is required to complete all the same training as IRB Members.

6.3.2 The IRB Office Staff will be trained to internal IRB office policy(s) and /or procedure(s)

6.3.3 Participation in specific IRB staff training meetings is required. In addition, training related to the staff person's job functions will be provided as needed.

6.3.4 The IRB staff is expected to read periodicals and other materials necessary to remain current with industry standards. For example, the IRB Discussion Forum, which promotes the discussion of ethical, regulatory, and policy concerns with human subjects research.

6.4 Expired Training

6.4.1 Failure to complete required training could result in the interruption of the research investigator's research activities.

6.4.2 Any person who obtained HSP certification deemed equivalent by the IRB Management will be allowed to maintain that certification until its expiration, which has been defined as three years from the date training was completed. Upon expiration, he/she will be required to take the HSP course Texas Health utilizes at the time of re-certification.

7.0 External References:

7.1 **Food and Drug Administration (FDA)**

7.2 **21 CFR 50, Protection of Human Subjects**

7.3 **21 CFR 312, Investigational New Drug Applications (INDs)**

7.4 **21 CFR 812, Investigational Device Exemptions (IDEs)**

7.5 **FDA Good Clinical Practice (GCP)**

7.6 **Information Sheet Guidance for IRBs, Investigators and Sponsors**

7.7 **NIH and Clinical Research**

7.8 **NIH Bioethics Resources**
7.9 **Office of Biotechnology Activities**
7.10 **Office of Civil Rights (HIPAA Privacy Rule)**
7.11 **Office of Human Research Protections (OHRP)**
7.12 **45 CFR 46. Protection of Human Subjects**
7.13 **45 CFR 160, 162 & 164, Privacy Rule (HIPAA)**
7.14 **Inclusion of Children Policy Implementation Page**
7.15 **Policy guidance and documents**
7.16 **Privacy Protection using Certificates of Confidentiality**
7.17 **OHRP Frequently Asked Questions**
7.18 **The Belmont Report**
7.19 **Texas Health & safety Code- HIPAA, Chapter 181**
7.20 **Texas Health & safety Code- Informed Consent Forms, Chapter 313**
7.21 **Medline Plus Medical Dictionary**
7.22 **MediLexicon Medical Dictionary**
7.23 **Social Psychology Glossary**

Applicability of external clinical practice/procedure guidelines and other clinical resources may be dependent upon resources available at the hospital or a health care professional's licensure and/or certification.

8.0 Related Documentation and/or Attachments:

8.1 *Training Updates:* In the event that regulatory/policy standards change, the IRB website will be updated and a notification from the eIRB system will be sent to report and reflect these new changes, as warranted. In addition, this training curriculum will be updated accordingly.

8.2 *National Conferences and Workshops:* the Research Community is encouraged to participate in conferences and workshops periodically, such as:
a) Association for the Accreditation of Human Research Protection Programs (AAHRPP) Conferences
b) Office for Human Research Protections (OHRP) Workshops
c) Public Responsibility in Medicine and Research (PRIM&R) Conferences

8.3 *IRB website:* Educational topics are available on the IRB website along with guidance, resource documents, application forms, and links to regulatory agencies and other helpful resources including;
a) *eIRB:* Links users to the eIRB system as well as giving guidance on how to submit new applications, continuing review applications, and amendments.
b) *Texas Health Research Policies:* Links users to THR corporate policies regarding research.
c) *Human Subject Research Regulations and Guidelines:* Discussion of regulations and principles by which THR IRB members and staff review protocols
d) *Educational/Training Opportunities and Resources:* Links users to Human Subjects Protection Training

e) *On-line Resources*: Links users to information regarding ethics in research, investigational device exemptions and consent form language readability.

8.4 *Training Record Retention:* Training record will be retained as indicated below:

8.4.1 Unapproved research records: Records for studies involving adults and minors will be retained for 10 years from the last communication (that would affect course of study) between the research investigator, research study staff, and the IRB

8.4.2 Approved research records: See table 17-III in the Human Subject Research Records and Documents

a) Records for studies involving adults will be retained for 10 years after completion of the research.

b) Studies involving minors will be retained until the minor reached age 21 or until 10 years after completion of the research, whichever date is later.

9.0 Required Statements:

9.1 *Required statement if policy includes physician tasks:*

"The physicians on the medical staff of the hospital are practitioners independent of the hospital unless they are practitioners participating in the care of patients as part of a post-graduate medical education program. They are not agents, servants or employees of the hospital unless they are part of a graduate medical education program of the hospital."