1 PURPOSE

1.1 This guidance establishes the procedure for educating Sharp HealthCare (SHC) Institutional Review Board (IRB) members, IRB staff, investigators, and site research staff to ensure adequate training in human research protection and qualifications and credentialing of all staff.

1.2 The guidance begins when the individual becomes engaged with SHC (e.g., medical staff, contracted staff, employee, or student) for human subjects' research purposes.

1.3 The guidance ends when the individual's involvement with SHC research involving human subjects ceases.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program (HRPP) Change Log.

3 POLICY STATEMENT

3.1 The Center for Research (CFR) works with SHC entities and other institutions to offer comprehensive human research protection education to the SHC research community.

3.2 Education is offered in many areas of research, including ethical standards, related both to research and to professional conduct, SHC policies and procedures, and applicable federal, state, and local law. The foundation of ethical training at SHC is the Belmont Report, which is made available at training sessions (see 7.1).

3.3 IRB members, IRB staff, investigators, and all site research staff involved in the design, conduct, or reporting of research are required to complete initial and continuing education and training on human subject protection and conducting research involving human subjects, as applicable.

3.3.1 Investigators should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.

3.3.2 IRB approval will not be granted for proposed research in which members of the research team have not completed the required human research protections training.

3.3.3 Initial and continuing training and education requirements including timeframes for IRB members, IRB staff, and site research staff involved with research is specified.

3.4 All educational requirements by all site research staff must be met for IRB study approval (initial and continuation).

3.4.1 If site research staff education requirements are not fulfilled, the study is not approved until all site research staff meet requirements.

3.4.2 If the study is ongoing and SHC Protecting Human Research Subjects (PHRP) training requirements are due, the study could be suspended until education requirements met.

3.5 The CFR is responsible for developing and providing HRPP education for IRB members, IRB staff, and the research community on human research protections.

3.6 Monitoring of education requirements of IRB members, IRB staff, and all site research staff is performed regularly as applicable to the role. Tracking compliance with education requirements is maintained in IRBANA.

4 RESPONSIBILITIES

4.1 CFR staff perform these procedures.

4.2 IRB members, IRB staff, and all site research staff must fulfill the required training and information requirements set forth in this guidance.

4.3 Investigators ensure that site research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.

4.4 CFR monitor investigator and site research staff education requirements during the initial IRB review process and during the continuation request process.

5 PROCEDURE

5.1 Education Planning

5.1.1 Before the beginning of a new IRB Year (October 1), the CFR reviews and updates this HRPP education guidance.

5.1.2 The CFR incorporates input received from IRB members, IRB staff, and investigators and from monitoring and evaluation activities. Trends in research at SHC are considered, and new federal, state, or local regulations (or published guidances) are integrated. Compliance activities (e.g., internal, and external audits) also provide input into the education plan, which is presented to the Director of Research and other senior administrators for review and approval.

5.1.3 A complete list of educational activities offered to the SHC research community is maintained by the CFR and is available on the SHC Research website. See *WORKSHEET: Education Activities List (HRP-340).*

5.2 Required Initial and Continuing Training

5.2.1 Institutional Official Required Training

5.2.1.1 Table 1.0 specifies the required training for the Institutional Official, IRB chair, and IRB vice-chair. IRB members are encouraged to complete this training as well.

5.2.1.2 The IRB staff maintains education records and appropriate certificates of completion for the Institutional Official.

Table 1.0: Institutional Official Required Training

	Module	Timeline
Required Initial Training	SHC Protecting Human Research Participants (PHRP) Training	Within 30 days of appointment
	SHC HRPP Orientation	Within 30 days of appointment
	HIPAA Training[1]	Within 30 days of appointment
Required Continuing Training	SHC Protecting Human Research Participants (PHRP) Training	Every three years
	SHC HRPP Orientation	Every three years
	HIPAA Training[2]	Annually
Ongoing Education	IRB Member Education Topics	Monthly – included on IRB agenda
	SHC-Sponsored Education Events	Yearly
	Professional Organization-Sponsored Education Events	When available locally
Evaluation	Attendance, timely completion of assignments, and HRPP understanding	Periodically

5.2.2 IRB Members Required Training

5.2.2.1 IRB member qualifications are reviewed by the IRB Chair, Vice Chair, and IRB Specialists during the recruitment process. IRB members are formally appointed by the IRB Chair.

5.2.2.2 IRB members, including IRB Chairs, are evaluated periodically to ensure the IRB contributes to the ethical and regulatory review of research at SHC, such as attendance, timely completion of assignments, and understanding of the HRPP (e.g., ethical principles, program policies and guidances, regulations). Feedback from these evaluations is communicated to each IRB member and IRB Chair.

[1] HIPAA training must be completed before handling Protected Health Information (PHI) or within 30 days of appointment and must be renewed according to institution requirements. (SHC POLICY: Compliance/Privacy Education and Training [01510]; SHC POLICY: Research and the HIPAA Privacy Rule [16508])

5.2.2.3 The IRB Specialists maintain education records and appropriate certificates of completion for IRB members.

5.2.2.4 Table 2.0 specifies the required training for all IRB members.

Table 2.0: IRB Member Required Training

	Module	Timeline
Required Initial Training	SHC Protecting Human Research Participants (PHRP) Training	Within 30 days of appointment
	SHC HRPP Orientation for IRB Members	Within 30 days of appointment
	HIPAA Training[2]	Within 30 days of appointment
Required Continuing Training	SHC Protecting Human Research Participants (PHRP) Training	Every three years
	SHC HRPP Orientation for IRB Members	Every three years
	HIPAA Training for SHC employees	Annually
	Compliance Module 3 for Non-SHC employees	Annually
Ongoing Education	IRB Member Education Topics	Monthly – included on IRB agenda
	SHC-Sponsored Education Events	Yearly
	Professional Organization-Sponsored Education Events	When available locally
Evaluation	Attendance, timely completion of assignments, and HRPP understanding	Periodically

5.2.3 IRB Specialist Required Training

5.2.3.1 IRB Specialist qualifications are reviewed during the hiring process and annually or as needed to ensure a high level of commitment to the HRPP. IRB Specialist qualifications include the Public Responsibility in Medicine and Research (PRIM&R) Certified IRB Professional (CIP) designation.

5.2.3.2 The Human Resources department maintains education records and appropriate certificates of completion for all IRB Specialists.

5.2.3.3 Table 3.0 specifies the required training for an IRB Specialist.

Table 3.0: IRB Specialist Required Training

	Module	Timeline
Required Initial Training	PRIM&R CIP Certification	Within one year
	SHC Protecting Human Research Participants (PHRP) Training	Within 30 days of SHC employment
	SHC HRPP Orientation	Within 30 days of SHC employment
	HIPAA Training for SHC employees[2]	Within 30 days of SHC employment
Required Continuing Training	SHC Protecting Human Research Participants (PHRP) Training	Every three years
	PRIM&R Training	Annually
	SHC HRPP Orientation	Every three years
	HIPAA Training for SHC employees[2]	Annually
Ongoing Education	SHC-Sponsored Education Events	Quarterly
Evaluation	Performance	Yearly

5.2.4 CFR Senior Management and Other CFR Staff Required Training

5.2.4.1 CFR staff qualifications are reviewed during the hiring process and annually or as needed to ensure a high level of commitment to the HRPP.

5.2.4.2 Director of Research maintains education records and appropriate certificates of completion for all CFR staff.

5.2.4.3 Table 4.0 specifies the required training for CFR staff.

Table 4.0: CFR Staff Required Training

	Module	Timeline
Required Initial Training	Protecting Human Research Participants (PHRP) Training. SHC will accept: - SHC Protecting Human Research Participants (PHRP) Training - CITI Program's Biomedical Humans Subjects Research (HSR) Courses - ACRP Ethics and Human Subject Protection Course	Within 30 days of SHC employment
	SHC HRPP Orientation	Within 30 days of SHC employment
	HIPAA Training for SHC employees[2]	Within 30 days of SHC employment
Required Continuing Training	Protecting Human Research Participants (PHRP) Training. SHC will accept: - SHC Protecting Human Research Participants (PHRP) Training - CITI Program's Biomedical Humans Subjects Research (HSR) Courses - ACRP Ethics and Human Subject Protection Course	Every three years
	SHC HRPP Orientation	Every three years
	HIPAA Training for SHC employees[2]	Annually
Ongoing Education	SHC-Sponsored Education Events	Quarterly
	Professional Organization-sponsored Education Events	When available locally
Evaluation	Performance	Yearly

5.2.5 Investigator and Clinical Trials Specialists (CTS) Required Training:

5.2.5.1 Investigators at SHC are evaluated according HRPP policies, guidances, and regulations.

5.2.5.2 Investigators ensure that site research staff is qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study. See *FORM: Principal Investigator Attestation (HRP-219)*.

5.2.5.3 Investigators and site research staff education requirements are monitored by the CFR during the initial IRB review process and during the continuation request process. All educational requirements by all site research staff must be met for IRB study approval (initial and continuation). If site research staff education requirements are not fulfilled, the study is not approved until all site research staff meet requirements. If the study is

ongoing and education requirements are due, the study could be suspended until education requirements met.

- Investigators and site research staff who are medical staff members or not SHC employees must complete the required compliance training. See *GUIDANCE: Badge ID and Credentialing for Non-Sharp Staff (HRP-093*) and *FORM: Badge ID and Credentialing (HRP-234).*
- If individuals from other institutions ("third-party" or contract employees) conduct research under the auspices of SHC, they must complete human subjects' protections training, but may do so at their home institution. A letter, certificate, or email notification by a representative from their home institution will satisfy this requirement.
- New SHC employees can meet the training requirement if they have completed human subjects' protections training at their prior institution within the applicable timeframe.

5.2.5.4 There may be additional protocol-specific educational requirements or certification required for investigators and site research staff based on additional regulations. The CFR may provide specific training tailored to the review of certain protocol types (e.g., protocols involving stem cells).

5.2.5.5 All IRB-required education records and appropriate certificates of completion are maintained by the investigator and site staff. Individual investigators choose their own training process (self-train or sponsor portals) and maintain their own training records.

5.2.5.6 CFR staff is a resource for any questions regarding HRPP education for the research community.

5.2.5.7 Table 5.0 specifies the required training for investigators and clinical trials specialists (CTSs), also known as Clinical Research Coordinators (CRCs).

Table 5.0: Investigator and Clinical Trials Specialists (CTS) / Clinical Research Coordinators (CRC) Training

	Module	Timeline
Required Initial Training	Protecting Human Research Participants Training. SHC will accept: - SHC Protecting Human Research Participants (PHRP) Training - CITI Program's Biomedical Humans Subjects Research (HSR) Courses - ACRP Ethics and Human Subject Protection Course	Within 30 days of SHC engagement
	NIH Financial Conflict of Interest (FCOI) Training[3] required for investigators receiving grant funding from the PHS (e.g., NIH)	Within 30 days of SHC engagement
	SHC Employees: HRPP Orientation	Within 30 days of SHC employment
	Non-SHC Employees/Medical Staff: Required Compliance/Safety Training	Within 30 days of SHC engagement
	HIPAA Training[2]	Within 30 days of SHC engagement
	Protocol-Specific Education	Prior to site protocol activation at trainings including Sponsor Site Initiation Visit (SIV) and/or

Table 5.0: Investigator and Clinical Trials Specialists (CTS) / Clinical Research Coordinators (CRC) Training		
	Module	Timeline
		Investigator Meeting (IM) or post-SIV/IM self-training
	Investigator Brochure – Education/Review	Prior to site protocol activation
	Pharmacy	Sponsor Site Initiation Visit
	Good Clinical Practice	Within 90 days of SHC engagement, if required by site or sponsor
Required Continuing Training	Protecting Human Research Participants (PHRP) Training. SHC will accept: - SHC Protecting Human Research Participants (PHRP) Training - CITI Program's Biomedical Humans Subjects Research (HSR) Courses - ACRP Ethics and Human Subject Protection Course	Every three years
	Good Clinical Practice Training	Every three years, if required by site or sponsor
	NIH Financial Conflict of Interest Training required for investigators receiving grant funding from the PHS (e.g., NIH)[3]	As required by funding agency
	SHC Employees: HRPP Orientation	Every three years
	Non-SHC Employees/Medical Staff: Required Compliance/Safety Training	Annually
	HIPAA Training for SHC employees	Annually
	Revised Protocol - Specific Education	As required by sponsor and prior to revised protocol activation
	Revised Investigator Brochure – Education/Review	As required by sponsor and prior to revised protocol activation
Ongoing Education	SHC-Sponsored Education Events	Quarterly
	Professional Organization-sponsored Education Events	When available
Evaluation	Understanding of HRPP	Yearly

5.3 Ongoing Education - Contributing to the Improvement of Expertise

5.3.1 SHC-sponsored education opportunities for continuing education in human research protections are provided on a regular basis (*WORKSHEET: Education Activities List [HRP-340]*).

5.3.2 IRB member, IRB staff, investigators, and all site research staff attendance is encouraged at regulatory and professional meetings and conferences both locally and nationally and web broadcasts and seminars at SHC and available in the greater community.

5.3.3 The CFR supports and encourages professional certification for qualified CFR staff and investigators or designees.

5.3.4 The IRB members, IRB staff, investigators, site research staff, and other individuals responsible for the protection of human research participants have access to a wealth of educational material, available online and in printed format, or offered as courses or workshops. See *WORKSHEET: Education Activities List (HRP-340)*.

5.4 Monitoring Education Requirements

5.4.1 The CFR evaluates the effectiveness of the education provided. Results of these evaluations are used to adjust the content of educational materials, improve delivery methods, identify appropriate audiences, and collaborate and communicate with others on updating their education and training. See *FORM: Education Continuous Quality Improvement (CQI) Assessment (HRP-232).*

6 MATERIALS

6.1 GUIDANCE: Badge and Credentialing for Non-Sharp Staff (HRP-093)
6.2 FORM: Principal Investigator's Attestation (HRP-219)
6.3 FORM: Education Continuous Quality Improvement (CQI) Assessment (HRP-232)
6.4 FORM: Badge ID and Credentialing (HRP-234)
6.5 WORKSHEET: Education Activities List (HRP-340)
6.6 SHC Protecting Human Research Participants (PHRP) Online Training Instructions

7 REFERENCES

7.1 The Belmont Report

This document is available on www.sharp.com/research, IRBANA or by contacting research@sharp.com.