1 PURPOSE

1.1 This guidance establishes the process to determine which activities require Sharp HealthCare (SHC) Institutional Review Board (IRB) review.

1.2 The guidance begins when planning or preparing for any research or clinical investigation activity that involves human subjects.

1.3 The guidance ends when IRB involvement in the SHC research or clinical investigation activity is determined.

2 REVISIONS FROM PREVIOUS VERSION

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

3 POLICY STATEMENT

3.1 This guidance covers all human subjects' research including preparatory to research activities that involve interventions or interactions with living individuals (e.g. advertising, recruitment, and/or screening of potential subjects for research) and/or accessing or obtaining identifiable, private information from or about living or deceased individuals for the purpose of conducting research (e.g., review of medical records or use of California state death data records).

3.1.1 California law requires IRB review and approval of research using California-produced death data files containing personal identifying information (i.e., state-issued death certificates and indices held by the state registrar, local registrars and county recorders)

3.2 In this guidance, human research means any research or clinical investigation that involves human subjects as defined in *GUIDANCE: Definitions (HRP-001)*.

4 RESPONSIBILITIES

4.1 Investigators perform these procedures.

5 PROCEDURE

5.1 Investigators should review the definitions to determine whether an activity is human research. See *GUIDANCE: Definitions (HRP-001).* They may also contact a member of the SHC IRB staff for assistance with this determination.

5.2 When submitting human subjects' research to the SHC IRB for review *use FORM: Initial IRB Review Application (HRP-211)*.

5.3 Examples of activities that may or may not require SHC IRB review:

ACTIVITY	DESCRIPTION	IRB REVIEW
Case Report Studies	Retrospective review of a patient's medical record with intent to document a specific situation or the experience of an individual without intent to form a research hypothesis, draw conclusions or generalize findings. The data will be de-identified.	NO if 1-3 records *Greater than 3 records requires IRB approval*
	Prospective: A single subject study with clear intent, before recruiting or interacting with the participant, to use *data that would not ordinarily be collected in the course of treatment*. The intent is to report and publish the case study.	YES
Classroom Assignments/ Research Methods Classes	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge.	NO *Instructors have an obligation to protect students and others*
Clinical Investigations	Experiments using a test article on one or more human subjects that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the Food and Drug Administration. Products regulated include foods (dietary supplements that bear	YES

ACTIVITY	DESCRIPTION	IRB REVIEW
	a nutrient content claim or a health claim, infant formulas, food and color additives), drugs for human use, medical devices for human use, biological products for human use, and electronic products.	
"Compassionate" or Treatment Use of an Investigational Drug or Device	A treating physician determines an unapproved drug or device is the best treatment for a patient, and ALL of the following criteria apply: 1. The patient has a condition that is life-threatening or a serious disease, 2. No comparative or satisfactory alternative treatment is available, 3. A controlled, clinical trial of drug/device is ongoing, 4. Sponsor is pursuing marketing approval.	YES
Data Preparatory to Research	Used when designing a research study or to assess the feasibility of conducting a study	YES
Planned Emergency Research with a Waiver of Consent	The exception to the consent requirements applies to a limited class of research activities involving individuals who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized representative.	YES *See GUIDANCE: Planned Emergency Research with a Waiver of Consent (HRP-022) for the Conditions to conduct the research and for Requirements for IRB approval.*
Emergency Use of an Investigational Drug or Device	A treating physician determines an unapproved drug or device is the best treatment for a patient, and ALL of the following criteria apply: 1. The test article is used one time per institution to treat a single patient, 2. The patient has a condition that is life-threatening or severely debilitating, 3. No standard treatment is available, 4. There is not sufficient time to obtain IRB review and approval, 5. The emergency use is reported to the IRB within five working days; when possible, the treating physician should consult with the IRB prior to use.	IRB NOTIFICATION REQUIRED WITHIN 5 DAYS OF USE *See GUIDANCE: Emergency Use Review (HRP-023) for more information.*
	Sponsor or manufacturer of the drug/device requires IRB approval to release it in an emergency use situation.	YES
Ethnographic Research	The Investigator or his/her staff will participate, overtly or covertly, in people's daily lives for an extended period of time. They will watch what happens, listen to what is said, ask questions and collect data to create a broader understanding of a particular environment, ethnic group, gender, etc.	YES
Innovative or Novel Procedures, Treatment, or Instructional Methods	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants in order to compare to standard procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, thus to develop or contribute to generalizable knowledge.	YES

ACTIVITY	DESCRIPTION	IRB REVIEW
	The use of innovative interventions that are designed solely to enhance the well-being of an individual patient and have a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to the particular individual.	NO
Internet Research	Online websites are set up for the purposes of collecting data regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc.	YES
Journalism	Activities focused on the collection, verification, reporting, and analysis of information or facts on current events, trends, newsworthy issues or stories about people or events. There is no intent to test a hypothesis.	NO *Exercise of professional ethics is expected*
Oral Histories	Interviews that collect, preserve and interpret the voices and memories of people, communities, and participants in past events as a method of historical documentation. The intent is to document a particular past or unique event in history.	NO *Exercise of professional ethics is expected*
Pilot Studies	Pilot studies that meet the definition of human research, regardless of the number of subjects enrolled or the duration of the studies.	YES
Quality Assurance (QA) and Quality Improvement (QI) Activities	Clinical QI/QA: Systematic, data-guided activities designed to implement promising ways to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs or business practices in the local setting. Intent is limited to improving care, operations, etc.	No
	Non-clinical QI/QA: Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs. Examples include teaching evaluations or customer service surveys. Intent is limited to evaluating services or programs.	No
	When proposed QI/QA activities may have research intent.	Maybe *Contact SHC IRB for guidance*
Repositories and Registries (e.g., data, specimens)	A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple investigators or multiple research projects.	YES
	Storage of human tissue, blood, genetic material or data that has been de-identified by Sharp HealthCare Study personnel at the time of collection.	YES *Some activities may not require IRB review*
Standard Diagnostic or Therapeutic Procedures	The collection of data about established and accepted diagnostic, therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge.	YES
	Alteration in patient care or assignment for research purposes.	YES
	A diagnostic procedure added to a standard treatment for the purpose of research.	YES
	An established and accepted diagnostic, therapeutic procedure or instructional method, performed only for the benefit of a patient but not for the purposes of research.	NO
Student Conducted Research	Thesis or dissertation projects conducted to meet the requirements of a graduate degree.	YES

ACTIVITY	DESCRIPTION	IRB REVIEW
	See *FORM: Nursing Entity Project Approval Form (HRP-235)*	
SHC serving as the Coordinating Center for a Multi-center Research Project	SHC *is not* an enrolling site and the SHC PI has agreed to serve as the coordinating center for a multi-center trial, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES
	SHC *is* an enrolling site and the SHC PI has agreed to serve as the coordinating center for the multi-center trial, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.	YES

6 MATERIALS

6.1 GUIDANCE: Definitions (HRP-001)
6.2 GUIDANCE: Planned Emergency Research with Waiver of Consent (HRP-022)
6.3 GUIDANCE: Emergency Use Review (HRP-023)
6.4 FORM: Initial IRB Review Application (HRP-211)
6.5 FORM: Nursing Entity Project Approval (HRP-235)

7 REFERENCES

7.1 DHHS: 45 CFR §46.102
7.2 FDA: 21 CFR 50.3; 21 CFR §56.102 and 56.103; 21 CFR 312.3(b); 21 CFR 812.3(h)
7.3 CA Statute: California Health and Safety Code 102231

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