## 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 are available via the 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 Reports | Retrospective review of 1-3 patient medical records with intent to document a specific situation or the experience of the individual(s) without intent to form a research hypothesis, draw conclusions or generalize findings. Any images and/or audio/visual recordings must be de-identified. Any health information should be de-identified. See *GUIDANCE: Case Reports or Limited Case Series (HRP-094), POLICY: Consent to Photograph & Publication (01601), and Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use* for more information. | NO |
| Limited Case Series | A description (i.e., publication or presentation) of the clinical characteristics or treatment(s) provided to four or more patients that share a common condition. This activity constitutes "research." Any images and/or audio/visual recordings must be de-identified. Any health information should be de-identified. See *GUIDANCE: Case Reports or Limited Case Series (HRP-094), POLICY: Consent to Photograph & Publication (01601), and Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use* for more information. | YES |

| ACTIVITY | DESCRIPTION | IRB REVIEW |
|---|---|---|
| Case Studies | An intensive, prospective, systematic investigation of a single individual, group, community, or some other unit in which the researcher examines in-depth data relating to several variables and involves the use of data that would not ordinarily be collected during treatment. This activity constitutes "research" and requires IRB approval prior to initiation. The intent is to publish or present the case study results. | 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<br>*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 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. | YES |
| "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 the following criteria apply:<br>1. The patient has a condition that is life-threatening or a serious disease,<br>2. No comparative or satisfactory alternative treatment is available,<br>3. A controlled, clinical trial of drug/device is ongoing,<br>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 need 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<br>*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 the following criteria apply:<br>1. The test article is used one time per institution to treat a single patient,<br>2. The patient has a condition that is life-threatening or severely debilitating,<br>3. No standard treatment is available,<br>4. There is not sufficient time to obtain IRB review and approval,<br>5. The emergency use is reported to the IRB within five working | IRB NOTIFICATION REQUIRED WITHIN 5 DAYS OF USE<br>*See GUIDANCE: Emergency Use Review (HRP-023) for more information.* |

| ACTIVITY | DESCRIPTION | IRB REVIEW |
|---|---|---|
| | days; when possible, the treating physician should consult with the IRB prior to use. | |
| | 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. 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 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 |
| | 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 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 |
| Scholarly and Journalistic Activities | 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. This includes the collection and use of information, that focus directly on the specific individuals about whom the information is collected. There is no intent to test a hypothesis. | NO<br>*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<br>*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.<br>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.<br>Intent is limited to evaluating services or programs. | No |

| ACTIVITY | DESCRIPTION | IRB REVIEW |
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| | When proposed QI/QA activities may have research intent. | Maybe<br>*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<br>*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.<br>See *FORM: Nursing Entity Project Approval Form (HRP-235)* | YES |
| SHC serving as the Coordinating Center for a Multi-center Research Project | SHC *is not* an enrolling site and the SHC Principal Investigator (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 |
| Public Health Surveillance Activities | Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.<br>• Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.<br>• Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.<br>• Including those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters). | NO |
| Criminal Justice Agency Activities | Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. | NO |
| National Security | Authorized operational activities (as determined by the relevant | NO |

| ACTIVITY | DESCRIPTION | IRB REVIEW |
|---|---|---|
| Activities | federal agency) in support of intelligence, homeland security, defense, or other national security missions. | |
| Secondary Research Involving Newborn Screening Specimens | Secondary research involving non-identifiable newborn screening specimens. | NO |

## 6 MATERIALS

6.1 POLICY: Consent to Photograph & Publication (01601)
6.2 Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use
6.3 GUIDANCE: Definitions (HRP-001)
6.4 GUIDANCE: Planned Emergency Research with Waiver of Consent (HRP-022)
6.5 GUIDANCE: Emergency Use Review (HRP-023)
6.6 GUIDANCE: Case Reports or Limited Case Series (HRP-094)
6.7 FORM: Initial IRB Review Application (HRP-211)
6.8 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; 21 CFR 56.103; 21 CFR 312.3(b); 21 CFR 812.3(h)
7.3 CA Statute: California Health and Safety Code 102231
7.4 OHRP FAQ Newborn Blood Spot

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