Human Subjects Protection Program
Investigator Guidance
October 17, 2024

ACTIVITIES THAT REQUIRE IRB REVIEW

Overview

- This guidance may be used by investigators to determine which activities require IRB review. Examples of activities that may or may not require IRB review are included in this guidance. All activities that constitute "human research" that are performed by CHLA employees and students must be reviewed and approved by the CHLA IRB or an external IRB (when approved by CHLA), or be certified exempt from IRB review prior to initiation.

- Investigators should review the definitions of "human subject" and "research" found in SOP HRP-001: Definitions. Investigators may also contact a member of the HSPP staff for assistance with this determination.

- It is **strongly recommended** that investigators request a formal determination about whether an activity is human research by submitting an application in iStar. Some funding agencies, sponsors, meetings, conferences, and journals may require a formal determination from the investigator's institution.

  - **IMPORTANT NOTE:** CHLA IRB review and approval, certification of exemption, research and/or human subject determinations **must** be obtained prior to any contact, intervention, interaction with human subjects, or any use of specimens, records, or data. The CHLA IRB **does not** grant retroactive approvals, exemptions, or determinations for activities that have already been performed. In addition, the CHLA IRB does not make consenting and HIPAA determinations for activities that are not research.

Examples of Activities that May or May Not Require IRB Review

Type of Activity	IRB Review Required?
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. Refer to the *Differences between Research, Quality Improvement Activities, and Case Reports* guidance document for further details.	**NO** - *if limited to the review of 1-3 patient records from all participating sites and all data will be recorded from medical records.* **YES -** *More than 3 patient records from all participating sites and/or some or all data will be obtained from*

	state death files containing personal identifying information requires IRB approval.
Clinical Investigations • Experiments using a test article that are regulated by the Food and Drug Administration (FDA) or support applications for research or marketing permits for products regulated by the FDA. • Products regulated by the FDA include food, 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; Expanded Access Programs • A treating physician determines an unapproved drug or device is the best treatment for a patient, and ALL of the following criteria apply: o The patient has a condition that is life-threatening or a serious disease, o No comparative or satisfactory alternative treatment is available, o A controlled, clinical trial of drug/device is ongoing, and o Sponsor is pursuing marketing approval.	**YES**
Data and Specimen Repositories and Registries • Collection and/or storage of data and/or human tissue, fluids, genetic material for current or future research use.	**YES**
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: o The test article is used one time per institution to treat a single patient, o The patient has a condition that is life-threatening or severely debilitating, o No standard treatment is available, o There is not sufficient time to obtain IRB review and approval, and o 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. • Sponsor or manufacturer of the drug/device requires IRB approval to release it in an emergency use situation.	**IRB NOTIFICATION REQUIRED WITHIN 5 DAYS OF USE** **YES**
Standard Diagnostic or Therapeutic Procedures • The collection of data about established and accepted diagnostic, therapeutic procedures, or instructional methods for research.	**YES**

• Alterations to patient care or assignment to a standard treatment for research purposes. • A diagnostic procedure added to a standard treatment for research purposes.	
Student Research • Thesis or dissertation projects conducted to meet the requirements of a graduate degree.	**YES**
Classroom Assignments / Research Methods Classes • Activities designed for educational purposes only that teach research methods or demonstrate course concepts.	**NO**
CHLA serving as the Coordinating Center for a Multicenter Research Project • CHLA *is not* an enrolling site and the CHLA 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. • CHLA *is* an enrolling site and the CHLA 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**
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**
Internet Research • Online websites set up for the purposes of collecting data regarding a particular topic for research purposes. This may include the completion of questionnaires/surveys, collection of personal data, etc.	**YES**
Quality Assurance (QA) and Quality Improvement (QI) Activities • Clinical QI/QA: Systematic, data-guided activities designed 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. • 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. QI/QA activities that have a research intent.	**NO –** *refer to the Differences between Research, Quality Improvement Activities, and Case Reports guidance document for further details.* **YES**