Human Research Protection Program Plan

Revised January 6, 2020

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Scope

Throughout this document “Institution” refers to Children’s Hospital Los Angeles (CHLA).

Purpose

This Institution is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Institution’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Institution’s Human Research Protection Program, called the Human Subject Protection Program (HSPP), is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The HSPP is based on all individuals in this Institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Definitions

Agent

An individual who is **employed** by Children’s Hospital Los Angeles is considered an agent of this Institution and is authorized to act on its behalf. There is no human subject protection policy regarding when an individual who is **not an employee** acts as an agent of the institution.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Institution.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Engaged in Human Research

In general, this Institution is considered engaged in Human Research when this Institution’s employees or agents for the purposes of the Human Research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. This Institution follows the Office for

Human Research Protections (OHRP) guidance on "Engagement of Institutions in Research"[1] to apply this definition and exceptions to this definition.

Human Research:

Any activity that either:

- Is "Research" as defined by the Department of Health and Human Services (DHHS) and involves "Human Subjects" as defined by DHHS ("DHHS Human Research"); or
- Is "Research" as defined by the Food and Drug Administration (FDA) and involves "Human Subjects" as defined by FDA ("FDA Human Research").

Human Subject as Defined by DHHS

A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

- **Intervention** means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Private Information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable Biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

[1] http://www.hhs.gov/ohrp/policy/engage08.html

Human Subject as Defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[2]

The following activities are not considered Research as Defined by DHHS:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- 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.
    - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
    - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
    - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

[2] For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

- 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.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
- Secondary research involving non-identifiable newborn screening blood spots.

Research as Defined by FDA

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Mission

The mission of this Institution's Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Institution.

Ethical Requirements

In the oversight of all Human Research, this Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution's institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional Official/Organizational Official (IO/OO), and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report":

- Respect for Persons

- Beneficence
- Justice

Legal Requirements

1. This Institution commits to apply its ethical standards to all Human Research regardless of funding.
2. All Human Research must undergo review by one of the institutionally designated IRBs.
3. Activities that do not meet the definition of Human Research do not require review and approval by one of the Institution's IRBs and do not need to be submitted to one of the Institution's IRBs unless there is a question regarding whether the activity is Human Research.
4. When this Institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of Human Subjects.
5. When this Institution is engaged in FDA Human Research, this Institution commits to apply the FDA regulations relevant to the protection of Human Subjects.
6. Any questions about whether an activity meets the regulatory definitions of Human Research must be referred to the Human Subjects Protection Program who will provide a determination.

Other Requirements

1. When reviewing research that involves community-based research, the IRB obtains consultation or training.
2. All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:
    - Confirming the qualifications of investigators for conducting the research
    - Conducting initial review, continuing review, and review of modifications to previously approved research
    - Post-approval monitoring
    - Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
    - Consent process and other language issues
    - Ensuring all necessary approvals are met
    - Coordination and communication with local IRBs

3. For clinical trials, this Institution commits to apply the "International Conference on Harmonisation – Good Clinical Practice E6" (ICH-GCP).
4. This Institution prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees") and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments.")
5. When Human Research is conducted or funded by the Department of Justice (DOJ), this Institution commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.
6. When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D[3]. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.
7. When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.
8. When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying the Department of Energy (DOE) O 443.1B and to use "DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocol that Utilize Personally Identifiable Information (PII)."
9. When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.
10. When Human Research is subject to the European Union General Data Protection Regulations (GDPR), this Institution coordinates with legal counsel to ensure that the research activities conform to broader institutional policies related to GDPR, where

[3] Quick applicability table for DHHS Subparts:

	DHHS	DOD	ED	EPA	VA
Subpart B	X	X		X	
Subpart C	X	X			X
Subpart D	X	X	X	X	X

applicable, as well as legal counsel's interpretation of study-specific GDPR requirements.

Sponsored Human Research

For both sponsored and non-sponsored Human Research, this Institution abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Research Protection Program

The categories of Human Research overseen include:

- All forms of human research
- Research involving fetuses.
- Research involving devices that require an Investigational Device Exemption (IDE) issued by FDA.
- Research involving devices that require an abbreviated IDE.
- Research conducted or funded by the Department of Defense (DOD)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Education (ED)
- Research conducted or funded by the Department of Energy (DOE)
- Emergency use of a test article in a life threatening situation.
- Activities involving humanitarian use devices.
- Investigator held abbreviated IDE.
- Investigator held Investigational New Drug (IND) or IDE.
- Research involving pregnant women as subjects.
- Research involving adults unable to consent.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving children as subjects.
- Research using the short form of consent documentation.

The categories of Human Research not overseen include:

- Classified Research (Classified research is secret research to which access is restricted by law to a particular hierarchical class of people. A security clearance is required to review classified research.)
- Research conducted or funded by the Veteran Administration (VA)
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available on the following HSPP Website: https://www.chla.org/research/hspp.

Human Research Protection Program Components

Institutional Official/Organizational Official (IO/OO)

1. The Vice President for Research Operations is designated as the IO/OO.
2. This individual has direct authority and responsibility for the Human Subjects Protection Program and is the signatory on the federal-wide assurance for the Office of Human Research Protections (OHRP).
3. The IO/OO has the authority to take the following actions or delegate these authorities to a designee:
    - Create the Human Research Protection Program budget.
    - Allocate resources within the Human Research Protection Program budget.
    - Appoint and remove IRB members and IRB chairs.
    - Hire and fire research review staff.
    - Determine what IRBs the Institution will rely upon.
    - Approve and rescind authorization agreements for IRBs.
    - Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
    - Create policies and procedures related to the Human Research Protection Program that are binding on the Institution.
    - Suspend or terminate research approved by one of the Institution's IRBs.
    - Disapprove research approved by one of the Institution's IRBs.
4. The IO/OO has the responsibility to:
    - Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
    - Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
    - Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
    - Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
    - Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Institution cannot approve

research that has not been approved by one of the IRBs designated by the Institution.

- Ensure that the IRB Chair(s) and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Research protection program.
- Ensure that the Human Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

Investigator Responsibilities

- Do not commence research until you have the IRB approval letter and obtained all other required department/division and ancillary approvals. If there are any questions about whether you are conducting research involving human subjects, contact the reviewing IRB before commencing the study.
- Comply with all requirements and determinations of the reviewing IRB.
- Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.

- Submit proposed modifications to the reviewing IRB prior to their implementation.
- Do not make changes or modifications to the research without prior IRB review and approval, unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing reviews when requested by the reviewing IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
  - The protocol is permanently closed to enrollment, and
  - All subjects have completed all protocol related interventions and interaction.
    - For research subject to federal oversight other than FDA:
      - No additional identifiable private information about the subjects is being obtained, and
      - Your analysis of private identifiable information is completed.
- If research approval expires, stop all research activities and immediately contact the reviewing IRB.
- Promptly report to the reviewing IRB any new information that requires prompt reporting.
- Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- For studies regulated by a federal department or agency, follow any additional obligations, as applicable

CHLA Institutional Review Board (IRB)

- CHLA IRB reviews non-exempt human subject research. The IRB assists with establishing policy for the HSPP and reviews issues related to unanticipated problems involving risks to subjects and/or others, serious and continuing non-compliance, terminations and suspensions, and findings from not for cause audits. The IRB may obtain expertise from outside individuals/consultants when the expertise is not represented among the current IRB membership. The IRB receives information from legal counsel, Conflict of Interest in Research Committee and the Radiation Safety Committee (if applicable).
- IRB Committee reviews human subject research to determine that:
  - Risks to participants are minimized by (a) using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and (b) when appropriate, by using procedures already being performed on participants for diagnostic or treatment purposes.

- Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result from participation in a study. In evaluating risks and benefits, the IRB Committee should consider only those risks and benefits that result from the research (as distinguished from risks and benefits of therapies participants would receive if not participating in the research). The IRB Committee should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of participants is equitable considering the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations and potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by Federal and State regulations and Institutional policies and procedures including the IRB.
- When appropriate, the research plan makes adequate provisions for monitoring data collected to assure the safety of participants.
- When appropriate, there are adequate provisions to protect privacy of participants and to maintain the confidentiality of data.
- There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The IRB Committee must determine if additional safeguards need to be included in the study to protect the rights and welfare of these participants.
- When appropriate, the informed consent document includes the additional elements of informed consent.
- When appropriate, the need for ancillary care, additional monitoring, counseling, and social support are provided.
- Conducts timely continuing reviews of approved research, as appropriate.
- Reviews all proposed human subject research in accordance with the basic ethical principles (Respect for Persons, Beneficence, Justice) of The Belmont Report.
- Reviews, and has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.

- Participates in mandatory annual training, including the required CITI training modules.
- Reviews all research activities and documents its findings regarding ethical considerations, scientific merit, adherence to Federal regulations and IRB policies and procedures.
- Reviews and monitor ongoing research for adherence to the Federal regulations and IRB policies and procedures.

IRB Chair

This individual is responsible for oversight of the IRB and the convened meetings of the IRB. This individual also reviews exempt and expedited research and represents the IRB at CHLA meetings and/or delegates this responsibility to other IRB members as needed. This individual is authorized to suspend or terminate Human Research approved by the CHLA IRB.

IRB Vice Chair(s)

These individuals are responsible for oversight of the IRB and the convened meetings of the IRB when the Chair is unavailable. These individuals also review exempt and expedited research and represent the IRB at CHLA meetings when the Chair is unavailable.

IRB Staff Responsibilities

- Perform preliminary reviews of protocols submitted for IRB review in order to prepare guidance to the Committee reviewers.
- Prepare detailed correspondence advising investigators of IRB feedback and study status on behalf of the CHLA IRB.
- Ensure timely renewal of ongoing research applications.
- Assist the Director with supervision of office systems including maintaining the iStar electronic submission system.
- Assist with maintenance and updating of Human Subjects Protection Program (HSPP) policy and procedures, forms and website.
- Assist investigators with preparation of IRB submissions.
- Act as liaison to facilitate communication between investigators and the IRB.
- Maintain knowledge of current federal and state regulations pertaining to the conduct of research and administration of IRBs.
- As funding permits, attend annual national IRB conferences such as PRIM&R in order to maintain professional knowledge and expertise.

- Attend Committee meetings to provide consultation on federal regulations that pertain to Human Research.
- Prepare detailed and accurate minutes of meetings including information about deliberations, discussion and resolution of controversial, medical, and ethical issues and determinations discussed by the Committee.
- Assist the Director with planning and implementation of education and training programs for investigators, research staff and IRB members.
- Participate in outreach and training activities for CHLA, including but not limited to educational presentations, workshops, and composition of written materials.

Director Responsibilities

- Administers the HSPP and is responsible for establishing, evaluating and overseeing the administrative operations, policies and procedures of the HSPP and supervising the educational and quality assurance functions of the HSPP office.
- Updates the CHLA Federalwide Assurance even if no changes have occurred, in order to maintain an active Assurance approved by the Office for Human Research Protections. Amendments to the Assurance are to be reported promptly to OHRP. This includes changes to IRB Committee rosters and the addition or deletion of an IRB.
- Maintains policies and procedures reflecting the current practices of the IRB in conducting reviews and approvals under its Assurance. These policies and procedures will be kept current by the CHLA IRB. Changes in policies and procedures are determined by the IRB, HSPP staff and IRB Chair and Vice Chair, and the IO/OO.
- Develops the annual budget, and discuss any needs with the IO/OO, the IRB Chair and the IRB staff in order to accommodate the volume and type of research reviewed, space, facilities and staff.
- Assists with quality improvement activities and sets goals and objectives for improving the HSPP internally and providing oversight for the research community externally.
- Assures CHLA policies and procedures are effectively applied in compliance with State and Federal laws and regulations, the FWA, OHRP, FDA, NIH, OCR, and any other applicable Federal agency.
- Provides regular training and education to IRB members and keeps the IRB apprised of current events pertaining to the protection of human subjects.
- Supports and facilitates the IRB review and approval process.
- Takes action on non-compliance according to HSPP policies and procedures, as necessary.

- Mentors and trains HSPP staff as needed, investigators, and key study personnel on human subject protections and the IRB review and approval process. Provides annual evaluations to the HSPP staff.

Quality Assurance & Education Specialist

- Designs, develops, implements and maintains the Clinical Research Quality Assurance/Quality Improvement Program at CHLA.
- Responsible for performing the quality improvement and quality assurance activities of the Human Subjects Protection Program.
- As funding permits, attends appropriate conferences to gather new ideas and approaches to clinical research quality assurance programs.
- Performs random audits in accordance with applicable audit plans, SOPs, or as requested by the HSPP Director.
- Performs directed audits as requested by the IRB Chair, IRB, or by the HSPP Director.
- Assists with investigations of allegations of noncompliance.
- Performs other activities as requested by the IRB Chair, IRB, or by the HSPP Director.
- Performs study initiation consultations for all newly approved studies that have a human subjects interaction.
- Provides ongoing consultation and support to including set-up of the study, regulatory compliance, project management and data related issues.
- Trains new clinical research staff including clinical research coordinators, clinical research nurses, research and project assistants in clinical trial related clinical research management services.
- Prepares and annually updates the Quality Assurance and Improvement manual.
- Assembles information for and prepares the quarterly Quality Improvement report including control charts for IRB activity, serious adverse events, and protocol deviations.
- Configures customized activity reports in collaboration with iStar staff to monitor IRB activities.
- Develops and implements educational programs to train the research community in research documentation procedures, protocol adherence and regulatory compliance.

All Members of the Institution

All individuals within the Institution have the responsibility to:

- Be aware of the definition of Human Research.
- Consult the IRB when there is uncertainty about whether an activity is Human Research.

- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the IO/OO.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the IO/OO.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.

Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process.

IRBs

1. There is one CHLA IRB designated by the IO/OO that can be relied upon by the CHLA HSPP. The scope of its review is available on the HSPP website.
2. This Institution may rely upon the IRBs of another institution or organization provided one of the following is true:
    - The IRBs are part of an AAHRPP accredited institution or organization.
    - The use of a single IRB has been pre-determined by study sponsor or grant or established by prior arrangement (e.g. reliance network).
    - This Institution's investigator is a collaborator on Human Research that is primarily conducted at another institution or organization and the investigator's role does not include interaction or intervention with subjects.
    - The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)
    - Reliance on an external IRB requires an Authorization Agreement and an active Institutional Profile, as well as a local review for compliance with local policies of the Institution. When Human Research carried out at this institution or by its agents is reviewed by an IRB at another institution or organization, this HRPP will follow established policies and procedures that specify which studies are eligible for reliance, how reliance is determined, and will provide information to researchers about reliance criteria and the process for seeking IRB reliance.
3. The IRBs relied upon by this Institution have the authority to:
    - Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the IO/OO. Officials of this

Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.

- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.
- Serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

4. This institution will comply with the determinations of the reviewing IRB, follow reporting and conflict of interest disclosure requirements as specified in the authorization agreement, conduct monitoring, identify an appropriate contact person, ensure researchers have appropriate qualifications and provide local context information (and any updates) to the reviewing IRB.
5. When this institution provides IRB review for other institutions, this HRPP will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site. This includes ensuring the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.
6. The IRB will review the research in accordance with established policies and procedures to determine that research is ethically justifiable, according to all applicable laws, including initial review, continuing review, review of modifications to previously approved research and unanticipated problems involving risks to subjects or others. The IRB will also have the ability to suspend or terminate IRB approval; as well as have the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed.
7. The IRB will notify the researcher (and organization) of its decisions, make relevant IRB policies and records available to the relying institution or organization and specify an IRB contact for communication.

8. IRB members and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the IO/OO.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the IO/OO, IRB, and other individuals involved with the Human Research Protection Program.
- Determine whether someone is acting as an agent of the Institution.
- Determine who meets the definition of “Legally Authorized Representative” and “Children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.
- Determine whether any Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland conforms with EU General Data Protection Regulations (GDPR).

Department/Division Head Deans and Department Chairs

Department/Division Head Deans and Department Chairs have the responsibility to:

- Oversee the review and conduct of Human Research in their department or school.
- Forward complaints and allegations regarding the Human Research Protection Program to the IO/OO.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Research Administration Office

The Research Administration Office has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

Education and Training

IRB members, IRB staff, and others involved in the review of Human Research must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program. See the IRB Web site for a link to this training. This training is valid for a three-year period, after which time a refresher CITI course or additional training must be completed. Investigators and research staff must complete the initial and continuing training described in the INVESTIGATOR MANUAL (HRP-103).

Questions and Additional Information for the IRB

The Human Subjects Protection Program wants your questions, information, and feedback.

Contact and location information for the Human Subjects Protection Program is:

Name: Alisa Irwin
Title: Interim Director
Office: Human Subjects Protection Program
4650 Sunset Blvd, MS #84
Los Angeles, California 90027
Email: airwin@chla.usc.edu
Phone: 323-361-1846

Reporting and Management of Concerns

1. Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, Human Subjects Protection Program, IO/OO, Legal Counsel, Deans, or Department Chairs.
2. The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The IO/OO has the responsibility to investigate all other reports and take corrective actions as needed.
3. Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the IO/OO or designee.

    To make such reports, contact the IO/OO:

    Name: Jodi Ogden Rivera, MBA, CRA
    Title: Vice President

Office: Research Operations
4650 Sunset Blvd, MS #84
Los Angeles, California 90027
Email: jogden@chla.usc.edu
323-361-4661

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and institutional requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

Disciplinary Actions

The IO/OO may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the IO/OO such actions are required to maintain the Human Research Protection Program.

Approval and Revisions to the Plan

This Human Research Protection Program Plan is to be approved by the IO/OO. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO/OO has the responsibility to review this plan to assess whether it is providing the desired results. The IO/OO has the authority to amend this plan as deemed necessary.

Approved: Date: January 6, 2020

Jodi Ogden Rivera, MBA, CRA
Institutional Official
Vice President, Research Operations