Terminology

A

Active Project – Is a research project that is considered "open" at CSULB. IRBNet currently recognizes the following stages in the life of a project:

> Pending – A project has been submitted to the IRB and is currently under review. It has not received a formal IRB determination or IRB approval.
>
> Withdrawn – A project that was withdrawn from IRBNet prior to IRB approval.

Amendment – Is any change/modification made to an IRB approved protocol. Amendments may include, but are not limited to, procedural changes, adding or removing personnel, requesting additional subjects beyond the originally approved number, new funding sources, new or revised advertisements or recruitment methods, changes to the informed consent process and/or documents, changes to surveys, questionnaires or interview guides changes in design, addition of a research site, or any other changes in the research activity.

Anonymity – Means that there is no way for anyone (including the researcher) to personally identify participants in the study. Personally-identifying information includes, but is not limited to, names, addresses, e-mail addresses, phone numbers, government-issued ID numbers (e.g., social security numbers), photographs, and IP addresses. This also means that any study conducted face-to-face or over the phone cannot be considered anonymous; this rules out most qualitative research that involves interviews.

Annual Check-In/Continuing Review – The PI must submit an Annual Check–In form for a protocol approved by expedited review or submit a Continuing Review form for a protocol approved by the full IRB.

Adverse Event – An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy; subject becomes emotionally upset after considering question on research survey, etc.).

Assent – Agreement by an individual not able to give legally valid informed consent (i.e., a child or cognitively impaired person) to participate in research.

B

C

Children (Child) – Persons who have not attained the legal age for consent to be involved in the research interactions or interventions, under the applicable law of the jurisdiction in which the research will be conducted.

Coded Data – Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Coercion – Occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

Confidentiality – The ethical or legal right that information is considered private and will be held secret unless consent is provided permitting disclosure.

Conflict of Interest – involves a situation in which faculty, staff, or student employees have a financial interest or other personal consideration that may compromise, or have the appearance of compromising, their professional judgment in performing their University duties (e.g. teaching; designing, conducting, or reporting research; business decision–making; or other University obligations).

D

E

Exempt – Research that is classified as “exempt” means that the research qualifies as minimal risk and the only involvement of human subjects will be in one or more of six categories. The research is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects, but is still considered research requiring an IRB review for an exemption determination.

Existing (Data, Documents, Records, or Specimens) – Existing with regards to these materials means the items must be "on the shelf" or in existence at the time the project is submitted to the IRB for review.

Expedited Review – Expedited review means that the IRB chair, or designee, are responsible for the review and approval of a research application. Under the regulations only those studies that are minimal risk qualify for this type of review. Expedited review does not mean that the review occurs quickly.

F

Faculty Advisor (FA) – An individual affiliated with CSULB who has the expertise and knowledge to oversee/mentor a student PI. The responsibilities of the FA/mentor would include reviewing the student PI's IRB application to ensure the risks are clearly outlined and minimized, the proposed research has merit within the academic discipline, and complies with federal regulations and university policies.

FERPA (Family Education Rights and Privacy Act) – A federal law of 1974 that protects the privacy of student education records.

Full Board – Comprised of a chair and sufficient number of board members who review and vote on all new studies, continuing reviews and amendments of approved research that are considered to be greater than minimal risk or contain a new or novel component proposed as part of the research study.

G

Generalizable knowledge – Information where the intended use of the research findings can be applied to populations or situations beyond that studied.

Guardian – A person who is not the parent of a child, but who has been appointed by a court or juvenile court having jurisdiction over the child, to have a permanent self–sustaining relationship with the child and to make important decisions which have a permanent effect on the life and development of that child and to promote the general welfare of that child. A guardian may be a court or a juvenile court.

H

HIPAA (Health Insurance Portability and Accountability Act) – A federal law of 1996, the HIPAA Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information.

HIPAA Letter – A letter used by non "covered entities" to document compliance with the HIPAA Privacy Rule. The IRB requires this letter, or similar documentation, from the covered entity in instances when a covered entity, for research purposes, gives researchers access to protected health information maintained by that entity without the patient's explicit authorization.

Human Subject – DHHS definition: a living individual about whom an investigator (whether professor or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information. [45 CFR 46.102.(d)]

Human Subjects Protection Training (CITI) – All members of a research team conducting human subjects research are required to complete an education program and become "certified" in human subject protections through the Collaborative Institutional Training Initiative program (CITI).

I

IDE – Investigational device exemption

Identifiable – The identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable Private Information – Private 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 which the individual can reasonably expect will not be made public (e.g, a medical record). This information is considered individually identifiable if the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

IND – An investigational new drug application.

Individual Investigator Agreement (IIA) – Document to be completed by an individual community Investigator who is participating as an individual independent investigator and is requesting CSULB IRB oversight for their activities.

Informed Consent – A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, a subject may not waive or appear to waive any of his/her legal rights, or release or appear to release the investigator, the sponsor, the institution or agents of the institution from liability for negligence.

Informed Consent – A written description in lay terms of relevant study information. It is the document of study information that is communicated to the potential subject. When signed by the potential subject, it records the receipt of study related information by the subject and the subjects agreement to participate in the research study.

Institutional Official – The Institutional Official (IO) who is the signatory on the FWA filed with OHRP to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high–level official who has the authority to represent the institution named in the FWA.

Institutional Review Board (IRB) – An Institutional Review Board is a group of individuals charged with reviewing proposed research involving human subjects to ensure the protection of those subjects and compliance with federal human subjects regulations.

Interaction – Includes communication or interpersonal contact between investigator and participant (for example, survey or interview procedures).

Intervention – Includes both physical procedures by which data are gathered (for example, venipuncture, exercise, use of a computer mouse) and manipulations of the subject or the subject's environment that are performed for research purposes.

Investigation – A research inquiry for ascertaining facts; detailed or careful examination.

IRB Authorization Agreement (IAA) – A formal, written, agreement in which the reviewing IRB agrees to serve as the IRB of Record for another organization.

IRB Chair – The individual designated on the Institutional Review Board roster as the person assigned with leading the IRB.

IRB of Record – A reviewing IRB that assumes IRB oversight for another organization that meets the regularity definition of engaged in human subjects research.

IRB Reliance Agreement – A reliance agreement may be requested when you are conducting human subjects research under oversight of an IRB outside of CSULB.

IRBNet – Is an online submission platform used by the IRB to review, make determination, communicate, and manage protocol documents to ensure regulatory compliance. Upon completion of projects, IRBNet also serves as a document archive. Research conducted by CSULB faculty, students, or staff requiring review by the IRB must be submitted via IRBNet.

J

K

L

Legally Authorized Representative (LAR) – An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Letter of Permission/Authorization – A document submitted with a protocol application granting permission to conduct research in a facility or with an organization outside the University, and/or to use data from an outside entity.

M

Medical Device – A device is: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Minimal risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

N

NIH (National Institutes of Health) – NIH, comprising 27 separate Institutes and Centers is one of eight health agencies of the Public Health Service which, in turn, is part of the U.S. Department of Health and Human Services. NIH is the largest public funder of research in the world.

Nonscientist – An individual who has little or no formal scientific or medical training or experience and is a required member of the IRB.

O

OHRP (Office of Human Research Protections) – The Office for Human Research Protections (OHRP), an office of the U.S. Department of Health & Human Services, provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social–behavioral research.

P

Principal Investigator – (PI) is responsible for the content of the IRB application and the conduct of the research once approved. Even when responsibilities are delegated to members of the research team, the PI is ultimately responsible for the study. The PI can be a faculty member, staff or student.

Privacy – Is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Private Information – Includes 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 which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

Protocol – The formal design or plan of an experiment or research activity, specifically, the plan submitted to an IRB for review. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the research interaction or intervention to be employed, and the proposed methods of analysis that will be performed on the collected data.

Q

Quorum – A majority of voting members of an IRB, including at least one member whose primary expertise is in a nonscientific area.

R

Research – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research Misconduct – Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data or creative innovations that are nonetheless ethical, legal and meet professional standards.

Revision – To address an IRB request for modifications to the protocol application required for IRB approval.

Risk – The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude may vary from minimal to significant.

S

Systematic Investigation – Research development, testing and evaluation and subsequent gathering and analysis of information.

T

Termination – By requirement of the convened IRB, a permanent halt to some or all research activities in a previously approved IRB project.

U

Undue Influence – Often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, he or she offers comparable non–research alternatives for earning extra credit, the possibility of undue influence is minimized.

V

W

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Y

Z