C

– 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.

– 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.

– 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.

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

– 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

– 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.

H

– 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.

– 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.

– 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)]

– 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

– Investigational device exemption

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

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– 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 activites.

– 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.

– 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.

– 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.

– 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.

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

J

K

L

– 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.

– 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

– 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."

– 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, 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.

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

R

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

– 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.

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

– 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

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

T

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

U

– O f en occurs through an o f er of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an inves t gator might promise psychology students extra credit if they par t cipate in the research. If that is the only way a student can earn extra credit, then the inves t gator is unduly in f uencing poten t al subjects. If, however, he or she o f ers comparable non–research alterna t ves for earning extra credit, the possibility of undue in f uence is minimized.

V

W

X

Y

Z