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## 1 PURPOSE


1. This procedure establishes the definitions followed by the Office of IRB Administration (OIA).

## 2 REVISIONS FROM PREVIOUS VERSION

1. Remove “competitor of the sponsor” in item 10.


## 3 DEFINITIONS

1. **Administrative Review/Determination**: Can be performed by designated OIA staff; includes any of the following:
  - 1.1. Determination of research as exempt.
  - 1.2. Reviews of exempt research that do not require limited review.
  - 1.3. Determinations of projects as not human subjects research (NHSR).
  - 1.4. Reviews of projects that are NHSR.
  - 1.5. Local context review of research for which an external IRB is the IRB of record.
2. **Adverse Event (AE)**: Any untoward medical occurrence in a patient or research subject administered a pharmaceutical product or other research intervention and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product or research procedure, whether or not related to the medicinal (investigational) product or procedure.
3. **Allegation of Non-Compliance**: An unproved assertion of non-compliance.
4. **Apparent Immediate Hazard**: In the course of conducting research, it sometimes becomes evident that changes to a study need to be made to accommodate unforeseen conditions or occurrences. The principal investigator (PI) or designee is expected to react to the situation and eliminate/mitigate the potential hazard in order to protect the life or physical well-being of a research subject. Changes to a protocol to eliminate an apparent immediate hazard to subjects are exempt from the requirement to obtain approval from the IRB before implementing any modifications to previously approved research. Such instances are expected to be rare, and are reportable to the IRB.
5. **Case Report**: A prospective or retrospective review of a patient's clinical case used to develop a publication for the purposes of reporting on some novel aspect of the case (e.g., a new procedure, an unusual symptom presentation, etc.). A case report is distinguishable from research in that it does not intend to form a research hypothesis, draw conclusions, or contribute to generalizable knowledge.
6. **Children**: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. For purposes of Department of Education sponsored research, children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age of majority as determined under state law.
7. **Clinical investigation**: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under section 505(i) or 520(g) of the Food, Drug, and Cosmetic Act (FDCA), or is not subject to requirements for prior submission to the FDA under these sections of the FDCA, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
8. **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 those interventions on health-related biomedical or behavioral outcomes.
9. **Conflict of Interest (COI)**: An investigator or other key personnel has an interest that may conflict with production of an unbiased outcome of the study or otherwise affect the rights and welfare of human subjects:
  - 9.1. **Financial Conflict of Interest (FCOI)**: In accordance with institutional policies, must be disclosed to and reviewed by the COI independent review committee (IRC), who will produce a management plan for review by the IRB. IRB makes the final determination regarding disclosure in the informed consent form (ICF) and whether the management plan is adequate.
  - 9.2. **Other Conflict of Interest**: a non-financial interest that may inappropriately influence or bias

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the outcome of the study and affect the rights and welfare of human subjects. The IRB may require measures to mitigate the conflict and protect human subjects.


10. **Conflicting Interest**: An IRB member/consultant involved in research review is automatically considered to have a conflicting interest when the member/consultant or the member/consultant's spouse, domestic partner, children, and/or dependents have any of the following interests in the sponsor or the product or service being tested held by the member/consultant or the member/consultant's immediate family:
  - 10.1. Involvement in the design, conduct, or reporting of the research.
  - 10.2. Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.
  - 10.3. Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.
  - 10.4. Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.
  - 10.5. Board or executive relationship, regardless of compensation.
  - 10.6. Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
  - 10.7. Any other reason for which the member/consultant believes that he or she cannot be independent.
11. **Continuing Non-Compliance**: A pattern of non-compliance that indicates an inability or unwillingness to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.
12. **Controverted Issue**: Controverted issues are those that cause controversy and dispute among the IRB membership during a convened meeting. Controverted issues that arise during the convened meeting usually are the result of opposition to some aspect of the proposed research.
13. **Cooperative Research**: Those projects which are determined to be human subjects research and that involve more than one institution.
14. **Designated Reviewer**: The IRB chair or an experienced IRB member designated by the IRB chair to conduct non-committee reviews.
15. **Emergency Use**: The use of an investigational product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain FDA and/or IRB approval.
16. **Expanded Access**: A pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical investigations when no comparable or satisfactory alternative therapy options are available.
17. **Experienced IRB Member**: An IRB member is considered experienced if the IRB chair and/or OIA director consider the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
18. **Experimental Subject**: Under [Department of Defense Instruction \(DODI\) 3216.02](#), a living individual with whom there is an intervention or interaction, conducted for research purposes, where the primary purpose is obtaining data regarding the effect of the intervention or interaction. Research involving experimental subjects as defined in [DODI 3216.02](#) is a subset of research involving human participants.
19. **Expiration Date**: The date that represents the end date of the IRB approval period.
20. **External Investigator**: An investigator whose home institution has an IRB.
21. **Finding of Non-Compliance**: Non-compliance in fact.
22. **Generalizable Knowledge**: Universally or widely applicable truths, facts, or information.
  - 22.1. Activities designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual, the specific group of individuals studied, or an internal program.
  - 22.2. **IMPORTANT NOTE**: Results do not have to be published or presented to qualify the activity as being designed to develop or contribute to generalizable knowledge. Similarly,

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the intent to publish the results of an activity does not mean that the activity, in and of itself, has been designed to develop or contribute to generalizable knowledge.

23. **HIPAA**: The Health Insurance Portability and Accountability Act.
24. **Human Research**: Any activity that either:<sup>1</sup>
  - 24.1. Is research as defined by Department of Health and Human Services (DHHS) and involves human subjects as defined by DHHS; or
  - 24.2. Is research as defined by FDA and involves human subjects as defined by FDA.
25. **Human Subject**: 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 FDA-regulated research, “human subject” includes an individual (or their specimens in the case of device research) who is either the recipient of a test article or a control, whether patient or healthy individual. For the purpose of this definition:
  - 25.1. **Interventions**: Physical procedures, by which information or biospecimens are gathered (e.g. venipuncture) and/or manipulations of the human subject or the human subject's environment that are performed for research purposes.
  - 25.2. **Interaction**: Communication or interpersonal contact between investigator and human subject that are performed for research purposes.
  - 25.3. **Private Information**: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (e.g. their private residence, a bathroom, etc.), and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
  - 25.4. **Identifiable Private Information**: Information for which the identity of the human subject is or may be readily ascertained by the investigator or associated with the information.
  - 25.5. **Identifiable Biospecimen**: A biospecimen for which the identity of the human subject is or may be readily ascertained by the investigator or associated with the biospecimen.
26. **Human Subjects Research**: An activity that is either (a) “research” as defined below AND involves one or more “human subjects” as defined above or (b) a “clinical investigation” as defined above. “Clinical investigations” for treatment purposes (without research aims) are not considered “human subjects research” but OIA policies are applicable to the extent required by FDA regulations.
27. **Immediate Family**: Spouse, domestic partner; children, and/or dependents.
28. **Independent Investigator**: An investigator whose home institution does not have an IRB or who is not affiliated with an institution.
29. **Institutional Official (IO)**: The senior associate vice chancellor for health sciences to whom the Chancellor delegates authority to sign assurances of, and to oversee the university’s responsibility for, the protection of human subjects.
30. **Key Personnel**: Study team members that interact or intervene with the human subjects or their identifiable data.
31. **Management Plan**: The written plan issued by the UCSD IRC for the management, reduction or elimination of a potential or actual COI.
32. **Minimal Risk**: The probability and magnitude of harms or discomforts anticipated in the research that 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.
  - 32.1. For research involving prisoners, minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
  - 32.2. The phrase “ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” should not be interpreted to include the inherent risks

<sup>1</sup> The terms “human subject research,” “research involving human subjects,” “human subjects research,” “clinical research,” “clinical investigation,” “clinical study” and similar phrases are considered to be synonyms for the term human research.

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certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

33. **Minor Deviations:** A change to, or failure to adhere to, the research protocol or applicable OIA requirements that does not pose a risk of harm to the human subject's rights, safety or welfare, or to the integrity of the research data, and does not rise to the level of non-compliance. Minor deviations may result from the action or inaction of the participant, researcher, or research staff.
34. **Non-Committee Review:** Any of the following:
  - 34.1. Reviews of non-exempt research using the expedited procedure.
  - 34.2. Determinations of which human subjects can continue in expired research.
  - 34.3. Reviews of exempt research requiring limited review.
35. **Non-Compliance:** A failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, or with the requirements or determinations of an IRB that poses a risk of harm to subject's rights, safety or welfare, or the integrity of the research data. Non-compliance may be the result of the action or inaction of anyone conducting protocol procedures, but not research subjects.
  - 35.1. In the case of research funded or conducted by the Department of Defense (DOD), non-compliance includes failure of a person, group, or institution to act in accordance with [DODI 3216.02](#), its references, or applicable requirements.
36. **Prisoner:** Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
  - 36.1. For DOD research, the term includes military personnel in either civilian or military custody.
37. **Protected Health Information (PHI):** From HIPAA, individually identifiable health information transmitted or maintained by a covered entity.
38. **Quality Improvement (QI)/Quality Assurance (QA):** Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs. Intent is limited to evaluating or improving services, programs, patient care, operations, etc. within an institution.
39. **Related:**
  - 39.1. **Financial Interest:** A financial interest is related to the research when the interest is in:
    - 39.1.1. A sponsor of the research; or
    - 39.1.2. A product or service being tested.
  - 39.2. **Problem:** A problem (adverse incident, experience, event) is related to the research when there is at least 50% likelihood that the problem is causally related to participation in the research.
40. **Reliance Agreement:** A written agreement whereby an institution external to UCSD agrees to rely on the determinations of the UCSD IRB, UCSD agrees to rely on the determinations of an IRB external to UCSD, or the UCSD IRB agrees to serve as the IRB of record for an investigator not affiliated with UCSD. It may also be referred to as an IRB authorization agreement (IAA) or individual investigator agreement (IIA).
41. **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
42. **Restricted:** Applies to investigators who are delinquent in meeting IRB requirements.
43. **Serious Adverse Event (SAE):** An AE occurring in a patient or human subject enrolled in a research study is serious if it results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization, may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the patient or human subject and may require medical or surgical intervention to prevent one of the

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outcomes listed in this definition.

44. **Serious Non-Compliance**: Failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB that has a significant adverse impact (i.e. harms) either on the rights or welfare of participants or on the integrity of the data. For DOD research, serious non-compliance includes failure of a person, group, or institution to act in accordance with DODI 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.
45. **Single IRB (sIRB) Review**: A review performed by one institution (commonly referred to as the "IRB of record") for multi-site research to establish the expectation that an sIRB of record will be used in the ethical/scientific review of non-exempt human subjects research protocols.
46. **Suspension of IRB Approval**: An action of the IRB, IRB designee, institutional official, or designee of the institutional official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a termination of IRB approval. Suspended studies remain open and are subject to continuing review. For the purposes of this definition, an enrollment hold shall not be considered a suspension of IRB approval if no other research procedures have had their IRB approval withdrawn.
47. **Technical Submission**: A submission made in the electronic submission system to correct an administrative error or oversight related to system limitations and technical functioning of the electronic submission that does not constitute a modification to the conduct of the study or consent document language, and is not a personnel change or study document translation. Examples include: amendment to change consent from word format to pdf to meet system requirements for stamping; amendment to change labels of documents under supporting information to meet researchers' needs for specific document titles in the approval letter.
48. **Termination of IRB Approval**: An action of the IRB, IRB designee, institutional official, or designee of the institutional official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.
49. **Test article**: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the FDCA or under sections 351 and 354-360F of the Public Health Service Act (42 USC 262 and 263b-263n).
50. **Unanticipated Problem Involving Risks to Subjects or Others/Unanticipated Problem Report (UPR)**: An incident, experience, or outcome that meets all of the following criteria:
  - 50.1. Unexpected (in terms of nature, severity or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
  - 50.2. Related to participation in the research means there is a reasonable possibility, greater than or equal to 50%, that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
  - 50.3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

#### 4 RESPONSIBILITIES

1. Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.
2. Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

#### 5 PROCEDURE

1. None

#### 6 MATERIALS

1. None

#### 7 REFERENCES

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1. [21 CFR 50.3](#)
2. [21 CFR 56.102](#)
3. [21 CFR 312.3](#)
4. [21 CFR 812.2\(a\)](#)
5. [21 CFR 812.3\(p\)](#)
6. [45 CFR 46.102](#)
7. [45 CFR 46.114](#)
8. [45 CFR 160.103](#)
9. [Department of Defense Instruction 3216.02](#)