1 PURPOSE

1. This policy establishes the definitions followed by the human research protection program.

2 REVISIONS FROM PREVIOUS VERSION

1. Removal of determinations of Human Research and exempt from Non-Committee Review definition.
2. Revision of compliance, clinical investigation, related financial interest and human subjects definitions.
3. Formatting update. No changes to definitions.
4. Revision of minor deviation. Added administrative modification.

3 POLICY

1. Administrative Modification: When referring to previously approved human research, this is a modification which does not alter any elements of the human research pertaining to the criteria for approval and which has no substantive impact on the human subjects or the integrity of the data. When referring to human research previously determined to be exempt, this is a modification which does not alter the exempt determination.
2. Allegation of Non-Compliance: An unproved assertion of Non-Compliance.
3. 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.
4. Clinical investigation: Any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
5. 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.
6. 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 dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the Member/Consultant or the Member/Consultant's immediate family:
    - 6.1. Involvement in the design, conduct, or reporting of the research.
    - 6.2. Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.
    - 6.3. 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.
    - 6.4. Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.
    - 6.5. Board or executive relationship, regardless of compensation.
    - 6.6. 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.
    - 6.7. Any other reason for which the Member/Consultant believes that he or she cannot be independent.
7. Continuing Non-Compliance: A pattern of non-compliance that indicates an inability or unwillingness to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.
8. Cooperative Research: Those projects which are determined to be human subjects research and that involve more than one institution.
9. Designated Faculty: A faculty member trained and authorized by the IRB to approve exempt Human Research conducted by investigators or students in their department, division or school.
10. Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

11. Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
12. Experimental Subject: An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of 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.
13. Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.
14. Finding of Non-Compliance: Non-Compliance in fact.
15. HIPAA: The Health Insurance Portability and Accountability Act.
16. Human Research: Any activity that either[1]:
    16.1. Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
    16.2. Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.
17. 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:
    17.1. Intervention: Physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
    17.2. Interaction: Communication or interpersonal contact between investigator and subject.
    17.3. 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, 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).
    17.4. Identifiable Private Information: Information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
    17.5. Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.
18. 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 a medical device is used.
19. Immediate Family: Spouse, domestic partner; and dependent children.
20. Institutional Official: Vice Chancellor for Research.
21. Management Plan: the written plan for the management, reduction or elimination of a potential or actual conflict of interest.
22. Minimal Risk: The probability and magnitude of harm or discomfort 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[2].
    22.1. 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.

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[1] The terms "Human Subject Research," "Research Involving Human Subjects," "Human Subject Research," "Research Involving Human Subjects," "Clinical Research," "Clinical Investigation," "Clinical Study" and similar phrases are considered to be synonyms for the term Human Research.

[2] The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include the inherent risks 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).

23. Minor Deviations: A change to, or non-compliance with, the research protocol that does not pose a risk of harm to the subject's rights, safety or welfare, or to the integrity of the research data. Minor Deviations may result from the action or inaction of the participant, researcher, or research staff.
24. Non-Committee Review: Any of the following:
    24.1. Reviews of non-exempt research using the expedited procedure.
    24.2. Determinations of which subjects can continue in expired research.
25. 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.
    25.1. 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 Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements.
26. 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.
    26.1. For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody
27. Related: A financial interest is Related to the research when the interest is in:
    27.1. A sponsor of the research; or
    27.2. A product or service being tested.
28. Reliance Agreement: A legal agreement whereby an Institution external to UC Davis agrees to rely on the determinations of the UC Davis IRB, UC Davis agrees to rely on the determinations of an IRB external to UC Davis, or the UC Davis IRB agrees to serve as the IRB of record for an investigator not affiliated with UC Davis. May also be referred to as an IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA).
29. Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
30. 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:
    30.1. 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;
    30.2. 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
    30.3. 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.
31. Research or Experimentation Program or Project as Defined by Department of Education: Any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
32. Restricted: Applies to investigators who are delinquent in meeting IRB requirements.
33. Serious Non-Compliance: Non-compliance that adversely affects the rights or welfare of participants. For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 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.

34. 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.
35. 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.
36. Unanticipated Problem Involving Risks to Subjects or Others: An incident, experience, or outcome that meets all of the following criteria:
    - 36.1. 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;
    - 36.2. Related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
    - 36.3. 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

1. 45 CFR §46.102.
2. 45 CFR §46.114.
3. 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR§812.3(p