

UC San Diego

**INSTITUTIONAL REVIEW
BOARD ADMINISTRATION**

IRB Handbook

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Table of Acronyms

AE	Adverse event
ACQUIRE	Aligning and Coordinating Quality Improvement, Research and Evaluation
BOP	Bureau of Prisons
CAL/OSHA	California Division of Occupational Health and Safety
CRF	Case report form
COC	Certificate of confidentiality
CFR	Code of Federal Regulations
CO-I	Co-investigator
CITI	Collaborative Institutional Training Initiative
COI	Conflict of interest
CSUA	Controlled substance use authorization
CAPA	Corrective and preventive action plan
DOD	Department of Defense
DODI	Department of Defense instruction
ED	Department of Education
DOE	Department of Energy
DHHS	Department of Health and Human Services
DOJ	Department of Justice
DEA	Drug Enforcement Administration
DURC	Dual use research of concern
EH&S	Environment Health and Safety
EPA	Environmental Protection Agency
E-QUAL	Evidence Based Practice - Quality Improvement
FERPA	Family Educational Rights and Privacy Act
FDA	Food and Drug Administration
FCOI	Financial conflict of interest
FDCA	Food Drug and Cosmetic Act
GCP	Good clinical practice
GMP	Good manufacturing practice
HIPAA	Health Insurance Portability and Accountability Act
HERC	Human Exposure Review Committee
HRPP	Human Research Protection Program
HDE	Humanitarian Device Exemption
HUD	Humanitarian Use Device
IEO	Incident, Exposure or Outcome
IRC	Independent review committee
IIA	Individual investigator agreement

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ICF	Informed consent form				
ICH-GCP	International Council for Harmonisation-Good Clinical Practice				
IBC	Institutional biosafety committee				
IRB	Institutional review board				
IAA	IRB authorization agreement				
IRE	Institutional review entity				
IDE	Investigational device exemption				
IDS	Investigational drug service				
IND	Investigational new drug				
KBA	Knowledge base article				
LAR	Legally authorized representative				
NCATS	National Center for Advancing Translational Sciences				
NIH	National Institutes of Health				
NIJ	National Institute of Justice				
NTF	Note to file				
NHSR	Not human subjects research				
OCTA	Office of Clinical Trials Administration				
OCGA	Office of Contract and Grant Administration				
OCCA	Office of Coverage Analysis Administration				
OIA	Office of IRB Administration				
ORI	Office of Research and Innovation				
PPM	Policy and procedure manual				
PI	Principal investigator				
PHI	Protected health information				
PPRA	Protection of Pupil Rights Amendment				
PRMS	Protocol Review and Monitoring System				
QI/QA	Quality Improvement/Quality Assurance				
RSC	Radiation Safety Committee				
RDRC	Radioactive Drug Research Committee				
RCHSD	Rady Children's Hospital, San Diego				
RCI	Research Compliance and Integrity				
RPAC	Research Policy Analysis and Coordination				
SAE	Serious adverse event				
sIRB	Single IRB				
SCRO	Stem cell research oversight				
UCOP	University of California Office of the President				
UCSD	University of California, San Diego				
UCSDH	University of California, San Diego Health				
UCSDHP	University of California, San Diego Health Policies				
UPR	Unanticipated problem report/unanticipated problem involving risks to subjects or others				

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Scope

Throughout this document “institution” refers to University of California, San Diego (UCSD).

What is the purpose of this handbook?

This document, *OIA-103: IRB Handbook*, has been created to guide you, the researcher, through institution-specific policies and procedures related to conducting human subjects research, and contains double-underlined commonly-used research terms that are defined in [OIA-001 SOP: Definitions](#). This document discusses the practical aspects of working with the UCSD IRB and the institution’s human research protection program (HRPP) and is not meant to repeat, or substitute for, required training.

Additional information regarding human subjects research protection and relevant federal regulations and guidance is incorporated into required human subjects research protection training. For additional details about training, see [“What training do my staff and I need to conduct human subjects research?”](#) Other [relevant resources](#) should also be consulted depending on the scope and nature of the project.

Navigating through varied and complex research regulatory and administrative requirements takes time and skill, and the [Office of IRB Administration \(OIA\) staff](#) and [IRB website](#) are available to assist you as you prepare for and conduct your human subjects research.

What is human subjects research?

The [UCSD Policy and Procedure Manual \(PPM\) 100-5](#) defines the activities that this institution considers to be “human subjects research.” A decision tree for determining whether an activity is human subjects research can be found in the “[Choosing the Right Application](#)” [Kuali IRB](#) electronic submission system Knowledge Base Article (KBA) located in the [submissions section](#) of the [KBAs](#). Use this document or the [Kuali IRB self-help tool](#) for guidance as to whether an activity meets either the Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA) definition of human subjects research. Keep in mind that the IRB makes the final determination in ambiguous circumstances as to whether an activity constitutes human subjects research and is, therefore, subject to IRB oversight. When you independently determine that research is “not human subjects research,” best practice is to document this with rationale as a note to file (NTF) in the study records, which are subject to audit.

You are responsible for obtaining IRB review and approval, or an institutional determination that the human subjects research is exempt, **prior to** conducting any human subjects research. If you are unsure about whether an activity is human subjects research, [contact the OIA](#). If you wish to obtain a determination letter from the IRB, complete an [application for administrative determination or registration](#) through [Kuali IRB](#).

What is the human research protection program (HRPP)?

The HRPP is a comprehensive system focused on protection of the rights, safety and well-being of human subjects who participate in research. The OIA is but one aspect of human subjects protection, and the overall HRPP encompasses:

- The mission of the HRPP at UCSD.
- The ethical principles that the institution follows governing the conduct of human subjects research.
- The applicable laws that govern human subjects research.
- When the institution becomes “engaged in human subjects research” and when someone is acting as an agent of the institution conducting human subjects research.
- The types of human subjects research that may not be conducted.
- The roles and responsibilities of individuals within the institution including the:

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- Institutional official for protection of human subjects
- Institutional Review Boards (IRBs)
- Researchers (and any staff, students, or other individuals working under their direction)
- Department chairs
- OIA

All of the above have a shared commitment and responsibility to protect the rights and welfare of research subjects and together constitute the UCSD HRPP.

See [OIA General Guidance](#) for more information about OIA's part in the HRPP.

Who is eligible to be a principal investigator (PI)?

This institution generally applies [UCSD PPM 150-10](#) to all human subjects research. The IRB has determined that in addition to those allowed to serve as PI by [UCSD PPM 150-10](#), all staff and faculty of the institution may serve as PI for the purposes of overseeing human subjects research subject to IRB oversight. Trainees, including but not limited to, undergraduate students, graduate students, residents, and fellows, are not eligible to serve as PI. [UCSD PPM 150-10](#) describes how to request an exception to the policy. Unless granted an exception to policy [UCSD PPM 150-10](#) through the [Office of Research and Innovation \(ORI\) exception process](#), a trainee must secure a PI-eligible faculty or staff member to serve as PI on the study. This requirement does not restrict the trainee from publishing or presenting their work and is only intended to ensure that there is appropriate supervisory and regulatory oversight for the study.

May I include study personnel, who are not faculty members, students, employees, or volunteers of UCSD and/or Rady Children's Hospital San Diego (RCHSD), on my research?


If you wish to include study personnel who are not UCSD and/or RCHSD faculty members, students, employees, or volunteers, you must [contact the OIA](#) in writing to establish a reliance agreement before the external study personnel will be allowed to engage in human subjects research activities. (See section below "[What is an IRB reliance/reliance agreement?](#)")

Even with a reliance agreement in place, study personnel who are not UCSD/RCHSD faculty members, students, employees, or volunteers will not be granted a [Kuali IRB](#) system login and cannot be listed on the study personnel list in [Kuali IRB](#).

See [IRB Reliance \(Single IRB Review\)](#) for more information.

What training do my staff and I need to conduct human subjects research?

To meet IRB training requirements, you and study personnel are required to complete human subjects research protection training prior to engaging in human subjects research. You and study personnel should complete training before submitting a new study application for IRB review. Whenever study personnel are added to an active research project, the new personnel should complete training prior to engaging in research activities, including access to and analysis of identifiable private information. You are responsible for ensuring all study personnel working on your study are added to the study in [Kuali IRB](#) and have completed necessary training before they engage in research activities. The following study personnel must complete training:

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- PI and co-investigators (Co-I)
- Research personnel listed on the study personnel list, including study personnel who:
 - obtain informed consent from research participants,
 - are key personnel, who otherwise interact or intervene with human subjects or their identifiable data, and/or
 - are named as a contact person in the informed consent and/or recruitment materials for research.

Basic Human Subjects Research Protection Training

You and study personnel involved in human subjects research, regardless of the risk level, may complete one of the following [Collaborative Institutional Training Initiative \(CITI\)](#) courses, as applicable to the type of research, to meet the basic human subjects research protection training requirement:

- CITI basic course for Biomedical Research; or
- CITI basic course for Social and Behavioral Research.

OIA staff have access to UCSD personnel training records on the CITI website so it is not necessary for you to upload CITI training certificates into [Kuali IRB](#).

Training Certification Period

Training completed through [CITI](#) is valid for a three-year period. You and your study personnel are responsible for maintaining current training certification. Training may be renewed before the expiration date by taking either a refresher course or by retaking the full course. You or members of the research team who have not completed human subjects research protection training, or whose current training has expired, may not take part in any aspects of the research that involve human subjects or subjects' identifiable private information, including identifiable biospecimens. OIA staff assess whether you meet applicable training requirements when reviewing applications for initial and continuing review. You are required to monitor training for all research staff and attest that required training is complete and current when completing applications for initial review, continuing review, and research amendments. **You and research staff whose required training is not current must cease all human subjects research activities until the training requirement is met.**

Acceptance of Training Taken at Other Institutions

The UCSD OIA cannot accept training taken in affiliation with other institutions, regardless of the platform used to complete the training [e.g., CITI, National Institutes of Health (NIH), etc.]. When CITI is used to satisfy the training requirement, the completion certification must indicate affiliation with "University of California, San Diego" to be considered acceptable.

Other Training Requirements

Federal, state, university and funding entity/sponsor policies may impose additional training requirements. You must consider and meet any additional study-related training requirements.

What financial interests do my staff and I need to disclose to conduct human subjects research?

All researchers responsible for the design, conduct or reporting of human subjects research must submit required conflict of interest (COI) disclosures to the institution via the [Kuali COI](#) system. These

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disclosures are required at the time of initial study review, and any updates must be submitted via an amendment in [Kuali COI](#) if a conflict arises or changes during the study. More information about disclosure requirements can be found on the COI Office's [webpage](#). The IRB will review the outcomes of the [COI](#) independent review committee (IRC) review in accordance with [OIA-055 SOP: Financial Conflicts of Interest](#), which may result in changes or added language to the consent document and/or the [Kuali IRB](#) application.

How do I submit new human subjects research to the UCSD IRB?

The UCSD IRB uses an electronic protocol submission system called [Kuali IRB](#), which provides the research community with electronic protocol management, online submissions, and a suite of tools for researchers and OIA staff. [Kuali IRB](#) is hosted at a secure, enterprise-class data center that supports and meets the requirements of federal regulations.¹ To submit a new study for review, complete the electronic application for a new protocol and upload all requested supplemental documents. Instructions for completing a new study application can be found in this KBA "[Steps to Submitting a New Application](#)." Templates for protocols, consent forms, and assent forms can be found on the OIA's [Forms, Templates and Instructions](#) webpage.

What is an IRB reliance/reliance agreement?

IRB reliance means that an IRB from one institution agrees to accept or "rely on" IRB review and approval from another IRB. A [reliance agreement](#) is a formal written agreement outlining the roles and responsibilities of the reviewing IRB and the relying institution/investigator. A [reliance agreement](#) is required whenever an external institution relies on the UCSD IRB for review of [human subjects research](#) and/or when an external IRB reviews [human subjects research](#) as the IRB of record for an investigator covered by the UCSD IRB.

The agreement may be in the form of an Individual Investigator Agreement (IIA) or an IRB Authorization Agreement (IAA). UCSD has multiple agreements in place, including the UC Reliance Registry, the [National Center for Advancing Translational Sciences \(NCATS\) SmartIRB](#) agreement, and master agreements with the [Western-IRB Copernicus Group](#) (WCG) IRB and [Advarra IRB](#). If you are planning to participate in collaborative or multi-site [research](#), and believe an IAA may be required, contact irbrel@ucsd.edu to see if an agreement is already in place. If no agreement is in place, OIA reliance team will work with you and the participating institution(s) to obtain the required agreement(s).

Investigators and research staff are not authorized to sign IRB [reliance agreements](#) themselves. Each agreement must be signed by the [institutional official](#) (or designee) of the relying and reviewing sites. If you receive an authorization agreement from an external institution, forward it to irbrel@ucsd.edu. OIA will determine whether the reliance will be permissible and will work with the external institution to complete the agreement. For more information, contact the UCSD IRB reliance team at irbrel@ucsd.edu.

Will the UCSD IRB review research on behalf of another institution or investigator?

¹ [FDA Guidance: Part 11, Electronic Records; Electronic Signatures – Scope and Application](#)

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The UCSD IRB will review research on behalf of another institution when all requirements for the review are met. One important requirement, as described above, is an executed reliance agreement between the external institution and UCSD/RCHSD. Other requirements for UCSD's IRB to review a study on behalf of an external institution are described in [OIA-059 SOP: UCSD Serving as the IRB of Record](#).

Many federal funding agencies and departments require institutions to use single IRB (sIRB) review to review all domestic sites participating in a multisite study. The UCSD IRB will act as an sIRB for these studies upon request. However, submitting multisite studies for IRB review requires planning and coordination, and the costs associated with UCSD's IRB review of external sites must be included in the project budget.

Federal regulations do not require that sIRB review be conducted for international sites engaged in human subjects research. As such and given the complexities of international laws, the UCSD IRB will generally decline to serve as the IRB of record for international sites.

Please contact the UCSD IRB reliance team at irbrely@ucsd.edu as early in the planning process as possible if you plan to be the lead PI for a multi-site study and would like the UCSD IRB to act as the sIRB for the study.

See [IRB Reliance \(Single IRB Review\)](#) webpage for more information.

Will the UCSD IRB rely on an external IRB for review of research conducted by UCSD and/or RCHSD faculty or staff?

The UCSD IRB will rely on an external IRB when all requirements are met. A reliance agreement, as described above, must be in place between the reviewing IRB and the UCSD IRB. For information about additional requirements, refer to [OIA-058 SOP: UCSD Relying on an External IRB](#). Additional information can be found in checklists [OIA-442 CHECKLIST: External IRB Review Clearance](#) and [OIA-443 CHECKLIST: External IRB Review Acceptance](#).

You must complete a two-step process when a study is to be reviewed by an external IRB.

The first step you must complete to receive clearance is to submit an "[administrative determination or registration](#)" review application through [Kuali IRB](#) to "request to rely on external IRB." Instructions for completing such an application can be found in the KBA "[Submitting for Administrative Determinations](#)".

The administrative review application will be reviewed by the reliance team. Note that this review is not a duplicate IRB review, but rather is an administrative review of the UCSD application to ensure that UCSD local context will be considered as part of the external IRB's review of UCSD as a participating site and confirm that reliance agreements have been completed, as appropriate. The **clearance** notification is issued by UCSD IRB through the "revisions required" function in [Kuali IRB](#). After the clearance notification has been sent to the research team, the project is considered to be "cleared" by UCSD IRB for submission to the external IRB, and you may proceed with the external IRB-required submission process.

Once approval from the external IRB is obtained, you will complete step two, submitting the study for acceptance in [Kuali IRB](#). To submit the study for acceptance, respond to the clearance notification "revisions required" notice in [Kuali IRB](#) and upload additional documents, including the external IRB approval letter and other relevant documents, such as approved (stamped) consent forms and recruitment materials, as applicable. Instructions for completing this step of the external reliance process can be found in the KBA "[Submitting for Reliance Acceptance](#)".

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The reliance team will review all documents administratively and issue the acceptance letter via [Kuali IRB](#). The IRB process to allow research activities to commence at UCSD is only complete once the UCSD IRB has issued the acceptance letter for the study. See [IRB Reliance \(Single IRB Review\)](#) for more information.

Even though the IRB review and approval comes from the external IRB, you remain responsible for meeting other UCSD requirements to conduct the research. This includes obtaining and maintaining all required ancillary committee reviews/approvals, including, but not limited to, [Radiation Safety Committee \(RSC\)](#); [Human Exposure Review Committee \(HERC\)](#); [Institutional Biosafety Committee \(IBC\)](#); [Radioactive Drug Research Committee \(RDRC\)](#); [Environment, Health & Safety \(EH&S\)](#); and [COI IRC](#), if applicable.

During the conduct of the research, you must comply with the external IRB's requirements for submissions and for reporting non-compliance and unanticipated problems involving risks to subjects or others/unanticipated problem report (UPR). You must obtain information about, and plan for, the external IRB's requirements before starting the study.

How do I write an investigator protocol?

The IRB [Forms, Templates & Instructions page](#) includes multiple protocol template versions. You should select the protocol that is best suited to your proposed study design.

Some key points to remember when developing a protocol include:

- Delete all instructional text from templates prior to submission.
- Certain sections of the template may not be applicable to your project. Please mark inapplicable sections with "N/A."
- Keep an electronic copy of the study protocol. The OIA recommends that you date the protocol version so that subsequent modifications can be easily tracked and submitted to the IRB.
- You may not include any individuals from the following populations as subjects in human subjects research involving an interaction and/or intervention with subjects unless you indicate in your application that these populations will be included. For human subjects research that does not involve an interaction and/or intervention with subjects, the following populations may be incidentally included in the human subjects research as long as the research does not specifically target these populations for inclusion in the research and the research will not collect information about an individual's status as a member of one of these populations.
 - Adults who lack the capacity to provide legally effective consent
 - Individuals who are not yet adults (infants, children, teenagers)
 - Pregnant subjects
 - Prisoners
 - Students/Staff/Subordinates of key personnel
- When a study is an investigator-initiated clinical trial,² you will be required to submit an NIH-style protocol.³ To aid you in creating such a protocol, we provide an interventional protocol template at the link above.

² NIH's Definition of a Clinical Trial | [grants.nih.gov](https://grants.nih.gov/grants.nih.gov)

³ <https://grants.nih.gov/policy/clinical-trials/protocol-template.htm>

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How do I create a consent document?

The IRB [Forms, Templates & Instructions page](#) has current consent templates.

These templates have been developed to incorporate all of the required and additional appropriate elements of informed consent, as required by regulations.^{4,5} Review the IRB's [OIA-314B WORKSHEET: Requirements for Informed Consent](#), to ensure that all required elements of consent are addressed in your consent form. When you are developing or revising your consent form, OIA recommends that you date the revisions of your consent documents to ensure that you are able to easily identify and use the most recent version of the form approved by the IRB. Once the study is approved, you must use the current IRB-approved consent form and follow the consent process you describe in your IRB-approved application when you consent subjects for your study.

In the case that you do not want to include some of the required or additional elements of consent that apply to the study in the study consent form, the IRB does have the authority to alter or waive the requirements for informed consent provided the criteria in [OIA-410 CHECKLIST: Waiver or Alteration of the Consent Process](#) are met. You will need to describe in the [Kuali IRB](#) application why the waiver or alteration is necessary in order to be able to conduct the study.

Short form consent form consent and documentation may be permitted at the study level for all subjects, though this is expected to be rare, or in circumstances in which a potential non-English speaking participant is identified and there is no translated informed consent form available.⁶ The short form consent form is available in several languages on the [Forms, Templates & Instructions page](#). When using the short form consent form for consent documentation, there must be an impartial witness to the oral consent presentation to the study participant. If the subject is a non-English speaker, a qualified interpreter who is fluent in English and the participant's preferred language must be present. The appropriate signature block(s) should be completed on the short form consent form and the summary according to [OIA-091 SOP: Written Documentation of Consent](#).

The short form consent form is generally expected to be used for occasional and unexpected enrollment of non-English speaking participants. If study enrollment will be open to non-English speaking subjects but they are not specifically targeted, use of a short form consent process must be indicated in the [Kuali IRB](#) application and approved by the IRB. When this occurs, if the study is greater than minimal risk and/or the study has multiple study visits/interactions, the long form consent form must be translated into the language spoken by the subject and the subject reconsented with the translated long form consent form. When submitting the translated long form consent form to the IRB for approval, you must indicate when subjects who consented with the short form consent form will be reconsented. As a best practice, the IRB recommends that reconsent occur within 30 days of the initial consent.

If your research study meets the requirements for an [exemption](#), you may use an abbreviated process for obtaining consent. A template exempt information sheet is available on the [Forms, Templates & Instructions page](#). The template exempt information sheet contains all of the required elements below. Consent can be verbal, but you must provide the following information to participants through an information sheet or written script:

⁴ [45 CFR 46.116](#)

⁵ [21 CFR 50 Subpart-B](#)

⁶ [21 CFR 50.27](#)

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- A statement that the subject is being asked to participate in a research study;
- A description of the procedure(s) the participant will be asked to complete;
- A statement that participation is voluntary;
- The investigator's name and contact information;
- For NIH-funded research, a statement that the study is covered by a certificate of confidentiality (CoC);⁷ and
- For research conducted outside of the United States, disclosure of any additional risks due to local context.

Screening scripts may be used for some studies where basic information to assess an individual's eligibility for the study can be determined as a part of the IRB-approved screening and consent process. Such scripts are often written in a more conversational manner and the general elements to be included in the script should identify the purpose of the screening procedure, what information individuals will be asked to provide, privacy/confidentiality of the provided information, and indicate that participation in the screening process is voluntary. If screening scripts are to be employed for a specific study, they must be approved by the IRB.

Consent forms are reviewed by the IRB and once approved, are stamped with an approval date.

What are the different levels of IRB review?

Research activities submitted to the IRB may fall under one of the following classifications:

- Administrative Review
 - Not human subjects research (NHSR): Activities must meet the institutional definition of human subjects research to fall under IRB oversight. The definitions of human subject and human subjects research are provided in [UCSD PPM 100-5](#) and in [OIA-001 SOP: Definitions](#). Activities that do not meet the criteria for human subjects research are not subject to IRB oversight or review. Review the [OIA-310 WORKSHEET: Human Research Determination](#), consult the [OIA website](#), or review "[What is human subjects research?](#)" above, for more details. Some common examples of activities that would be considered not human subjects research are: analysis of a de-identified dataset where the identity of the individuals cannot readily be ascertained and re-identification will not be attempted, study design, writing up a paper based on aggregate de-identified results from a colleague, case studies of 3 or fewer patients, etc.
 - Not engaged: Your project may be human subjects research but in certain circumstances, the institution is not considered to be "engaged" in research. If you are uncertain whether UCSD is engaged in research, [contact the OIA](#). See [OIA-311 WORKSHEET: Engagement Determination](#) for more information. A common example of such an activity would be releasing data or specimens from UCSD to a researcher at another institution to carry out their own research.
 - Exempt: Certain categories of human subjects research may be exempt from regulations. Exempt research is human subjects research that meets certain criteria for exemption from the Common Rule regulations when the procedures to be employed meet the criteria at [45 CFR 46.104](#). It is the institution's responsibility, via OIA, rather than the investigator's, to determine whether human subjects research is exempt from IRB review. Review the [OIA-312 WORKSHEET: Exemption Determination](#) or the [OIA website](#) for information on the categories of research that may be exempt. Common examples of

⁷ [42 USC 241\(d\)](#)

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exempt studies include: survey based research, interview/focus group based research, medical record reviews when not federally funded, etc.

- Review using the expedited procedure: Certain categories of non-exempt human subjects research may qualify for review using the expedited procedure, meaning that the project may be approved by an IRB designated reviewer, rather than the convened board. Review the [OIA-313 WORKSHEET: Eligibility For Review Using the Expedited Procedure](#) for reference on the categories of research that may be reviewed using the expedited procedure. Common examples of expedited studies include: blood draws totaling less than 50 ml which occur 2 times a week or less, non-invasive data/specimen collection procedures, etc.
- Review by the convened IRB: Non-exempt human subjects research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB. Common examples include: clinical trials of investigational drugs and devices, blood draw studies exceeding the volume or frequency thresholds, invasive procedures, procedures utilizing ionizing radiation, etc.

What are the decisions (determinations) the IRB can make when reviewing proposed research?

The IRB may approve research, approve research pending modifications to the research to secure approval, defer research, table research, or disapprove research:

- Approval: Made when all criteria for approval are met. See ["How does the IRB decide whether to approve human subjects research?"](#) below.
- Approve pending modifications: Made when IRB members require specific modifications to the research before approval can be finalized.
- Deferred: Made when the IRB determines that the board is unable to approve the research and the IRB suggests modifications that might make the research approvable or requests more information or clarification to understand whether the research is approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, describes any outstanding questions or requested clarifications, and gives you an opportunity to respond to the IRB in person or in writing.
- Tabled: Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When the IRB tables the research, the study is automatically scheduled for review at the next IRB meeting with available and adequate expertise, as determined by the OIA staff.
- Disapproval: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives you an opportunity to respond to the IRB in person or in writing, as determined by the IRB.

See ["How Will I Learn the Outcome of the IRB review?"](#) and the OIA [Submission FAQs](#) for more information.

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How does the IRB decide whether to approve human subjects research?

The IRB is required to follow regulatory criteria^{8,9} in making a decision about whether research can be approved. In addition, the IRB will also follow extra-regulatory criteria derived from the three [Belmont Report](#) principles of beneficence, justice, and respect for persons. Relevant criteria for IRB approval of non-exempt human subjects research can be found in the [OIA-314 WORKSHEET: Criteria For Approval And Additional Considerations](#). This worksheet refers to other checklists that might also be relevant. All checklists and worksheets can be found on the [OIA website](#). These checklists are used for initial review, continuing review, and review of modifications (amendments) to previously approved human subjects research.

You are encouraged to use the checklists to write your investigator protocol in a way that addresses the criteria for approval. Please do not include the checklists in your application.

See [OIA's Guidance Page](#) for more information.

How will I learn the outcome of the IRB review?

The IRB will provide you with a notification indicating one of the following determinations:

- the submission is not human subjects research (NHSR)
 - If your submission is NHSR, you may start the research when all other required institutional approvals have been obtained.
- the submission is human subjects research – not engaged
 - If your submission is human subjects research – not engaged, you may start the research when all other required institutional approvals have been obtained.
- the research is exempt from the requirement for IRB review
 - If your protocol is exempt, you may start the research when all other required institutional approvals have been obtained.
- the IRB-approved the human subjects research
 - If your protocol is approved, you may start the research when all other required institutional approvals have been obtained.
- the IRB-approved the human subjects research pending additional modifications
 - If a protocol is not fully approved and the IRB **requires modifications** to secure approval, you will receive notification of this determination with details of the requested modifications. If you accept the modifications, you must make the requested modifications and submit them to the IRB through [Kuali IRB](#). Any revised documents must be submitted in both a tracked changes and clean version. Upon submission of the modifications, the IRB will review the application and if all requested modifications are made, the IRB will issue a final approval. If you do not accept the modifications, you must develop responses to each of the modifications requested addressing the rationale for not making the requested modification and submit your responses to the IRB through [Kuali IRB](#). If appropriate, this response can also include alternative modifications which intend to address the concern(s) of the IRB. The responses will be placed on the next available agenda for review by a convened IRB. In either case, research cannot

⁸ [21 CFR 56.111](#)

⁹ [45 CFR 46.111](#)

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commence until the final approval letter is received through [Kuali IRB](#) and all other required institutional approvals have been obtained.

- the IRB deferred the human subjects research
 - If the IRB **defers** the human subjects research, the notification of this determination will include the reasons for deferral, suggestions to make the study approvable, and any questions or requests for clarification from the IRB. The notification will give you an opportunity to respond and you will need to address each individual suggestion, question, and request for clarification separately, and submit the responses to the IRB in [Kuali IRB](#). Any revised documents must be submitted in both a tracked changes and clean version. The responses will be placed on the next available agenda for review by a convened IRB with appropriate and available expertise. Generally, this will be the same committee that reviewed the previous submission. In most cases, if the IRB's reasons for the deferral are addressed in the modifications, the human subjects research can be approved.
- the IRB disapproved the human subjects research
 - If the IRB **disapproves** the human subjects research, the notification of this determination will include a statement of the reasons for disapproval and will give you an opportunity to respond.

In all cases, you have the right to appeal any IRB decision in writing. Depending on the circumstances, the IRB may invite you to present at a convened IRB meeting.

Will IRB approval expire?

If you receive a notification that the protocol is NHSR, not engaged, or exempt, the project will not expire.

IRB approval of most minimal risk research reviewed using the expedited procedure does not expire. Notable exceptions include research which is FDA-regulated or federally funded and cannot be initially reviewed through the expedited process. IRB approval of greater than minimal risk research and some minimal risk research that is federally funded and initially approved before January 19, 2019 will be given an expiration date. If the research goes through expedited or full IRB review, you will receive a notification when the research is approved and an approval letter will be published in [Kuali IRB](#). The approval letter and [Kuali IRB](#) will state if IRB approval of the research will expire and state the expiration date. This approval period, whose end is the expiration date, is based on multiple considerations, including the risk of the research.

Research that is greater than minimal risk will usually be granted a one-year approval; however, in some instances, these studies may receive an approval term that is less than one year.

At least 30 days before the IRB approval expiration date, you must submit an application to the IRB requesting either continuing review or study closure. See "[How do I submit a continuing review?](#)" section below for the requirements for continuing review and study closure.

What are my obligations after IRB approval?

- 1) As the principal investigator, you are ultimately responsible for the conduct of the study. Even though you may delegate authority to members of your research team to perform tasks under your supervision, you remain responsible for ensuring the study is conducted in a compliant manner.
- 2) Do not start human subjects research activities until you receive the final IRB approval letter.
- 3) Do not start human subjects research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources or oversight. See "[What other internal reviews are also](#)

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[involved in the protection of human subjects?](#) for information about other entities whose approval you may need prior to starting your research.

- 4) Ensure that there are adequate resources to carry out the research in a safe and compliant way. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- 5) 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.
- 6) Obtain verbal or written agreement from each member of the research staff that they understand and will perform their role and responsibilities in carrying out the research.
- 7) Update the [Kuali IRB](#) application with any changes in study personnel.
- 8) Personally conduct or supervise the human subjects research.
 - a) Conduct the human subjects research in accordance with the current IRB-approved protocol and study application.
 - b) When required by the IRB, ensure that consent is obtained in accordance with the current IRB-approved protocol and study application.
 - c) Protect the rights, safety, and welfare of human subjects involved in the research.
 - d) Ensure that adequate and accurate research records are maintained, including, but not limited to, records of IRB correspondence (submissions, approval letters), consent form versions, protocols, reports, and other relevant documents. You must ensure these records are maintained independently outside [Kuali IRB](#), which is not intended as a document repository for investigator required records.
- 9) Report changes in funding as soon as you receive notification of an award.
- 10) Do not make any modifications to approved research without first obtaining prior approval from the IRB, unless the modification is necessary to protect participants from imminent harm, or the modification qualifies as an administrative modification. To request approval of a modification, see [“How do I submit a modification?”](#)
- 11) Respond promptly to notifications from the IRB.
- 12) When required, submit a continuing review application to the IRB. The expiration date for your research is stated in the approval letter. See [“How do I submit a continuing review?”](#) for instructions for submitting a continuing review report.
- 13) Complete a closure form when the human subjects research is completed. See [“How do I close out a study?”](#) for more information.
- 14) Report to the IRB any of the reportable events listed in [Appendix A](#) within the reporting timeline as outlined in that appendix.
 - a) The IRB will review your report to determine if the reportable event meets the definition of serious non-compliance, continuing non-compliance or an unanticipated problem involving risks to subjects or others, commonly called an unanticipated problem report (UPR), as listed in [OIA-001 SOP: Definitions](#).
 - b) Examples of UPRs include:
 - i) internal¹⁰ adverse events that are unexpected, involve new or increased risks, and are related to the research,
 - ii) other unanticipated information, other than adverse events, that is related to the research and may put participants or others at increased risk of harm.
- 15) Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees”).
- 16) Do not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”).
- 17) See additional requirements of various federal agencies in Appendix B. These represent additional requirements and do not supersede any of the obligations in this section.

¹⁰ In this context, “internal” refers to adverse events that occur with subjects enrolled by a site under the UCSD IRB’s jurisdiction.

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18) If you meet the definition of a sponsor-investigator¹¹ in your study, meaning you are the “holder” of the Investigational New Drug (IND) or Investigational Device Exemption (IDE), you must fulfill the obligations of both the sponsor and investigator as defined by FDA regulations. See [Appendix B-2](#).

How do I obtain and document informed consent and assent?

Informed consent is an essential safeguard to ensure ethical research. The informed consent process encompasses initial contact with the participant and spans the entire study, so it involves much more than obtaining the participant’s signature on a consent form. OIA considers advertisements and recruitment activities, including pre-consent study conversations with research participants, to be part of the informed consent process. You are obligated to confirm the participant’s ongoing consent to research interventions and interactions and to keep the participant informed of any changes that might affect their willingness to continue to participate in research (e.g. changes to procedures or risks). For detailed procedures, review [OIA-090 SOP: Informed Consent Process for Research](#), and [OIA-091 SOP: Written Documentation of Consent](#).

In addition to the consent documentation requirements stated in [OIA-091 SOP: Written Documentation of Consent](#), the following are some additional considerations for working with consent documents:

Long form consent forms:

- Always use the current, stamped consent form as approved by the IRB. The final signed version of the IRB-approved consent document should not be altered in any way (e.g., directional marks for participant/legally authorized representative signatures, highlighting, or comments).
- Complete all items in the signature block, including dates and applicable checklists or checkboxes. The subject or legally authorized representative and the individual obtaining consent sign and date the consent document.¹²
- When required by the IRB or sponsor, the subject’s or legally authorized representative’s signature and date on the consent document are to be witnessed by an impartial individual who signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the subject.
- Best practices in human subjects research specify that in addition to following these procedures, details of the consent/assent conversation should be documented in the subject’s study file. UCSDH requires that if the subject is participating in a study involving an investigational device, therapeutic, or involving a billable moment, a copy of the signed and dated consent/assent form must be placed in the subject’s medical record in accordance with [UCSDHP 340.1](#) (UCSDH Pulse Page). If the subject does not have a medical record, a medical record must be created for the subject in accordance with [UCSDHP 300.2](#) (UCSDH Pulse Page).

Short form consent forms:

- Refer to [OIA-091 SOP: Written Documentation of Consent](#) for additional information on compliant use of the short form consent form method of consent documentation.
- The subject or legally authorized representative signs and dates the short form consent form.
- The individual obtaining consent signs and dates the summary.¹³
- The impartial witness to the oral presentation signs and dates the short form consent form and the summary.
- Copies of the signed and dated consent document and summary are provided to the subject or legally authorized representative.

¹¹ [21 CFR 312.3](#), [21 CFR 312.22](#), [21 CFR 312 Subpart D](#), [21 CFR 812.3](#), [21 CFR 812 Subpart C](#), [21 CFR 812 Subpart E](#)

¹² Parties to the consent, including the participant/legally authorized representative; person obtaining consent; and witness, if applicable, should personally sign and date the document(s) at the time the consent is executed.

¹³ The written summary may be a separately approved summary or the approved consent document in English.

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- If the study is a medical experiment¹⁴ under California law, a copy of the experimental research participant's bill of rights must be provided to the subject or legally authorized representative.
- Best practices in human subjects research specify that in addition to following these procedures, details of the consent/assent conversation should be documented in the subject's study file. UCSDH requires that if the subject is participating in a study involving an investigational device, therapeutic, or involving a billable moment, a copy of the signed and dated consent/assent form must be placed in the subject's medical record in accordance with [UCSDHP 340.1](#) (UCSDH Pulse intranet page). If the subject does not have a medical record, a medical record must be created for the subject in accordance with [UCSDHP 300.2](#) (UCSDH Pulse intranet page).

Assent forms:

The IRB may require assent from children or adults who are unable to consent for themselves, but who are able to express assent or dissent. Template assent forms can be found on the OIA [Forms, Templates & Instructions](#) web page. Follow [OIA-092 SOP: Assent Process for Research](#) and [OIA-093 SOP: Written Documentation of Assent](#), if your study requires assent. University of California Office of the President's (UCOP) Research Policy Analysis & Coordination (RPAC) has issued [RPAC-21-01 Surrogate Consent for Research - guidance](#) on fulfilling California requirements for determining capacity, obtaining, and documenting surrogate consent.

Electronic consent process:

Institutionally approved, IRB accepted technologies (e.g. REDCap, DocuSign, etc.) must be used for the capture of electronic signatures. For FDA-regulated studies, such technologies must be [21 CFR Part 11 \("Part 11"\)](#) compliant. For studies subject to HIPAA provisions, such technologies must be HIPAA compliant. See [Research Data and IT Services](#) for current allowable technologies.

When consent will be obtained electronically, any long form consent form to be used must contain the IRB's approved electronic consent language regarding subject's rights when providing consent electronically.

Reconsent:

You are required to provide to subjects information that may affect their willingness to continue participation in the study for the duration of their participation in the study. When submitting new information (e.g. reportable events) or amendments to the study, you should consider and propose a reconsenting plan for the study. Depending on the nature of information reported to the IRB about a study, or changes proposed to a study, the IRB may require the reconsent of all, some, or none of the subjects in a study. The IRB will communicate this determination to you in writing.

I plan to share data and/or specimens from my study with another study or with researchers outside of UCSD/RCHSD. What do I need to consider?

If data and/or specimens will be obtained as a part of a study and prospective informed consent will be sought from subjects or their legally authorized representative prior to participation, the information about what will be disclosed, to whom, and in what format (e.g. identifiable, coded, de-identified, etc.) should be

¹⁴ [California Health and Safety Code Section 24174](#)

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included in the consent form. OIA's consent template provides template language for investigators to use to address this topic.

If already collected data and/or specimens will be obtained from archives/repositories (e.g. EPIC) for research purposes under a waiver of consent, the IRB will expect there to be a sufficient privacy and confidentiality protection plan in place and the investigator may be asked to show that the research use of these data/specimens is allowable based on the terms of the consent under which they were originally collected, be it clinical, educational, or research. Further sharing of these data/specimens outside of the research team may be allowable; however, the IRB will want to know in what format the data/specimens will be released (e.g. identifiable, coded, de-identified, etc.), to whom they will be released, and for what purpose.

It is important to note that simply releasing data and/or specimens to individuals at another institution for the purposes of those individuals conducting research with the data/specimens does not engage UCSD in human subjects research and thus IRB approval may not be required for this release. Please consult with the OIA by emailing irb@ucsd.edu if you are unsure if IRB approval is needed.

Regardless of the above, any time that data and/or specimens are leaving the university or being shared with those outside of the university, there are other institutional approvals which may be required. All releases of data and/or specimens should be accompanied by an appropriate agreement as to how they will be used. Such agreements are handled by the [Office of Contract and Grant Administration \(OCGA\)](#).

When health data will leave the university or be shared outside of the university, the [Health Data Oversight Committee \(HDOC\)](#) may need to also review the proposed use prior to the data leaving or being shared.

How do I submit a modification?

Please note that investigators must not implement study modifications until the IRB has approved the modification application, *unless the modification is an administrative modification, as defined below, or is intended to protect human subjects from imminent harm.*

Modifications are submitted via the amendment pathway in [Kuali IRB](#). Complete the amendment application in [Kuali IRB](#) and upload clean and tracked changes versions of any updated documents. The KBA "[Steps to Submitting an Amendment](#)" provides step-by-step directions on how to complete this process. Amendment submissions must ensure a rationale is provided for all changes proposed.

Modifications are categorized into administrative modifications, minor changes, and significant changes.

- Administrative modifications are not required to be submitted to the IRB prior to implementation and may be acknowledged administratively if submitted in [Kuali IRB](#).
 - An 'administrative' modification to previously approved human subjects research is one which does not alter the criteria for approval, recruitment or consent language, and does not have an effect on the subjects or integrity of the data in any way.
 - An 'administrative' modification to exempt human subjects research is one which does not alter the exempt determination. A listing of administrative modifications is available on OIA's [exempt amendments webpage](#).
 - You should contact the OIA at irb@ucsd.edu or 858-246-4777 if it is unclear whether the proposed modification qualifies as an 'administrative' modification. Implementation of

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modifications that are not 'administrative' prior to IRB approval may result in a [finding of non-compliance](#).

- A 'minor' modification is a proposed change in research-related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Minor modifications may be reviewed using the expedited procedure (see [OIA-313 WORKSHEET: Eligibility for Review Using the Expedited Procedure](#).)
- A 'significant' modification is a proposed change in research-related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Significant modifications often require review by the convened IRB, unless the study was initially approved via expedited procedures (see [OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations](#)).

How do I submit a continuing review?

Complete a renewal submission in [Kuali IRB](#) and upload required documents. The KBA on "[Steps to Submitting a Continuing Review/Renewal](#)" provides step-by-step directions on how to complete this process.

Before submitting the [research](#) for continuing review, you must:

- Ensure all financial disclosures are current and accurate. If necessary, submit an updated disclosure via [Kuali COI](#).
- Ensure that each member of the research team has completed the required [Human Subjects Protection Training](#) and has been trained on the protocol procedures they will complete.
- Obtain verbal or written agreement from each member of the research staff that they understand and will perform their role in the [research](#).

Continuing review must be received by IRB at least 30 days before the protocol [expiration date](#) stated in the current IRB approval letter. The IRB will review the application and provide a notification of the review determination via [Kuali IRB](#).

If modifications are required at continuing review, the modification must be submitted separately from the continuing review application. However, a modification submission and continuing review submission are permitted in [Kuali IRB](#) at the same time. See the section "[How do I submit a modification?](#)" above.

If the continuing review submission is not received at least 30 days before the protocol [expiration date](#) in the approval letter, you will be required to develop and implement a suitable corrective and preventive action plan (CAPA).

If the continuing review submission is not received by the protocol [expiration date](#) in the approval letter, meaning the research approval expires, you will be required to develop and implement a suitable CAPA **and** may be [restricted](#) from submitting new [human subjects research](#) until the completed continuing review submission has been received and approved.

When human subjects research approval expires, all human subjects research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, [interventions](#) and [interactions](#) with subjects, and collection or analysis of [identifiable private information](#). Continuing human subjects research procedures during an approval lapse is a violation of UCSD policy and, in some cases, federal regulations. If current subjects will be harmed by stopping human subjects research procedures that are available outside the human subjects research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping research procedures that are not available outside the human subjects research context, request IRB

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approval for “continuation of subjects in expired research” from the IRB by submitting a written accounting to IRB of the potential harm enrolled subjects may incur if study procedures are stopped, the procedures that must continue to prevent harm, and the number of subjects who need to continue the specified procedures.

How do I close out a study?

Complete a “request close” submission and upload required documents. The KBA on [“Steps to Submitting a Closure”](#) provides step-by-step directions on how to complete this process.

If the submission for closing out a human subjects research study is not received by the protocol expiration date in the approval letter, meaning the research approval expires, you will be required to develop and implement a suitable CAPA **and** may be restricted from submitting new human subjects research until the completed closure application has been received and approved.

How long do I need to keep records?

Research records belong to the Regents of the University of California. These records are confidential and must be stored securely in your university office, in your department, or in another approved location at the university or approved archiving facility. Records to be kept include, but are not limited to, submissions made in [Kuali IRB](#), consent forms, [HIPAA](#) authorization forms, case report forms (CRFs), tapes or transcripts, all other data collection instruments and source documents, and training records. If multiple retention requirements apply to the research, the longer requirement must be followed. All records must be accessible for inspection and copying by authorized representatives of the IRB, regulatory agencies, and study sponsor. Identifiable records must not be accessed or used for research purposes after study closure.

- UCOP requires that research data be kept in accordance with the [University of California Research Data Policy](#).
- DHHS regulations require records from federally funded research to be kept for 3 years after completion of all research activities.
- FDA regulated research records must be kept for 2 years after a marketing application is approved.
 - For FDA-regulated research where no application is filed or the application is not approved, the retention period is 2 years after the investigation is discontinued and FDA is notified.
 - Contractual obligations may require records to be maintained according to the agreement terms with the trial sponsor.
- [HIPAA](#) requires records involving the generation, disclosure, and/or use of protected health information (PHI) to be retained for at least 6 years after the last subject has completed study activity. Contact the [Office of Compliance and Privacy](#) (UCSD Pulse Intranet page) for more information about [HIPAA](#)-related matters and document retention requirements.

What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review (e.g. emergency use or compassionate use)?

[Contact the OIA](#) immediately to discuss the circumstances. If there is no time to make this contact, see the [OIA-322 WORKSHEET: Emergency Use](#) for the regulatory criteria allowing such use and ensure

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these are followed. Note that the requirements for emergency use of drugs/biologics differ slightly from those for emergency use of devices.

Use the expanded access consent form template on OIA's [Forms, Templates & Instructions](#) page to prepare your consent document, as emergency use is a sub-category of expanded access, if there is sufficient time to obtain informed consent from the patient or the patient's legally authorized representative. If there is insufficient time to obtain informed consent, you must consult with a physician who is not a member of the research team to certify, in writing, that the following are true:

- The subject is confronted by a life-threatening situation necessitating the use of the test article.
- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
- Time is not sufficient to obtain consent from the subject's legally authorized representative.
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

Within 5 business days of the use, you must submit or update a [Kuali IRB](#) emergency use application reporting details of the use to the IRB, along with the certification described above, if applicable.

Individuals treated with an unapproved drug, biologic, or device without prior IRB review cannot have their data included in any research analysis unless explicitly IRB-approved in a separate research protocol.

What other internal reviews are also involved in the protection of human subjects?

Other institutional entities not listed in this section may have oversight authority and impose additional requirements. This is not meant to be an exhaustive list and should not be regarded as such. Below are the most common institutional offices encountered by researchers when conducting human subjects research.

Institutional Biosafety Committee (IBC) – The IBC reviews research involving:

- Recombinant DNA
- Materials that are infectious (or potentially infectious) to plants, animals, or humans (including replication-defective viral vectors)
- Material that falls under the [Cal OSHA Bloodborne Pathogen Standard](#). This includes any work with human cell lines, human blood or blood products, and human body fluids.
- Storage of biohazardous materials that are not being used.

The IBC reviews research for compliance and conformance with institutional policies; recommends appropriate medical surveillance for study personnel on the project after review by occupational health; and recommends modifications, curtailment, or termination of any project when it is in the best interest of the health and safety of the campus community. You may contact the IBC directly for review requirements.

Conflict of Interest (COI) Independent Review Committee (IRC) – Any actual or perceived COI as defined by institutional policy, consistent with applicable federal and state regulations, is required to be reported to and reviewed by the IRC. The IRC will inform the IRB when investigators conducting human subjects research have significant financial interests that constitute a financial COI. The IRB has the final authority and may grant final approval of research studies with a disclosed COI, provided that the PI has taken appropriate steps to eliminate or manage the conflict, consistent with the IRC determination (see

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[OIA-055 SOP: Financial Conflicts of Interest](#). Should the IRB or the IRC require changes in the research study to mitigate a conflict, you will be required to submit the revisions for IRB review and approval.

[Moore's Cancer Center Protocol Review & Monitoring Committee \(PRMC\)](#) – The PRMC is charged with the review and monitoring of protocols involving cancer patients and/or their data and/or specimens. The PRMC provides a centralized mechanism for prospective evaluation of scientific merit, resource allocation, and clinical cancer research monitoring. You must submit the study to PRMC for review and approval. The IRB will not approve a protocol involving cancer patients and/or their data or specimens without the approval/exemption of the PRMC.

[Human Exposure Review Committee \(HERC\)](#) – The HERC is responsible for the surveillance of all uses of radioactive materials and ionizing radiation, including, but not limited to, diagnostic x-rays, fluoroscopy, computed tomography, and dual x-ray absorptiometry (DEXA) imaging in research involving human subjects. You are required to identify, in [Kuali IRB](#), all proposed radiation use. The HERC may require amendments to the design of the study, restrictions, or specific wording in the informed consent document to ensure conformance with the university's radioactive material license and state and federal regulations.


[Stem Cell Research Oversight Committee \(SCRO\)](#) – The SCRO 1) provides oversight of all issues related to derivation and use of human adult and embryonic stem cell lines; 2) reviews and approves the scientific merit of research protocols; 3) reviews compliance of all human adult and embryonic stem cell research with all relevant regulations and guidelines; and 4) facilitates education of investigators involved in human adult and embryonic stem cell research. You are required to identify, in [Kuali IRB](#), all human adult and embryonic stem cell studies. The SCRO is administered by OIA, and the electronic submission for SCRO is combined with the IRB submission in [Kuali IRB](#) to facilitate parallel review between the two committees, when necessary.

[Dual Use Research of Concern \(DURC\) Institutional Review Entity \(IRE\)](#) – DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat, with broad potential consequences, to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The UCSD DURC IRE evaluates research that involves one or more of the fifteen DURC agents and/or toxins and which produces, aims to produce or can be reasonably anticipated to produce one or more of the seven experimental effects of concern.

[Office of Coverage Analysis Administration \(OCAA\)](#) – All studies involving human subjects research that utilize medical center resources and/or facilities require prospective coverage analysis. OCAA comprises a team of analysts who specialize in Medicare policies and healthcare guidelines. The analysts work closely with you and the study team to review and finalize the coverage analysis. Coverage analysis prospectively identifies the financial responsibility for each item or service provided in a human subjects research study.

[UCSD Controlled Substances Program](#) – UCSD currently maintains federal Drug Enforcement Administration (DEA) registrations governing the use of controlled substances for research. Clinical trials performed at UCSD through the pharmacy or the Investigational Drug Service (IDS) do not require a [controlled substances use authorization \(CSUA\)](#). Investigators utilizing a controlled substance outside pharmacy or IDS management will be required to obtain a CSUA.

[IT Evaluation](#) – Clinical research that requires implementation or use of new applications, systems or devices that collect and/or transmit protected health information (PHI) or personally Identifiable Information (PII) requires an IT evaluation prior to the start of the study. The IT evaluation includes steps to determine if the proposed technology use is secure and complies with UC policies as well as state and

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federal regulations. It is recommended that the evaluation precede IRB submission to avoid delays in study startup.

- UC San Diego Health and Health Sciences researchers can find more information about the Information Security Review on the [Information Security Reviews webpage](#) (UCSD Pulse intranet page).
- UC San Diego Campus researchers can find more information about ITS security services on the [Security blink page](#).

What other resources are available to assist me?

In addition to the internal review information above, the information below links you to resources you may find helpful, depending upon the nature of your project.

- [Altman Clinical and Translational Research Institute \(ACTRI\)](#)
 - [ACTRI Clinic](#)
 - [Clinical trial coordination](#)
 - [Investigational Drug Service \(IDS\)](#) and [IDS Policy](#) (UCSDH Pulse intranet page)
 - [Regulatory Support Unit/Protocol Development](#)
 - If you are conducting community-based participatory research, you may contact the ACTRI [Center for Community Health \(CCH\)](#) for information about:
 - Research studies using a community-based participatory research design.
 - Use of community advisory boards.
 - Use of participant advocates.
 - Partnerships with community-based institutions.
- [Budgeting](#)
- [Clinical Research Billing](#) (UCSD Pulse Intranet page)
- [Clinical Research Billing Regulations and References](#) (UCSD Pulse Intranet page)
- [Research Compass](#) – single portal to resources, expertise and best practices for the research community
 - [21 CFR Part 11 Validation](#)
 - [Budget Development](#)
 - [Clinicaltrials.gov mandatory reporting](#)
 - [Data and safety monitoring](#)
 - [Data management guidance](#) and [data management plan tool](#)
 - [Recruitment planning](#)
- [Hazardous shipping information and training](#)
- [Investigator Eligibility Exception Request](#)
- [Registrar's Office](#) (research using student data or records; [Student Matters PPM 160-2](#))
- [Research Instrument Support Services](#)
- [Study closeout](#)

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How do I get additional information and answers to questions?

This document and the policies and procedures for the HRPP are available on the [OIA Website](#).

If you have any questions or concerns about OIA or the IRB, contact the OIA at:

9500 Gilman Drive
Mail Code 0990
La Jolla, CA 92093-0990
Email: irb@ucsd.edu
Phone: (858) 246-4777

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding OIA or the IRB that cannot be addressed directly with OIA, contact the UCSD institutional official at savc@health.ucsd.edu or, if you wish to report anonymously or confidentially, contact the whistleblower hotline at 877-319-0265.

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Appendix A Prompt Reporting Requirements

Report the following to the IRB within 5 business days of awareness:

- 1) Change to the protocol without prior IRB review to eliminate an apparent immediate hazard to a subject.
- 2) Emergency use of a test article (i.e. unapproved drug, biologic, or device)
- 3) Premature suspension or termination of the research by the sponsor, investigator, or institution.

Report the following to the IRB within 10 business days of awareness:¹⁵

- 1) Information that indicates a new or increased risk, or a new safety issue. For example:
 - a) New information (e.g., an interim analysis, safety monitoring report, publication, sponsor report, labelling change, revised investigator's brochure, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk, or reveals a new risk.

**** Routine, annual updates of an investigator's brochure (IB) are not subject to the 10-day requirement. Routine, annual IB updates may be submitted via amendment, with or without consent changes, within 60 calendar days of site's receipt from sponsor/manufacture.**

NOTE: Risk information received from sponsor/manufacture or regulatory authority outside of the routine, annual IB update **remain subject to the 10-day notification requirement.**

 - b) Failure to follow the protocol due to the action or inaction of anyone conducting protocol procedures (e.g. nursing staff, IDS pharmacy staff, and/or laboratory staff) that resulted in harm to subjects or others or that indicates subjects or others might be at increased risk.
 - c) Subject complaint that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
 - d) Withdrawal, restriction, or modification of a marketed (approved) drug, device, or biologic used in a protocol.
- 2) An incident, experience, or outcome (IEO), which in the opinion of the investigator is **unexpected, related** (related means at least 50% likelihood; keep in mind that "don't know" represents less than a 50% likelihood of relatedness) to the research procedures, and indicates that subjects or others are at a **greater risk of harm** than was previously recognized.^{16, 17}
 - An IEO is "**unexpected**" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
 - An IEO is "**related**" to the research procedures if, in the opinion of the investigator, there is a reasonable possibility (at least 50% likelihood) that the incident, experience, or outcome may have been caused by the procedures involved in the research.
 - An IEO indicates that subjects or others are at a "**greater risk of harm**" when the IEO is "**unexpected**" and "**related**" and either 1) the IEO is a serious adverse event (as defined in [OIA-001 SOP: Definitions](#)) or 2) results in changes to the protocol, consent process, or consent document.
- 3) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).
- 4) Non-compliance with the federal regulations governing human subjects research or requirements or determinations of the IRB that pose a harm to the rights, safety, or welfare of the subject or to the integrity of the data. Non-compliance is the result of the action or inaction of the investigator or research staff. Minor deviations (as defined in [OIA-001 SOP: Definitions](#)) are not included in this category.

¹⁵ If information contained within a report has previously been submitted to OIA, do not submit a second time unless the updated report includes new information that would affect or revise the previous determination. Information that does not fall under any of the categories does not require reporting.

¹⁶ [Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance \(2007\)](#)

¹⁷ If you are uncertain about whether all of the criteria are met, the OIA advises submitting a reportable event for evaluation by OIA staff and/or the IRB.

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- 5) Failure to follow the IRB-approved protocol due to the action or inaction of anyone conducting protocol procedures (e.g. nursing staff, IDS pharmacy staff, and laboratory staff) that poses a harm to the rights, safety, or welfare of the subject or to the integrity of the data. Minor deviations (as defined in [OIA-001 SOP: Definitions](#)) are not included in this category.
- 6) Breach of confidentiality (inappropriate disclosure of or access to confidential information).
- 7) Complaint of a subject that cannot be resolved by the research team. The reporting window begins when the PI has determined that the complaint cannot be resolved by the research team.
- 8) Incarceration of a subject in a study involving interactions and/or interventions with subjects not approved by the IRB to involve prisoners. NOTE: interventions and/or interactions must cease until the IRB determines that inclusion of prisoners is approved.
- 9) Inquiry by a federal agency and any reports (e.g., FDA Form 483).
- 10) Written reports by study monitors and auditors that include reportable events that have not yet been reported.¹⁸
- 11) Data safety reports that include a recommendation to terminate or modify a study.

Report the following in the continuing review application:

- 1) Minor deviations that do not require prompt reporting as described above.
- 2) Annual reports for humanitarian use devices (HUDs) and IDEs.
- 3) [Office of Compliance and Privacy](#) audit reports that do not contain findings requiring prompt reporting as described above.
- 4) Data and safety monitoring board/data monitoring committee/data and safety monitoring committee (and similar data safety monitoring bodies) reports that only indicate that the study may continue unchanged.

¹⁸ The IRB requires only audit and monitoring reports that include information that must be reported under any of the other numbered items above. If the report does not include reportable information, you do not need to submit it. If the monitoring report includes information that falls under category 1(b), 3, 4, or 5 above please include a CAPA, indicate whether the event was previously reported or include a statement that you will submit separate or updated reportable event submission(s) with preventive action plans for the new reportable events included on the report.

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Appendix B-1 Additional Requirements for DHHS-Regulated Research¹⁹

1. When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent, may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.
2. Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject's consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol and consent. This is the case even if that data includes identifiable private information about the subject.
3. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.
4. When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.

¹⁹ [Withdrawal of Subjects from Research Guidance \(2010\)](#)

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Appendix B-2 Additional Requirements for FDA-Regulated Research

The requirements found in this appendix are in addition to any requirements described earlier in this handbook.

1. The FDA defines a human subject as 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. When medical device research involves in vitro diagnostics and unidentified tissue specimens the FDA defines the unidentified tissue specimens as human subjects.²⁰
2. When a subject withdraws from a study:²¹
 - a. The data (including specimens) collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
 - b. An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.
 - c. If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous section, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.
 - d. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access, for purposes related to the study, the subject's medical record or other confidential records requiring the subject's consent.
 - e. An investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.
3. When the PI is the IND or IDE "holder," also known as a sponsor-investigator, they must fulfill all responsibilities/obligations listed in Section 4 and/or 5 below as well as the obligations of sponsors.²²
4. For FDA-regulated research involving investigational drugs:
 - a. Investigators must abide by FDA restrictions on promotion of investigational drugs:²³
 - i. For clinical investigations requiring an IND,²⁴ the IRB will not approve the investigation until one of the following are satisfied:
 1. The IRB receives evidence that an IND with no clinical holds has been approved (e.g. inclusion of an IND number on the protocol or other sponsor document); or
 2. The IRB receives evidence that an IND application was received by the FDA and 30 calendar days have elapsed with no communication(s) from the FDA.
 3. The IRB receives evidence of a determination that the FDA has found the clinical investigation to be IND exempt.
 - ii. An investigator, or any person acting on behalf of an investigator, must not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.
 - iii. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

²⁰ [Studies Using Leftover, Deidentified Human Specimens Require IRB Review – Letter to Industry October 18, 2021](#)

²¹ [FDA Guidance for Sponsors, Clinical Investigators and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials](#)

²² For drugs and biologics, [21 CFR 312.50-59](#). For devices, [21 CFR 812 Subpart C](#) and [21 CFR 812.140\(b\)](#).

²³ [21 CFR 312.7](#)

²⁴ [FDA Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed](#)

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- iv. An investigator must not commercially distribute or test market an investigational new drug.
- b. Investigators must follow FDA requirements for general responsibilities/obligations of investigators:²⁵
 - i. An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the IRB-approved investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.
 - ii. An investigator must, in accordance with the provisions of [21 CFR Part 50](#), obtain the informed consent of each human subject to whom the drug is administered, except as provided in [21 CFR 50.23](#) or [21 CFR 50.24](#).
 - iii. Additional specific responsibilities of clinical investigators are set forth in [21 CFR 312.60-21 CFR 312.69](#).
- c. Investigators must follow FDA requirements for control of the investigational drug:²⁶
 - i. An investigator must administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.
 - ii. The investigator must not supply the investigational drug to any person not authorized to receive it.
- d. Investigators must follow FDA requirements for investigator recordkeeping and record retention:²⁷
 - i. Disposition of drug:
 - 1. An investigator is required to maintain adequate records of the receipt, storage, and disposition of the drug, including dates, quantity, and use by subjects.
 - 2. If the investigation is terminated, suspended, discontinued, or completed, the investigator must return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under [21 CFR 312.59](#).
 - ii. Case histories:
 - 1. An investigator is required to prepare and maintain adequate and accurate case histories that record all pertinent observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
 - 2. Case histories include the CRFs and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.
 - iii. Record retention:²⁸ An investigator must retain required records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.
- e. Investigators must follow FDA requirements for investigator reports:²⁹
 - i. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.
 - ii. Safety reports: An investigator must immediately report to the sponsor any serious adverse event, whether or not considered drug related, including those listed in the protocol or investigator's brochure and must include an assessment of whether there is a reasonable possibility that the drug caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the drug and the event (e.g., death from anaphylaxis). In that case, the investigator must immediately report the event to the sponsor. The investigator must record non-

²⁵ [21 CFR 312.60](#)

²⁶ [21 CFR 312.61](#)

²⁷ [21 CFR 312.62](#)

²⁸ The record retention requirements in this [appendix](#) represent only the requirements of the FDA. Longer retention periods may be required by other agencies or the institution depending on the characteristics of the research. Please see ["How Long Do I Need to Keep Records"](#) for additional requirements.

²⁹ [21 CFR 312.64](#)

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serious adverse events and report them to the sponsor according to the timetable for reporting specified in the protocol.

- iii. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.
- iv. Financial disclosure reports:
 1. The clinical investigator must provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under [21 CFR Part 54](#).
 2. The clinical investigator must promptly update this information if any relevant changes occur during the course of the investigation and for one year following the completion of the study.
- f. Investigators must follow FDA requirements for assurance of IRB review:³⁰
 - i. An investigator must assure that an IRB that complies with the requirements set forth in [21 CFR Part 56](#) will be responsible for the initial and continuing review and approval of the proposed clinical study.
 - ii. The investigator must also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others/unanticipated problem report (UPR), and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- g. Investigators must follow FDA requirements for inspection of investigator's records and reports:³¹
 - i. An investigator must upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to [21 CFR 312.62](#).
 - ii. The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies or do not represent actual results obtained.
- h. Investigators must follow FDA and other requirements for handling of controlled substances:³²
 - i. If the investigational drug is subject to the [Controlled Substances Act 21 USC 801 Chapter 13](#), the investigator must take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.
 - ii. Investigators must follow California requirements for controlled substances for research taking place in California.³³ Contact legal counsel for requirements of other states and countries.
 - iii. Investigators must follow University of California requirements for controlled substances.³⁴
- i. For investigator-initiated research involving investigational drugs, investigators must follow FDA requirements in [21 CFR Part 312, Subpart B](#)³⁵ for obtaining IND clearance/approval.
 - i. Follow [OIA-306 WORKSHEET: Drugs](#) for information concerning legal and regulatory requirements that apply to the use of investigational test articles.
5. For FDA-regulated research involving investigational devices:
 - a. Investigators must follow FDA requirements for general responsibilities of investigators:³⁶
 - i. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the IRB-approved investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with [21 CFR Part 50](#).

³⁰ [21 CFR 312.66](#)

³¹ [21 CFR 312.68](#)

³² [21 CFR 312.69](#)

³³ [State of California Research Advisory Panel Guidelines](#)

³⁴ [University of California Policy BFB-BUS-50: Controlled Substances](#)

³⁵ [21 CFR Part 312 Subpart B](#)

³⁶ [21 CFR 812.100](#)

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- b. Investigators must follow FDA requirements for specific responsibilities of investigators:³⁷
- i. Awaiting approval: An investigator may determine whether potential subjects would be interested in participating in an investigation, but must not request the written informed consent of any subject to participate, and must not allow any subject to participate before obtaining IRB and FDA approval.
 1. When the IRB determines an IDE is required for a clinical investigation, the IRB will not approve the investigation until one of the following are satisfied:
 - a. The IRB receives a copy of a letter from the FDA indicating that an IDE has been approved; or
 - b. The IRB receives evidence that an IDE application was received by the FDA and 30 days have elapsed with no communication(s) from the FDA.
 - c. The IRB receives evidence of a determination that the FDA has found the clinical investigation to be exempt from the requirement to obtain an IDE in accordance with [21 CFR Part 812.2\(c\)](#).
 - ii. Compliance: An investigator must conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.
 - iii. Supervising device use: An investigator must permit an investigational device to be used only with subjects under the investigator's supervision. An investigator must not supply an investigational device to any person not authorized to receive it.
 - iv. Financial disclosure:
 1. A clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under [21 CFR 54](#).
 2. The investigator must promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the study.
 - v. Disposing of device: Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.
- c. Investigators must maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:³⁸
- i. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.
 - ii. Records of receipt, use or disposition of a device that relate to:
 1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
 2. The names of all persons who received, used, or disposed of each device.
 3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
 - iii. Records of each subject's case history and exposure to the device. Case histories include the CRFs and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. Such records must include:
 1. Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
 2. Documentation that informed consent was obtained prior to participation in the study.
 3. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.

³⁷ [21 CFR 812.110](#)

³⁸ [21 CFR 812.140](#)

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4. A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.
- iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.
- v. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.
- vi. Record retention:³⁹ An investigator must retain required records for a period of 2 years following the latter of: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for *De Novo* classification.
- d. Inspections:⁴⁰
 - i. Entry and inspection: A sponsor or an investigator who has authority to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).
 - ii. Records inspection: A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, must permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.
 - iii. Records identifying subjects: An investigator must permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.
- e. Prepare and submit the following complete, accurate, and timely reports:⁴¹
 - i. Unanticipated adverse device effects: An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
 - ii. Withdrawal of IRB approval: An investigator must report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
 - iii. Progress: An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
 - iv. Deviations from the investigational plan:
 1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency.
 2. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.
 3. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB approval also is required.
 - v. Informed consent: If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
 - vi. Final report: An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

³⁹ The record retention requirements in this [appendix](#) represent only the requirements of the FDA. Longer retention periods may be required by other agencies or the institution depending on the characteristics of the research. Please see "[How long do I need to keep records?](#)" for additional requirements.

⁴⁰ [21 CFR 812.145](#)

⁴¹ [21 CFR 812.150](#)

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- vii. Other: An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.
- f. For investigator-initiated research involving investigational devices, follow FDA requirements in [21 CFR Part 812, Subpart B](#)⁴² for obtaining IDE approval.
 - i. Follow [OIA-307 WORKSHEET: Devices](#) for information concerning legal and regulatory requirements that apply to the use of investigational test articles.

⁴² [21 CFR Part 812 Subpart B](#)

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Appendix B-3 Additional Requirements for Clinical Trials [International Council for Harmonisation-Good Clinical Practice (ICH-GCP)]⁴³

1. The clinical trial should be conducted in accordance with the ethical principles that have their origin in the [Declaration of Helsinki](#) and that are consistent with GCP and the applicable regulatory requirements.
2. Under ICH-GCP, a sponsor-investigator is defined as “an individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
3. Investigator's Qualifications and Agreements
 - a. The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
 - b. The investigator should be thoroughly familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator's brochure, in the product information and in other information sources provided by the sponsor.
 - c. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.
 - d. The investigator should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.
 - e. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.
4. Adequate Resources
 - a. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
 - b. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
 - c. The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
 - d. The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product, and their trial-related duties and functions.
 - e. The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.
 - f. If the investigator retains the services of any individual or party to perform trial-related duties and functions, the investigator should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.
5. Medical Care of Trial Subjects
 - a. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.
 - b. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator should inform a subject when medical care is needed for intercurrent illnesses of which the investigator becomes aware.
 - c. It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

⁴³ [Integrated Addendum to ICH E6\(R1\): Guidelines for Good Clinical Practice E6\(R2\)](#)

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- d. Although a subject is not obliged to give their reasons for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reasons, while fully respecting the subject's rights.
6. Communication with IRB
 - a. Before initiating a trial, the investigator should have written and dated approval from the IRB for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.
 - b. As part of the investigator's written application to the IRB, the investigator should provide the IRB with a current copy of the investigator's brochure. If the investigator's brochure is updated during the trial, the investigator should supply a copy of the updated investigator's brochure to the IRB.
 - c. During the trial the investigator should provide to the IRB all documents subject to review.
7. Compliance with Protocol
 - a. The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which was given approval by the IRB. The investigator and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.
 - b. The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval from the IRB of an amendment, except where necessary to eliminate an immediate hazard to trial subjects, or when the changes involves only logistical or administrative aspects of the trial (e.g., change in monitors, change of telephone numbers).
 - c. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.
 - d. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard to trial subjects without prior IRB approval. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendments should be submitted: a) to the IRB for review and approval, b) to the sponsor for agreement and, if required, c) to the regulatory authorities.
8. Investigational Product
 - a. Responsibility for investigational product accountability at the trial site rests with the investigator.
 - b. Where allowed/required, the investigator should assign some or all of the investigator's duties for investigational product accountability at the trial site to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator.
 - c. The investigator and/or a pharmacist or other appropriate individual, who is designated by the investigator, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product. These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product received from the sponsor.
 - d. The investigational product should be stored as specified by the sponsor and in accordance with applicable regulatory requirements.
 - e. The investigator should ensure that the investigational product are used only in accordance with the approved protocol.
 - f. The investigator, or a person designated by the investigator, should explain the correct use of the investigational product to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.
 - g. Randomization procedures and unblinding: The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.
9. Informed Consent of Trial Subjects
 - a. In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirements, and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB's written approval of the written informed consent form and any other written information to be provided to subjects.

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- b. The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB's approval in advance of use. The subject or the subject's legally authorized representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.
- c. Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.
- d. None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally authorized representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.
- e. The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally authorized representative, of all pertinent aspects of the trial including the written information and the approval by the IRB.
- f. The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally authorized representative and the impartial witness, where applicable.
- g. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally authorized representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally authorized representative.
- h. Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally authorized representative, and by the person who conducted the informed consent discussion.
- i. If a subject is unable to read or if a legally authorized representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally authorized representative, and after the subject or the subject's legally authorized representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative.
- j. Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:
 - i. That the trial involves research.
 - ii. The purpose of the trial.
 - iii. The trial treatments and the probability for random assignment to each treatment.
 - iv. The trial procedures to be followed, including all invasive procedures.
 - v. The subject's responsibilities.
 - vi. Those aspects of the trial that are experimental.
 - vii. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
 - viii. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
 - ix. The alternative procedures or courses of treatment that may be available to the subject, and their important potential benefits and risks.
 - x. The compensation and/or treatment available to the subject in the event of trial-related injury.
 - xi. The anticipated prorated payment, if any, to the subject for participating in the trial.
 - xii. The anticipated expenses, if any, to the subject for participating in the trial.


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- xiii. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
 - xiv. That the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally authorized representative is authorizing such access.
 - xv. That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
 - xvi. That the subject or the subject's legally authorized representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
 - xvii. The persons to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
 - xviii. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
 - xix. The expected duration of the subject's participation in the trial.
 - xx. The approximate number of subjects involved in the trial.
 - k. Prior to participation in the trial, the subject or the subject's legally authorized representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally authorized representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.
 - l. When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally authorized representative (e.g., children, or incompetent patients), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.
 - m. Except as described above, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.
 - n. Non-therapeutic trials may be conducted in subjects with consent of a legally authorized representative provided the following conditions are fulfilled: a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally. b) The foreseeable risks to the subjects are low. c) The negative impact on the subject's well-being is minimized and low. d) The trial is not prohibited by law. e) The approval of the IRB is expressly sought on the inclusion of such subjects, and the written approval covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed. See [OIA-417 CHECKLIST: Cognitively Impaired Adults](#) for full requirements related to adults who lack capacity to provide legally effective consent.
 - o. In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally authorized representative, if present, should be requested. When prior consent of the subject is not possible, and the subject's legally authorized representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval by the IRB, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally authorized representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested. (See [OIA-322 WORKSHEET: Emergency Use](#) and [OIA-419 CHECKLIST: Waiver of Consent Process for Emergency Research](#) for full requirements related to emergency use.)
10. Records and Reports

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- a. The investigator/institution should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be attributable, legible, contemporaneous, original, accurate, and complete.
 - b. The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.
 - c. Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.
 - d. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections. Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.
 - e. The investigator should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial section of ICH-E6 (R2) GCP requirements and as required by the applicable regulatory requirements. The investigator should take measures to prevent accidental or premature destruction of these documents.
 - f. Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator as to when these documents no longer need to be retained.
 - g. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator.
 - h. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator should make available for direct access all requested trial-related records.
11. Progress Reports
- a. The investigator should submit written summaries of the trial status to the IRB annually, or more frequently, if requested by the IRB.
 - b. The investigator should promptly provide written reports to the sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.
12. Safety Reporting⁴⁴
- a. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., investigator's brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authorities and the IRB.
 - b. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
 - c. For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).
13. Premature termination or suspension of a trial
- a. If the trial is prematurely terminated or suspended for any reason, the investigator should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirements, should inform the regulatory authorities. In addition:

⁴⁴ See [Appendix A](#) of this handbook for a listing of reportable events and their required reporting timelines.

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- b. If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator should promptly inform the sponsor and the IRB, and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.
 - c. If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution where applicable and the investigator should promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension.
 - d. If the IRB terminates or suspends its approval of a trial, the investigator should inform the institution where applicable and the investigator should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension of IRB approval.
14. Final Reports by Investigator. Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator should provide the IRB with a summary of the trial's outcome, and the regulatory authorities with any reports required.

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Appendix B-4 Additional Requirements for Department of Defense (DOD)⁴⁵ research

1. When appropriate, research protocols must be reviewed and approved by the IRB prior to the DoD approval. Consult with the DoD funding component to see whether this is a requirement.
2. Employees of the DoD (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the DoD cannot be paid for conducting research while on active duty.
3. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
4. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service specific requirements.
5. Components of the DoD might have stricter requirements for research-related injury than the DHHS regulations.
6. The training requirements listed in the "[What training do my staff and I need to conduct human subjects research?](#)" section of this document apply to all personnel who conduct, review, approve, oversee, support, or manage human subjects research. Depending on the project, there may be additional, specific educational requirements or certification required. Any additional requirements will be directed by the funding agency.
7. When assessing whether to support or collaborate with this institution for research involving human subjects, the DoD may evaluate this institution's education and training policies to ensure the personnel are qualified to perform the research.
8. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
 - a. Prohibit an individual from receiving pay of compensation for research during duty hours.
 - b. An individual may be compensated for research if the participant is involved in the research when not on duty.
 - c. Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
 - d. Non-federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
9. When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.
10. Investigators must submit research approval documents to the DoD component for administrative review of the research before the research can begin. The research cannot start until the DoD component provides confirmation that the study may begin.
11. The following shall be promptly reported to the DoD human research protection officer:
 - a. When significant changes to the research protocol are approved by the IRB;
 - b. The results of IRB continuing review;
 - c. Change of reviewing IRB;
 - d. When the institution or investigator is notified by any federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DoD supported research protocol.
12. For DoD research that involves no more than minimal risk, an IRB may alter or waive other required elements of informed consent so long as it still preserves informed consent of the subject (i.e., the consent indicates the subject's participation in the research is completely voluntary and includes the requirement that the subject is informed of research risks).
13. The advance informed consent requirement may be waived by the Directorate Of Human Research Protections or its delegate, if the following conditions are met:
 - a. The research is to advance the development of a medical product necessary to the DoD.
 - b. The research may directly benefit the individual experimental subject.
 - c. The research is conducted in compliance with all other applicable laws and regulations.
14. Other specific requirements of DoD research can be found in the "Additional Criteria for Department of Defense (DOD) Research" section in the [OIA-318 WORKSHEET: Additional Federal Criteria](#), and in [OIA-024 SOP: Reportable Events](#).

⁴⁵ [DOD Instruction 3216.02](#)

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Appendix B-5 Additional Requirements for Department of Energy (DOE)⁴⁶ Research

1. The investigator must report the following within ten business days to the DOE human subject research program manager:
 - a. Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
 - b. Any suspension or termination of IRB approval of research.
 - c. Any significant non-compliance with HRPP procedures or other requirements.
2. The investigator must report the following within three business days to the DOE human subjects research program manager:
 - a. Any compromise of personally identifiable information must be reported immediately.⁴⁷
3. Other specific requirements of DOE research can be found in the “Additional Requirements for Department of Energy (DOE) Research” section in [OIA-318 WORKSHEET: Additional Federal Criteria](#).

⁴⁶ [U.S. Department of Energy Order DOE O 443.1C](#)

⁴⁷ Upon discovery

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Appendix B-6 Additional Requirements for Department of Justice (DOJ)⁴⁸ Research

Additional Requirements for DOJ Research conducted in the Federal Bureau of Prisons (BOP)

1. Implementation of bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
2. In all research projects the rights, health, and human dignity of individuals involved must be respected.
3. The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
4. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
5. The project must minimize risk to subjects; risks to subjects must be reasonable in relation to anticipated benefits. The selection of subjects within any one institution must be equitable. When, applicable, informed consent must be sought and documented.
6. Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both: no longer in BOP custody AND participating in authorized research being conducted by bureau employees or contractors.
7. The investigator must have academic preparation or experience in the area of study of the proposed research.
8. The investigator must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the investigator.
9. Except as noted in the informed consent statement to the subject, the investigator must not provide research information which identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertains.
10. The investigator must adhere to applicable provisions of the Privacy Act of 1974 and regulations pursuant to [28 CFR Part 512](#).
11. The research design must be compatible with both the operation of prison facilities and protection of human subjects. The investigator must observe the rules of the institution or office in which the research is conducted.
12. Any investigator who is a non-employee of the bureau must sign a statement in which the investigator agrees to adhere to the provisions of the DOJ regulation.
13. Except for computerized data records maintained at an official DOJ site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
14. Any investigator who is a non-employee of the BOP must sign a statement in which the investigator agrees to adhere to the requirements of [28 CFR Part 512](#).
15. If the investigator is conducting a study of special interest to the Office of Research and Evaluation (ORE), but the study is not a joint project involving ORE, the investigator may be asked to provide ORE with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.
16. The investigator must submit planned methodological changes in a research project to the IRB for approval, and may be required to revise study procedures in accordance with the new methodology.
17. The research must be reviewed and approved by the Bureau Research Review Board.
18. A non-employee of the bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
19. Except as noted in the consent statement to the subject, the investigator must not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example,

⁴⁸ [Bureau of Prisons, Department of Justice 28 CFR Part 512](#)

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research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

20. Before commencing a research project requiring participation by staff or inmates, the investigator must give each participant a written informed consent statement containing the following information:
 - a. Identification of the PIs;
 - b. Objectives of the research project;
 - c. Procedures to be followed in the conduct of research;
 - d. Purpose of each procedure;
 - e. Anticipated uses of the results of the research;
 - f. A statement of benefits reasonably to be expected;
 - g. A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk;
 - h. A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable);
 - i. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
 - j. A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility;
 - k. An offer to answer questions about the research project; and
 - l. Appropriate additional information as needed to describe adequately the nature and risks of the research.
21. An investigator who is a non-employee of the bureau, in addition to presenting the statement of informed consent to the subject, shall also obtain the subject's signature on the statement of informed consent prior to initiating the research activity. The investigator may not be required to obtain the signature if the investigator can demonstrate that the only link to the subject's identity is the signed statement of informed consent or that there is significantly more risk to the subject if the statement is signed. The signed statement shall be submitted to the chairperson of the appropriate local research review board.
22. The IRB application must include a summary statement, which includes:
 - a. Names and current affiliations of the investigators.
 - b. Title of the study.
 - c. Purpose of the study.
 - d. Location of the study.
 - e. Methods to be employed.
 - f. Anticipated results.
 - g. Duration of the study.
 - h. Number of subjects (staff or inmates) required and amount of time required from each.
 - i. Indication of risk or discomfort involved as a result of participation.
23. The IRB application must include a comprehensive statement, which includes:
 - a. Review of related literature.
 - b. Detailed description of the research method.
 - c. Significance of anticipated results and their contribution to the advancement of knowledge.
 - d. Specific resources required from the bureau.
 - e. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
 - f. Description of steps taken to minimize any risks.
 - g. Description of physical or administrative procedures to be followed to ensure the security of any individually identifiable data that are being collected for the study and destroy research records or remove individual identifiers from those records when the research has been completed.
 - h. Description of any anticipated effects of the research study on Institutional programs and operations.
 - i. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.


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24. The IRB application must include a statement regarding assurances and certification required by federal regulations, if applicable.
25. At least once a year, the investigator must provide the Chief, ORE, with a report on the progress of the research.
26. At least 12 working days before any report of findings is to be released, the investigator must distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance.
27. The investigator must include an abstract in the report of findings.
28. In any publication of results, the investigator must acknowledge the bureau's participation in the research project.
29. The investigator must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the bureau.
30. Prior to submitting for publication the results of a research project conducted under [28 CFR Part 512 Subpart B](#), the investigator must provide two copies of the material, for informational purposes only, to the Chief, ORE, Central Office, BOP.
31. Other specific requirements of DOJ research conducted within the federal BOP can be found in the "Additional Requirements for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)" section in [OIA-318 WORKSHEET: Additional Federal Criteria](#).

Additional Requirements for DOJ Research Funded by the National Institute of Justice (NIJ)⁴⁹

1. The project must have a privacy certificate approved by the NIJ Human Subjects Protection Officer.
2. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.
3. The confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
4. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.
5. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
6. Other specific requirements of DOJ research funded by NIJ can be found in the "Additional Requirements for Department of Justice (DOJ) Research Funded by National Institute of Justice (NIJ)" section in [OIA-318 WORKSHEET: Additional Federal Criteria](#).

⁴⁹ [National Institute of Justice Human Subjects Protection](#)

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Appendix B-7 Additional Requirements for US Department of Education (ED) Research^{50,51}

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA)⁵² and the Protection of Pupil Rights Amendment (PPRA)⁵³.
2. Provide a copy of all surveys and instructional material used in the research. Upon request, parents of children⁵⁴ involved in the research⁵⁵ must be able to inspect these materials.
3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.
4. Other specific requirements of ED research can be found in the “Additional Requirements for Department of Education (ED) Research” section in [OIA-318 WORKSHEET: Additional Federal Criteria](#).

⁵⁰ [Basic ED Policy for Protection of Human Research Subjects 34 CFR Part 97](#)

⁵¹ [US Department of Education Protection of Human Subjects in Research](#)

⁵² [34 CFR Part 99](#)

⁵³ [34 CFR Part 98](#)

⁵⁴ Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

⁵⁵ Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

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Appendix B-8 Additional Requirements for Environmental Protection Agency (EPA) Research⁵⁶ and Research Intended to be Submitted to the EPA

1. Research conducted, supported, or intended to be submitted to EPA is subject to EPA regulations.
2. Intentional exposure of pregnant women or children to any substance is prohibited.
3. Observational research involving pregnant women and fetuses are subject to additional DHHS requirements for research involving pregnant women ([45 CFR 46 Subpart B](#)) and additional DHHS requirements for research involving children ([45 CFR 46 Subpart D](#).)
4. Research involving children must meet category [40 CFR 26.404](#) or [40 CFR 26.405](#).
5. Other specific requirements of EPA research can be found in the "Additional Requirements for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the EPA" section in [OIA-318 WORKSHEET: Additional Federal Criteria](#).

⁵⁶ [40 CFR Part 26 Subpart A Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA](#)