

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 3.21
IRB Oversight by Non-UCSD “Centralized” IRBs

Policy

As noted by the United States Food and Drug Administration (FDA), “Use of a centralized IRB review process is consistent with the requirements of existing IRB regulations. Section 56.114 ([21 CFR 56.114](#), Cooperative Research) provides that, ‘institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.’” Further, the FDA notes in the conclusion of the FDA guidance on the use of centralized IRB review, “The Agency hopes that sponsors, institutions, institutional review boards (IRBs), and clinical investigators involved in multicenter clinical research will consider the use of a single central IRB (centralized IRB review process), especially if using centralized review would improve efficiency of IRB review.” In addition, [Correspondence from the Office for Human Research Protections](#), dated April 30, 2010, indicates that “the Office for Human Research Protections fully agrees with FDA’s position on the benefits of relying on a single central IRB for multicenter research.”

The University of California, San Diego, has entered into agreements with non-UCSD IRBs to provide “centralized” IRB oversight for specific types of clinical trials and other research that involves human subjects. The types of research and the procedures for using non-UCSD IRBs are provided below.

UCSD and Western Institutional Review Board (WIRB)

UCSD and WIRB have established an agreement whereby WIRB agrees to assume IRB oversight for some research conducted at or by UCSD. The following describes the scope of research activities for which UCSD will agree to allow WIRB to assume IRB oversight, and outlines the procedures for obtaining permission to submit to WIRB. UCSD has sole discretion on a study-by-study basis for allowing WIRB to assume oversight.

Procedures for Obtaining WIRB IRB Oversight of a Project

WIRB will not review research on behalf of UCSD without notification that the UCSD HRPP has cleared the study for WIRB oversight. The following procedures will be followed:

1. UCSD HRPP staff will screen the application for eligibility for WIRB IRB oversight. Screening involves use of a checklist to ensure that the following criteria are satisfied:
 - a) To be eligible for WIRB IRB oversight
 1. The research must be a multi-site (5 sites including UCSD) Phase II, Phase III or Phase IV industry-authored, industry-sponsored, clinical research study or a Phase I industry-authored, industry-sponsored, clinical research study, where the PI has submitted to the UCSD HRPP documentation that the UCSD Institutional Official (IO) for Human Subjects has reviewed the study and is providing discretionary approval for WIRB IRB oversight of the study. This documentation must also include the name of the PI, the title of the study, and the signature of the IO.
 2. The clinical trial agreement must be negotiated through the Office of Clinical Trials Administration (OCTA).

3. Documented approval from the following office:
 - i. UCSD Cancer Center Protocol Review and Monitoring Committee (PRMC) review and approval for trials involving patients with cancer or at a high risk of developing cancer during the study.
 4. Documented submission of the study for additional review (may be done in parallel), as appropriate:
 - i. Conflict of Interest Office/Independent Review Committee review and approval for projects that involve a PI, co-investigator or others associated with the study that have a conflict of interest.
 - b) Research activities that are not eligible for WIRB IRB oversight
 1. Research that has previously received initial review approval from a UCSD IRB.
 2. Research on transplant techniques, procedures or other interventions.
 3. Research on pregnant women, human fetuses, or neonates.
 4. Research involving stem cell therapies.
 5. Research involving an infectious agent as the therapeutic agent, gene therapy, recombinant DNA and/or gene transfer.
 6. Research involving research-related radiologic procedures unless the radiologic procedures prescribed by the protocol are within the uses in the approved labeling of the radiologic device(s) and are used for standard of care procedures.
 - c) Submission of completed [WIRB specific application Facesheets](#).
 - d) Submission of documents outlined on the [WIRB Initial Submission Screening Checklist](#).
2. HRPP staff reviews submitted information and confirms that study is eligible for WIRB IRB oversight and appropriate documents have been submitted. If the study is found to be not eligible or if appropriate documents have not been submitted, the UCSD HRPP will notify the PI in writing. The PI will respond to the HRPP correspondence with the requested action/documents, as appropriate. If the HRPP continues to find the study not eligible or documentation incomplete, the HRPP may decline the request for WIRB IRB oversight and assign the study for review by an appropriate UCSD IRB. If a project has been reviewed by a UCSD IRB, the project may not be submitted to WIRB for review.
 3. If HRPP agrees that the study is eligible for reliance on WIRB, a clearance notification (“Clearance”) will be sent to the UCSD PI.
 4. The UCSD PI submits the study to WIRB according to procedures and requirements agreed to between WIRB and UCSD, with the Clearance attached to the submission.
 5. WIRB sends the UCSD PI and UCSD HRPP Institutional Contact e-mail when WIRB has approved the study.
 6. UCSD HRPP will contact WIRB to release the approval documentation once approval from OCTA and Office of Coverage Analysis Administration (OCAA) has been provided to the HRPP Office.
 7. WIRB approval does not constitute funding or other institutional required approvals. Should a study involve UCSD review committees/department including PRMC, OCTA, OCAA and/or Independent Review Committee, it is the researcher’s responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens. If UCSD review committee(s) require revision of the consent/assent, an amendment must be provided to WIRB, and the WIRB fee for review will be paid by the study, per WIRB procedures.

UCSD PI Responsibilities

The PI's responsibilities associated with a study that has received approval from the WIRB IRB:

1. Notify WIRB and the UCSD HRPP of all communication to/from the FDA, OHRP or any other federal, state or local agency regarding a WIRB-approved study.
2. Adhere to UCSD IRB standard policies and procedures (SOPPs) as outlined in this SOPP, WIRB decisions and requirements, and all applicable federal, state, and local laws and regulations regarding the protections of human subjects in research.
3. Submit post-approval WIRB-required forms, reports, notices, and direct communications to WIRB in a timely manner.
4. Assure prompt payment of WIRB submission fees and UCSD HRPP WIRB submission review fee.
5. Submit post-approval amendment requests, unanticipated problems or other events that require prompt reporting and final report directly to WIRB following guidelines provided by WIRB.
 - a) For amendments involving consent revision(s), two copies of the revised consent (one copy with the changes underlined or bolded and one "clean" copy) should be submitted to the UCSD HRPP for review *before* submission to WIRB.
 - b) For an amendment that involves study staff changes that include the addition of "key personnel," the PI is attesting that the key personnel have completed the appropriate UCSD IRB CITI training.
 - c) For all amendments, a copy of the amendment including associated documents and WIRB-approval documentation should be uploaded to the HRPP project number as soon as possible following WIRB approval to ensure appropriate information will be available for UCSD departments/committees including Investigational Drug Service.
6. Submit a copy of the Continuing Review Report provided to WIRB to the UCSD HRPP.
7. Breaches of Confidentiality must also be submitted to the UCSD HRPP as well as other appropriate UCSD Offices including the Office of Research Compliance.
8. The process of study closure will follow WIRB guidelines; however, a copy of the study closure report should also be submitted to the UCSD HRPP.

Notification Requirements Between WIRB and UCSD

In addition to the notification requirements specified in the agreement between WIRB and UCSD, WIRB shall notify the UCSD HRPP Institutional Contact of the following events within the time period specified:

1. Within 24 hours of receipt:
 - a) Notifications of imminent harms or threats to UCSD research subjects, staff or faculty.
2. WIRB shall use good faith efforts to provide notice within 24 hours of receipt, but in no event later than five business days from the date of receipt, of the following events:
 - a) Notifications of breach of confidentiality of Protected Health Information (PHI) or any other identifiable medical information,
 - b) Notifications of an injury or potential injury to a research subject,
 - c) Notifications of legal actions or threats of legal actions against UCSD.
3. Within 10 business days:
 - a) Determinations of serious or continuing non-compliance, and unanticipated problems,
 - b) Subject complaints,

c) Study closure.

Resumption of UCSD IRB/HRPP Oversight

In the event UCSD decides to resume oversight of a study that has been sent to WIRB, or is in the process of being reviewed by WIRB, or has been approved by WIRB:

1. UCSD HRPP will notify WIRB of its decision to resume oversight of the study,
2. UCSD will notify WIRB once the UCSD IRB has approved the research,
3. WIRB may then close out its oversight of the study, as appropriate.

Public Dissemination of Information

Public dissemination of information associated with WIRB-approved studies must be reviewed and approved by the UCSD Communications and Public Affairs Office.

UCSD and The Copernicus Group, Inc. (CGIRB)

UCSD and CGIRB have established an agreement whereby CGIRB agrees to assume IRB oversight for some research conducted at or by UCSD. The following describes the scope of research activities for which UCSD will agree to allow CGIRB to assume IRB oversight, and outlines the procedures for obtaining permission to submit to CGIRB. UCSD has sole discretion on a study-by-study basis for allowing CGIRB to assume oversight.

Procedures for Obtaining CGIRB IRB Oversight of a Project

CGIRB will not review research on behalf of UCSD without notification that the UCSD HRPP has cleared the study for CGIRB oversight. The following procedures will be followed:

1. UCSD HRPP staff will screen the application for eligibility for CGIRB IRB oversight. Screening involves use of a checklist to ensure that the following criteria are satisfied:

a) To be eligible for CGIRB IRB oversight

1. The research must be a multi-site (5 sites including UCSD), Phase II, Phase III or Phase IV industry-authored, industry-sponsored, clinical research study or a Phase I industry-authored, industry-sponsored, clinical research study, where the PI has submitted to the UCSD HRPP documentation that the UCSD Institutional Official (IO) for Human Subjects has reviewed the study and is providing discretionary approval for CGIRB oversight of the study. This documentation must also include the name of the PI, the title of the study, and the signature of the IO.
2. The clinical trial agreement must be negotiated through the Office of Clinical Trials Administration (OCTA).
3. Documented approval from the following office:
 - i. UCSD Cancer Center Protocol Review and Monitoring Committee (PRMC) review and approval for trials involving patients with cancer or at a high risk of developing cancer during the study.
4. Documented submission of the study for additional review (may be done in parallel), as appropriate:
 - i. Conflict of Interest Office/Independent Review Committee review and approval for projects that involve a PI, co-investigator or others associated with the study that have a conflict of interest.

b) Research activities that are not eligible for CGIRB IRB oversight

1. Research that has previously received initial review approval from a UCSD IRB.

2. Research on transplant techniques, procedures or other interventions.
 3. Research on pregnant women, human fetuses, or neonates.
 4. Research involving stem cell therapies.
 5. Research involving an infectious agent as the therapeutic agent, gene therapy, recombinant DNA and/or gene transfer.
 6. Research involving research-related radiologic procedures unless the radiologic procedures prescribed by the protocol are within the uses in the approved labeling of the radiologic device(s) and are used for standard of care procedures.
- c) Submission of completed [CGIRB specific application Facesheets](#).
 - d) Submission of documents outlined on the [CGIRB Initial Submission Screening Checklist](#).
2. HRPP staff reviews submitted information and confirms that study is eligible for CGIRB IRB oversight and appropriate documents have been submitted. If the study is found to be not eligible or if appropriate documents have not been submitted, the UCSD HRPP will notify the PI in writing. The PI will respond to the HRPP correspondence with the requested action/documents, as appropriate. If the HRPP continues to find the study not eligible or documentation incomplete, the HRPP may decline the request for CGIRB IRB oversight and assign the study for review by an appropriate UCSD IRB. If a project has been reviewed by a UCSD IRB, the project may not be submitted to CGIRB for review.
 3. If HRPP agrees that the study is eligible for reliance on CGIRB, a clearance notification (“Clearance”) will be sent to the UCSD PI.
 4. The UCSD PI submits the study to CGIRB according to procedures and requirements agreed to between CGIRB and UCSD, with the Clearance attached to the submission.
 5. CGIRB sends the UCSD PI and UCSD HRPP Institutional Contact e-mail when CGIRB has approved the study.
 6. UCSD HRPP will contact CGIRB to release the approval documentation once approval from OCTA and Office of Coverage Analysis Administration (OCAA) has been provided to the HRPP Office.
 7. CGIRB approval does not constitute funding or other institutional required approvals. Should a study involve UCSD review committees/department including PRMC, OCTA, OCAA and/or Independent Review Committee, it is the researcher’s responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens. If UCSD review committee(s) require revision of the consent/assent, an amendment must be provided to CGIRB, and the CGIRB fee for review will be paid by the study, per CGIRB procedures.

UCSD PI Responsibilities

The PI’s responsibilities associated with a study that has received approval from the CGIRB IRB:

1. Notify CGIRB and the UCSD HRPP of all communication to/from the FDA, OHRP or any other federal, state or local agency regarding a CGIRB-approved study.
2. Adhere to UCSD IRB standard policies and procedures (SOPPs) as outlined in this SOPP, CGIRB decisions and requirements, and all applicable federal, state, and local laws and regulations regarding the protections of human subjects in research.
3. Submit post-approval CGIRB-required forms, reports, notices, and direct communications to CGIRB in a timely manner.
4. Assure prompt payment of CGIRB submission fees and UCSD HRPP CGIRB submission review fee.

5. Submit post-approval amendment requests, unanticipated problems or other events that require prompt reporting and final report directly to CGIRB following guidelines provided by CGIRB.
 - a) For amendments involving consent revision(s), two copies of the revised consent (one copy with the changes underlined or bolded and one “clean” copy) should be submitted to the UCSD HRPP for review *before* submission to CGIRB.
 - b) For an amendment that involves study staff changes that include the addition of “key personnel,” the PI is attesting that the key personnel have completed the appropriate UCSD IRB CITI training.
 - c) For all amendments, a copy of the amendment including associated documents and CGIRB-approval documentation should be uploaded to the HRPP project number as soon as possible following CGIRB approval to ensure appropriate information will be available for UCSD departments/committees including Investigational Drug Service.
6. Submit a copy of the Continuing Review Report provided to CGIRB to the UCSD HRPP.
7. Breaches of Confidentiality must also be submitted to the UCSD HRPP as well as other appropriate UCSD Offices including the Office of Research Compliance.
8. The process of study closure will follow CGIRB guidelines; however, a copy of the study closure report should also be submitted to the UCSD HRPP.

Notification Requirements Between CGIRB and UCSD

In addition to the notification requirements specified in the agreement between CGIRB and UCSD, CGIRB shall notify the UCSD HRPP Institutional Contact of the following events within the time period specified:

1. Within 24 hours of receipt:
 - a) Notifications of imminent harms or threats to UCSD research subjects, staff or faculty.
2. CGIRB shall use good faith efforts to provide notice within 24 hours of receipt, but in no event later than five business days from the date of receipt, of the following events:
 - a) Notifications of breach of confidentiality of Protected Health Information (PHI) or any other identifiable medical information,
 - b) Notifications of an injury or potential injury to a research subject,
 - c) Notifications of legal actions or threats of legal actions against UCSD.
3. Within 10 business days:
 - a) Determinations of serious or continuing non-compliance, and unanticipated problems,
 - b) Subject complaints,
 - c) Study closure.

Resumption of UCSD IRB/HRPP Oversight

In the event UCSD decides to resume oversight of a study that has been sent to CGIRB, or is in the process of being reviewed by CGIRB, or has been approved by CGIRB:

1. UCSD HRPP will notify CGIRB of its decision to resume oversight of the study,
2. UCSD will notify CGIRB once the UCSD IRB has approved the research,
3. CGIRB may then close out its oversight of the study, as appropriate.

Public Dissemination of Information

Public dissemination of information associated with CGIRB-approved studies must be reviewed and approved by the UCSD Communications and Public Affairs Office.

UCSD and Quorum Review Institutional Review Board

UCSD and the Quorum Review IRB have established an agreement whereby the Quorum Review IRB agrees to assume IRB oversight for some research conducted at or by UCSD. The following describes the scope of research activities for which UCSD will agree to allow the Quorum Review IRB to assume IRB oversight, and outlines the procedures for obtaining permission to submit to the Quorum Review IRB. UCSD has sole discretion on a study-by-study basis for allowing the Quorum Review IRB to assume oversight.

Procedures for Obtaining Quorum Review IRB Oversight of a Project

Quorum Review IRB will not review research on behalf of UCSD without notification that the UCSD HRPP has cleared the study for Quorum Review IRB oversight. The following procedures will be followed:

1. UCSD HRPP staff will screen the application for eligibility for Quorum Review IRB oversight. Screening involves use of a checklist to ensure that the following criteria are satisfied:
 - a) To be eligible for Quorum Review IRB oversight
 1. The research must be a multi-site (5 sites including UCSD) Phase II, Phase III or Phase IV industry-authored, industry-sponsored, clinical research study or a Phase I industry-authored, industry-sponsored, clinical research study, where the PI has submitted to the UCSD HRPP documentation that the UCSD Institutional Official (IO) for Human Subjects has reviewed the study and is providing discretionary approval for Quorum Review IRB oversight of the study. This documentation must also include the name of the PI, the title of the study, and the signature of the IO.
 2. The clinical trial agreement must be negotiated through the Office of Clinical Trials Administration (OCTA).
 3. Documented approval from the following office:
 - i. UCSD Cancer Center Protocol Review and Monitoring Committee (PRMC) review and approval for trials involving patients with cancer or at a high risk of developing cancer during the study.
 4. Documented submission of the study for additional review (may be done in parallel), as appropriate:
 - i. Conflict of Interest Office/Independent Review Committee review and approval for projects that involve a PI, co-investigator or others associated with the study that have a conflict of interest.
 - b) Research activities that are not eligible for Quorum Review IRB oversight
 1. Research that has previously received initial review approval from a UCSD IRB.
 2. Research on transplant techniques, procedures or other interventions.
 3. Research on pregnant women, human fetuses, or neonates.
 4. Research involving stem cell therapies.
 5. Research involving an infectious agent as the therapeutic agent, gene therapy, recombinant DNA and/or gene transfer.

6. Research involving research-related radiologic procedures unless the radiologic procedures prescribed by the protocol are within the uses in the approved labeling of the radiologic device(s) and are used for standard of care procedures.
 - c) Submission of completed [Quorum Review IRB specific application Facesheets.](#)
 - d) Submission of documents outlined on the [Quorum Review Initial Submission Screening Checklist.](#)
2. HRPP staff reviews submitted information and confirms that study is eligible for Quorum Review IRB oversight and appropriate documents have been submitted. If the study is found to be not eligible or if appropriate documents have not been submitted, the UCSD HRPP will notify the PI in writing. The PI will respond to the HRPP correspondence with the requested action/documents, as appropriate. If the HRPP continues to find the study not eligible or documentation incomplete, the HRPP may decline the request for Quorum Review IRB oversight and assign the study for review by an appropriate UCSD IRB. If a project has been reviewed by a UCSD IRB, the project may not be submitted to the Quorum Review IRB for review.
3. If HRPP agrees that the study is eligible for reliance on Quorum Review IRB, a clearance notification (“Clearance”) will be sent to the UCSD PI.
4. The UCSD PI submits the study to Quorum Review IRB according to procedures and requirements agreed to between Quorum Review IRB and UCSD, with the Clearance attached to the submission.
5. Quorum Review IRB sends the UCSD PI and UCSD HRPP Institutional Contact e-mail when Quorum Review IRB has approved the study.
6. UCSD HRPP will contact Quorum Review to release the approval documentation once approval from OCTA and Office of Coverage Analysis Administration (OCAA) has been provided to the HRPP Office.
7. Quorum Review IRB approval does not constitute funding or other institutional required approvals. Should a study involve UCSD review committees/department including PRMC, OCTA, OCAA and/or Independent Review Committee, it is the researcher’s responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens. If UCSD review committee(s) require revision of the consent/assent, an amendment must be provided to the Quorum Review IRB, and the Quorum Review IRB fee for review will be paid by the study, per Quorum Review IRB procedures.

UCSD PI Responsibilities

The PI’s responsibilities associated with a study that has received approval from the Quorum Review IRB:

1. Notify the Quorum Review IRB and the UCSD HRPP of all communication to/from the FDA, OHRP or any other federal, state or local agency regarding a Quorum Review IRB - approved study.
2. Adhere to UCSD IRB standard policies and procedures (SOPPs) as outlined in this SOPP, Quorum Review IRB decisions and requirements, and all applicable federal, state, and local laws and regulations regarding the protections of human subjects in research.
3. Submit post-approval Quorum Review IRB-required forms, reports, notices, and direct communications to Quorum Review IRB in a timely manner.
4. Assure prompt payment of Quorum Review IRB submission fees and UCSD HRPP Quorum Review IRB submission review fee.

5. Submit post-approval amendment requests, unanticipated problems or other events that require prompt reporting and final report directly to the Quorum Review IRB following guidelines provided by Quorum Review IRB.
 - a) For amendments involving consent revision(s), two copies of the revised consent (one copy with the changes underlined or bolded and one “clean” copy) should be submitted to the UCSD HRPP for review *before* submission to the Quorum Review IRB.
 - b) For an amendment that involves study staff changes that include the addition of “key personnel,” the PI is attesting that the key personnel have completed the appropriate UCSD IRB CITI training.
 - c) For all amendments, a copy of the amendment including associated documents and Quorum Review IRB-approval documentation should be uploaded to the HRPP project number as soon as possible following Quorum Review IRB approval to ensure appropriate information will be available for UCSD departments/committees including Investigational Drug Service.
6. Submit a copy of the Continuing Review Report provided to Quorum Review IRB to the UCSD HRPP.
7. ~~HRPP~~ Certificates of Confidentiality must also be submitted to the UCSD HRPP as well as other appropriate UCSD Offices including the Office of Research Compliance.
8. The process of study closure will follow Quorum Review IRB guidelines; however, a copy of the study closure report should also be submitted to the UCSD HRPP.

Notification Requirements Between the Quorum Review IRB and UCSD

In addition to the notification requirements specified in the agreement between the Quorum Review IRB and UCSD, the Quorum Review IRB shall notify the UCSD HRPP Institutional Contact of the following events within the time period specified:

1. Within 24 hours of receipt:
 - a) Notifications of imminent harms or threats to UCSD research subjects, staff or faculty.
2. The Quorum Review IRB shall use good faith efforts to provide notice within 24 hours of receipt, but in no event later than five business days from the date of receipt, of the following events:
 - a) Notifications of breach of confidentiality of Protected Health Information (PHI) or any other identifiable medical information,
 - b) Notifications of an injury or potential injury to a research subject,
 - c) Notifications of legal actions or threats of legal actions against UCSD.
3. Within 10 business days:
 - a) Determinations of serious or continuing non-compliance, and unanticipated problems,
 - b) Subject complaints,
 - c) Study closure.

Resumption of UCSD IRB/HRPP Oversight

In the event UCSD decides to resume oversight of a study that has been sent to the Quorum Review IRB, or is in the process of being reviewed by the Quorum Review IRB, or has been approved by the Quorum Review IRB:

1. UCSD HRPP will notify the Quorum Review IRB of its decision to resume oversight of the study,

2. UCSD will notify the Quorum Review IRB once the UCSD IRB has approved the research,
3. The Quorum Review IRB may then close out its oversight of the study, as appropriate.

Public Dissemination of Information

Public dissemination of information associated with Quorum Review IRB-approved studies must be reviewed and approved by the UCSD Communications and Public Affairs Office.

UCSD and National Cancer Institute Central Institutional Review Board (CIRB)

UCSD and CIRB have established an agreement whereby CIRB agrees to assume IRB oversight for some cancer research conducted at or by UCSD. The following describes the scope of research activities for which UCSD will agree to allow CIRB to assume IRB oversight, and outlines the procedures for obtaining permission to submit to CIRB. UCSD has sole discretion on a study-by-study basis for allowing CIRB to assume oversight.

Procedures for Obtaining CIRB IRB Oversight of a Project

Projects that can be reviewed by the CIRB cannot be submitted to the CIRB without notification from the UCSD HRPP that the project has cleared the study for CIRB oversight. The following procedures will be followed:

1. UCSD HRPP staff will screen the application for submission to the CIRB for IRB oversight. Screening involves use of a checklist to ensure that the following criteria are satisfied:
 - a) To be eligible for CIRB IRB oversight:
 1. The research must be on the list of CIRB reviewed projects that is available on the CIRB website.
 2. Documented approval from the following office:
 - i. Office of OCAA.
 3. Documented submission of the study for additional review (may be done in parallel), as appropriate:
 - i. Conflict of Interest Office/Independent Review Committee review and approval for projects that involve a PI, co-investigator or others associated with the study that have a conflict of interest.
 - b) Submission of completed [CIRB specific application Facesheets](#).
 - c) Submission of documents outlined on the [CIRB Initial Submission Screening Checklist](#).
2. HRPP staff reviews submitted information and confirms that study is eligible for CIRB IRB oversight and appropriate documents have been submitted. If the study is found to be not eligible or if appropriate documents have not been submitted, the UCSD HRPP will notify the PI in writing. The PI will respond to the HRPP correspondence with the requested action/documents, as appropriate. If the HRPP continues to find the study not eligible or documentation incomplete, the HRPP may decline the request for CIRB IRB oversight and assign the study for review by an appropriate UCSD IRB.
3. If the project includes procedures for purposes preparatory to research involving review of private information, such as preparing a research protocol, assisting in the development of a research hypothesis, or aiding in research recruitment, for instance identifying prospective research participants who meet the eligibility criteria for enrollment review, consent must be obtained or a waiver of consent must be granted. In order to grant a waiver

of consent, the submission of a memo must be done that describes: a) Justification why using these procedures would be considered minimal risk to the potential subjects. b) Justification why a waiver of consent would not adversely affect the rights and welfare of the potential subjects. c) Justification why these procedures could research not practicably be carried out without the waiver. d) Whenever appropriate, a procedure for providing potential subjects with additional pertinent information after participation. The UCSD IRB will determine whether a waiver consent may be granted. Expedited procedures may be used to make this determination.

4. If the procedures also include access to PHI, HIPAA authorization must be obtained, or a partial waiver of individual HIPAA authorization must be granted. In order for a partial waiver of HIPAA authorization to be granted, the memo must also clearly describe: a) A plan to a) protect identifiers from improper use and disclosure; and b) destroy identifiers at the earliest opportunity or provide justification for retaining the identifiers. b) Justification as to why these procedures could not 1. practicably be done without the waiver, and 2. be done without access to, use, or disclosure of the PHI. c) Justification that the privacy risk to individuals whose PHI will be used or disclosed is minimal and reasonable in relation to the anticipated benefit, if any, to the individuals. d) What PHI will be used and who will access, use or disclose the PHI. The UCSD IRB will determine whether a partial waiver of individual HIPAA authorization may be granted. Expedited procedures may be used to make this determination.
5. If HRPP agrees that the study is eligible for reliance on CIRB, a clearance notification will be sent to the UCSD PI that will also include documentation of waiver of consent and/or partial waiver of individual HIPAA authorization, as appropriate.
6. The UCSD PI submits the study to CIRB according to procedures outlined by CIRB.
7. The UCSD PI will submit a copy of the CIRB approval letter and approved consent/assent documents to the UCSD HRPP when CIRB has approved the study.
9. CIRB approval does not constitute funding or other institutional required approvals. Should a study involve UCSD review committees/department including Institutional Biosafety Committee and Human Exposure Review Committee, it is the researchers responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens. If UCSD review committee(s) require revision of the consent/assent, an amendment must be provided to CIRB.

UCSD PI Responsibilities

The PI's responsibilities associated with a study that has received approval from the CIRB IRB:

1. Notify CIRB and the UCSD HRPP of all communication to/from the FDA, OHRP or any other federal, state or local agency regarding a CIRB-approved study.
2. Adhere to UCSD IRB standard policies and procedures, CIRB decisions and requirements, and all applicable federal, state, and local laws and regulations regarding the protections of human subjects in research.
3. Following approval for the project by CIRB, submit a copy of the approval documentation from CIRB and a copy of the consent/permission/assent documents that will be used on the study.
4. Submit unanticipated problems or other events that require prompt reporting to CIRB following guidelines provided by CIRB.
 - a) The PI notifies the CIRB within 7 days of receipt of information related to serious adverse events that meet the criteria of an unanticipated problem.
 1. Submit a copy of report to the HRPP within the same timeframe.

- b) The PI notifies the CIRB within 14 days of receipt of information related to other unanticipated problems and/or serious or continuing noncompliance.
 1. Submit a copy of the report to the HRPP within 10 working day of awareness of the occurrence.
5. For an amendment that involves study staff changes that include the addition of “key personnel,” the PI is attesting that the key personnel have completed the appropriate UCSD IRB CITI training.
6. For all amendments, a copy of the amendment including associated documents and CIRB-approval documentation should be uploaded to the HRPP project number as soon as possible following CIRB approval to ensure appropriate information will be available for UCSD departments/committees including Investigational Drug Service.
7. Breaches of Confidentiality must be submitted to the UCSD HRPP as well as other appropriate UCSD Offices including the Office of Research Compliance within 10 working days of awareness of occurrence.
8. Submit a copy of the study closure report to the UCSD HRPP and study closure approval documentation from the CIRB within 30 days.

Applicable Regulations, Guidelines, and Links

[21 CFR 56.114](#)

[FDA Guidance for Industry – Using a](#)

[Centralized IRB Review Process in](#)

[Multicenter Clinical Trials](#)

[OHRP Correspondence – Use of a](#)

[Centralized Institutional Review Board](#)

[WIRB website](#)

[CIRB website](#)

[CGIRB website](#)

[Quorum Review website](#)

[WIRB Application Facesheets](#)

[WIRB Initial Review Checklist](#)

[CGIRB Application Facesheets](#)

[CGIRB Initial Review Checklist](#)

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