UCSD Human Research Protections Program: Here to help
Why Have a HRPP?

- Compliance with federal policy (DHHS 45 CFR Part 46, FDA 21 CFR Parts 50 and 56)
- Conduct research in an ethical manner with background of historical miscues/malevolence
- Provide education to support research
- Protect research subjects
HRPP

- Individual IRB committees: A, B, C, D, S and the “new” “O” committee
- Monthly meetings (“O” exception)
- 16 staff members
  - 7 analysts currently
  - 2 analysts joining staff
IRB/HRPP Overview

- 6 IRBs: 5 Biomedical, 1 Social & Behavioral Sciences
- More than 3600 active protocols
- More than 200 - 400 items uploaded each day via e-IRB services
IRB Decision Matrix

BENEFICENCE
- Risk/Benefit Analysis
- Experimental Design
- Qualifications of PI

JUSTICE
- Subject selection
- Inclusion/exclusion
- Recruitment

RESPECT FOR PERSONS
- Informed consent
- Surrogate consent
- Assent
- Protection of subjects (especially vulnerable populations)

Human Research Training Symposium 2016
IRB policies and procedures apply to:

- UCSD faculty, staff and students
- Research involving human subjects
- Research conducted completely or partially at UCSD, or approved off-site locations/facilities
- Investigators with agreements with the HRPP to review human subjects research
Criteria for Approval of Research

- Risks minimized
- Favorable risk/benefit ratio
- Equitable subject selection
- Informed consent sought
- Informed consent documented
- Data monitored for safety
- Privacy protected; confidentiality maintained
- Safeguards for vulnerable individuals
IRB: Helping to navigate the road to approval

OHRP
FDA
State laws/regulations
University policies/reviews
Ethical practices
The New Website
May 31, 2016 (Updated June 16, 2016)

**HRPP Office has Moved**

The HRPP Office has moved to the Altman Clinical and Translational Research Institute (ACTRI) building. The new HRPP Office phone number is 858-246-HRPP (858-246-4777). For more updated HRPP Office contact information, please see the [Contacts page](#).

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April 4, 2016

**Additional Sample Informed Consent**

An additional sample informed consent has been created for adult subjects for research where Rady Children’s Hospital - San Diego is a site of performance. The sample consent can be found on the [Biomedical Research forms page](#).

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March 14, 2016

**Additional Sample Informed Consent Forms and Wording About Changes to Harm Clause/HIPAA Authorization**

The [additional information](#) can be found on the [HRPP website](#).
Navigating the HRPP

• Communicating with the office
  • Uploaded documents
  • Phone calls
  • e mails
• Using the website
• HRPP documents
  • The cover letter
    • Consistent with the research plan
    • Provide guidance to IRB
  • Accurate description
Official Documentation

- Official documentation associated with a study are the following:
  - Documents uploaded by Investigator/study staff to the study file via e-IRB Services
  - Documents written by the HRPP provided over the HRPP Director’s signature
  - Documents that include the IRB stamp of approval
  - Documents placed in the IRB study file by HRPP Office personnel.

- E-mails and phone calls are not official documentation.
**Research Plan**

- Read the Research Plan instructions and respond appropriately

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**UCSD Human Research Protections Program**

**New Biomedical Application**

**RESEARCH PLAN INSTRUCTIONS**

These are instructions for completing the Research Plan that is available in MS Word format from the HRPP website.

The headings on this set of instructions correspond to the headings of the Research Plan.

General Instructions: Enter a response for all topic headings.

Enter “Not Applicable” rather than leaving an item blank if the item does not apply to this project.

<table>
<thead>
<tr>
<th>1. PROJECT TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter the project title here. It should match the title entered on the application Facesheets.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. PRINCIPAL INVESTIGATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Include Principal Investigator’s title and department. The UCSD IRB only recognizes one PI per study. This is for identification purposes, to match the Research Plan to the project application Facesheets. The complete list of investigators/key personnel should be entered on the Facesheets, section 7, Other Persons Associated With This Project.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. FACILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>List all locations where the project will be done and any specialized facilities (e.g., MRI, sleep lab) that the project will use. Note that item 9, Research Design and Methods, must clearly indicate where study procedures/activities will be done.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. ESTIMATED DURATION OF THE STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>State the duration of the entire study from opening of study for participant recruitment through end of follow-up, if any (study initiation through closure).</td>
</tr>
</tbody>
</table>
Consent/Permission/Assent

Use the consent, permission and assent samples

Instructions: Choose Edit...Select All, or click and drag to select all text below, then copy this text and paste it into your word processor consent document. Fill in the information noted in blue.

University of California, San Diego
Consent to Act as a Research Subject

[Title of study]

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study? [fill in name of PI (and associates, if appropriate)] is [are] conducting a research study to find out more about [fill in research topic]. You have been asked to participate in this study because you [fill in why the prospective volunteer was asked to participate and how they were selected]. There will be approximately [fill in total of expected participants enrolled at this site] participants at this site and approximately [fill in total expected enrollment at all sites, as appropriate] participants at all sites.

Why is this study being done? The purpose of this study is [fill in with a brief description of the research purpose(s)].

What will happen to you in this study and which procedures are standard of care and which are experimental? If you agree to be in this study, the following will happen to you: [List study procedure(s) here, making clear which procedure(s) or treatment(s) are experimental and which are standard of care].
Most Common Missing/Incomplete Information
Research Plan

• Description of study design and procedures
• Recruitment procedures
• Consenting procedures/waiver of consent/waiver of HIPAA authorization
• Risk/Risk management procedures
Most Common Missing/Incomplete Information
Research Plan (cont.)

- Data confidentiality procedures regarding the protection/storage/destruction/access of data
- Alternatives to participation
- Risk/Benefit ratio
- Role/Qualifications of research team
Common Missing/Incomplete Information
Consent/Permission/Assent Forms

• Statement that study is research and purpose of the research
• PI name and contact information
• Expected duration of study and subject’s involvement including duration of study visit/procedures
• Study procedures and location of procedures
• Alternatives to participation
Common Missing/Incomplete Information Consent/Permission/Assent Forms (cont.)

- Risk of loss of confidentiality and description of how confidentiality will be maintained
- Statement regarding voluntary participation and withdrawal
- Reasonable expected benefits to subjects and others
- UCSD HRPP contact information
- Future use of data/specimens including addition of Moore clause
Most Common IRB request
Consent/Permissions/Assent

- Use of appropriate language including lay terms
  - Adult/Parent – Eighth-grade reading level
  - Adolescent/Child – Language and length that is appropriate to the child’s age, experience, maturity, and condition
Most Common Missing/Incomplete Information
Continuing Review

- Information in the Continuing Review Facepages should be reflected in the Narrative Summary of Progress to Date, as appropriate.
- Number approved for enrollment by UCSD IRB, number enrolled, number needed to complete study.
- Provision of a copy of the stamped consent/permission/assent document(s) currently in use.
Title: Actions that can be taken by the IRB

- **Approve**
  - Satisfies all criteria for approval of research

- **Approve Pending**
  - Can be approved once receipt of requests for clarification/revisions have been reviewed and approved
Actions that can be taken by the IRB (cont.)

- **Defer**
  - Enough information not provided to access the project appropriately

- **Disapprove**
  - Risks to subjects clearly outweighs possible benefits
  - The research would not satisfy criteria for IRB approval even after substantial modifications
IRB Mission

- Provide research oversight
- Support researchers
- Education