1. Institutional Review Board (IRB) website Main Page – begin here

2. Do You Need IRB Review?

3. Start with the definition of Human Subject’s Research:

   Human subjects research is any research or clinical investigation that involves human subjects.

   1) Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

   AND

   2) A human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

   TIP: To determine if your Quality Assessment / Improvement activity (QA / QI) activity requires IRB review, assess whether the activity is designed to develop or contribute to generalizable knowledge. For more information, visit: QI projects vs. QI Research

   For activities that do NOT meet the definition human subject research, submit a self-determination:

   Submission Type:

   Administrative Determination or Registration includes:
   • Non-Human Subjects Research Self-Determination
   • Exempt Self-Determination
   • UCI Requests to Rely on Non-UCI IRB Review

   IMPORTANT! Be sure to select the correct ‘Submission Type’ when completing the application.

   When ‘Submission Type’ is changed, the contents of the form will be cleared and replaced with a set of new questions specific to the submission type. Common questions between different submission types will be saved.

   ○ Administrative Determination or Registration
   ○ Submit a Human Subject Protocol for UCI Institutional Review Board (IRB) Review
   ○ Submit a Human Stem Cell Protocol for Human Stem Cell Research Oversight (hSCRO) Review

4. For human subjects research, determine whether the research qualifies for Exempt Self-Determination (i.e., IRB review not required). UCI allows self-determination for Exempt Categories 1-4ii, with noted exceptions.

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1 Activities designed to develop or contribute to generalizable knowledge are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond a single individual or an internal program (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).
5. For human subject research that does NOT qualify for Exempt Self-Determination, IRB review is required. **Determine the level of risk** involved in your research.

6. All self-determinations and IRB applications must be submitted in **Kuali Research Protocols (KRP)**:
   b. Please carefully follow the guidance text and prompts in KRP, as the form will generate sections to completed based upon the responses given. Failure to complete requisite sections will result in the delay of IRB approval.

7. **Submission Deadlines**:
   a. **Self-Determinations** are NOT reviewed by the IRB and there are NO submission deadlines.
   b. **Exempt and Expedited IRB applications** are reviewed by a subcommittee of IRB members. There are no submission deadlines for Exempt and Expedited research as they are reviewed on a rolling basis **within 4-6 weeks of submission**.
   c. **Full Committee applications are reviewed monthly**. UCI has two biomedical IRBs and one Social/Behavioral IRB. See [HRP Calendar and Deadlines](#) for full Committee meeting dates and deadlines.

8. **IRB Review & Determinations**:
   a. The results of the IRB review can be found once logged into the protocol in **KRP**. Refer to either ‘Administrative Details’ or ‘Admin Notes & Files’.
   b. Full Committee meeting results are posted by 3 pm, the afternoon of the meeting.
   c. The IRB reviews the application and makes a determination:
      - **A - Approval**. The approval letter and stamped approved documents are available in KRP within 3-5 working days. Research studies should not begin until stamped approval documents are released.
      - **M - Minor changes required**. IRB “Action Items” are available in KRP within 10 working days.
      - **T - Tabled for re-review**. The application requires significant clarifications and revisions. IRB “Action Items” are available in KRP within 10 working days.

9. Review your **post approval responsibilities**

10. **Stay Up to Date** on current news and updates by subscribing to the IRB ListServ. Please send a blank email to or-era-join@department-lists.uci.edu.
Summary table:

<table>
<thead>
<tr>
<th>Non-Human Subjects Research (NHSR) Self-Determination</th>
<th>Exempt Self-Determination</th>
<th>Exempt Research that Requires IRB Approval</th>
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<tr>
<td>NOT Human Subject Research</td>
<td>Human Subject Research</td>
<td>Expedited</td>
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<tr>
<td></td>
<td></td>
<td>Full Committee</td>
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<tr>
<td>UCI IRB Review is NOT Required</td>
<td>UCI IRB Review Required</td>
<td></td>
</tr>
<tr>
<td>Administrative Determination Submission Required</td>
<td>IRB Protocol Submission Required</td>
<td></td>
</tr>
</tbody>
</table>

- Activities may begin once the self-determination form is completed.
- The UCI IRB will not review or approve the submission.
- The Education and Quality Improvement Program (EQUIP) will conduct routine quality assurance review of the submissions to ensure accuracy of the self-determinations.
- Amendments are not necessary unless activity no longer qualifies for the self-determination. In that case, amend the submission in Kuali Research Protocols (KRP) to allow for IRB review OR submit a new study in KRP.
- Existing self-determinations completed prior to the launch of KRP (September 2021) remain valid. Do not re-submit in KRP.

Regulations:
- OHRP: [Exempt Review Categories](#)
- OHRP: [Expedited Review Categories](#)
- OHRP: 45 CFR 46.110
- FDA: 21 CFR 56.110

IRB Contact Information:
- IRB Staff Contact Information
- IRB Staff Weekly Office Hours