



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**.

- **Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute [to generalizable knowledge](#)<sup>1</sup>

**AND**

- **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](#) or review the related [Quality Improvement \(QI\) Research vs. QI Projects](#) EQUIP Tips guidance document.



4. For activities that **DO NOT** meet the definition human subject research, UCI Researchers complete a Non-Human Subject’s Research Self-Determination in the IRB submission and Management system [Zot IRB](#) to register their research activity with the IRB prior to initiation:
  - a. Create a new IRB submission in [Zot IRB](#)
  - b. For question 8, complete and attach the HRP-503b [PROTOCOL NARRATIVE - Not Human Research Self-Determination](#).
  - c. For Question 9, click the checkbox to attest your answers quality the activities for non-human subject’s research self-determination
  - d. For question 17, under “Submission Type” select “Non-Human Subject’s Research Self-Determination” and complete related questions on the form.
5. For activities that meet the criteria of human subjects research, determine whether the research qualifies for [Exempt Self-Determination](#) (i.e., IRB review not required, but IRB registration is required). UCI allows self-determination for Exempt Categories 1-4i, [with noted exceptions](#). For additional guidance on exempt self-determination and Exempt Categories, see HRP-312 [WORKSHEET - Exemption Determination](#) document. If your activity appears to meet the criteria then
  - a. Create a new IRB application in [Zot IRB](#)
  - b. For question 8, complete and attach the HRP-503c [PROTOCOL NARRATIVE - Exempt Research Self-Determination](#).

<sup>1</sup> 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).



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- c. For Question 9: click the checkbox to attest your answers qualify study for exempt self-determination.
  - d. For question 17, under “Submission Type” select “Exempt Self-Determination” and complete related questions on the form.
- 6. IMPORTANT!** All Non-Human Subject’s Research Self-Determinations and Exempt Self-Determinations must be registered in [Zot IRB!](#)
- a. **DO NOT SUBMIT self-determinations to the IRB. The study status will remain as "Pre-Submission" and confirmation of registration will not be sent.**
  - b. Should the study sponsor require evidence of this determination, please provide them with a printout/PDF of the application:
- 7.** If there are changes to the self-exempt study such that IRB review is required, a new protocol should be submitted for IRB review with reference to the self-determination.
- 8.** For human subjects research that **does NOT qualify for Exempt Self-Determination**, IRB review is required. Begin the IRB submission process with [Determining the Level of Risk](#) involved in your research.
- 9. Guidance - IRB Application Summary Table:**

<a href="#">Non-Human Subjects Research (NHSR) Self-Determination</a>	<a href="#">Exempt Self-Determination</a>	<ul style="list-style-type: none"> <li>✓ <a href="#">Exempt Research that Requires IRB Approval</a></li> <li>✓ <a href="#">Expedited</a></li> <li>✓ <a href="#">Full Committee</a></li> </ul>
<b>NOT Human Subject Research</b>	<b>Human Subject Research</b>	
UCI IRB Review is NOT Required	UCI IRB Review Required	
Administrative Determination Submission Required	IRB Protocol Submission Required	
<ul style="list-style-type: none"> <li>• Activities may begin once the self-determination form is completed, and the Lead Researcher marks the self-determination attestation. The UCI IRB will not review or approve the study.</li> <li>• The Education and Quality Improvement Program (EQUIP) will conduct routine quality assurance review of the applications to ensure accuracy of the self-determinations.</li> <li>• <a href="#">Modifications are not necessary</a> unless activity no longer qualifies for self-determination. In that case, modify the application in <a href="#">Zot IRB</a> to allow for IRB review OR submit a new study in ZOT IRB.</li> <li>• Existing self-determinations completed prior to the launch of ZOT IRB remain valid. Do not re-submit in ZOT IRB.</li> </ul>	<ul style="list-style-type: none"> <li>• Activities may begin once UCI IRB Approval has been granted.</li> <li>• EQUIP will conduct routine quality assurance reviews of IRB approved protocols.</li> <li>• Minor changes to exempt research do NOT require modifications. Significant changes to exempt research require UCI IRB review and approval. See HRP website: <a href="#">Protocol Modifications</a></li> </ul>	



10. If IRB Review is required, follow the [“How to Submit in Zot IRB” website guidance](#) to ensure your IRB application is complete before you submit.

11. **Submission Deadlines:**

- a. Non-Human Subject’s Research / Exempt 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.

12. **IRB Review & Determinations:**

- a. Detailed information about IRB Committee review, determinations and considerations can be found in the [IRB Reviewer Desktop Reference](#) document.
- b. The IRB reviews the application and makes a determination:
  - a. **Approved.** The approval letter and stamped approved documents are available in Zot IRB within 3-5 working days. Research studies should not begin until stamped approval documents are released.
  - b. **Modifications Required.** IRB “comments” are available in Zot IRB within 10 working days.
  - c. **Deferred for Re-review.** The application requires significant clarifications and revisions. IRB “comments” are available in Zot IRB within 10 working days.

13. Review your [post-approval responsibilities](#)

14. [Stay Up to Date](#) on current news and updates by subscribing to the *IRB ListServ*. Please send a blank email to [or-irb-hrp+subscribe@uci.edu](mailto:or-irb-hrp+subscribe@uci.edu).

**Regulations:**

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

**UCI IRB Additional Guidance:**

- [IRB FAQ](#)
- [HRP Toolkit](#)

**IRB Administrative Staff Contact Information:**

- [IRB Staff Contact Information](#)
- [IRB Staff Weekly Office Hours](#)