IRB EQUIP TIPS –
Do You Need IRB Review? A Quick-Start Guide

V 7.0 September 2024

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.**

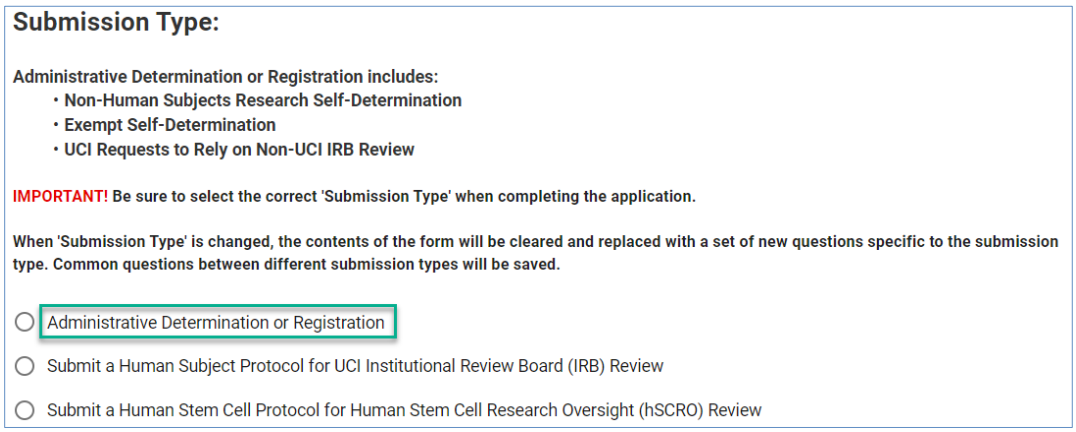
   - **Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute **to generalizable knowledge**[1]

     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 must submit a **Non-Human Subject's Research** Self-Determination in the IRB submission and Management system **Kuali Research Protocols (KRP)** to register their research activity with the IRB prior to initiation:



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).
   a. UCI allows self-determination for Exempt Categories 1-4i, **with noted exceptions.** If your activity appears to meet the criteria, submit an Exempt Self-Determination in KRP.
   b. For additional guidance on exempt self-determination and Exempt Categories, see UCI HRP Policy #12 starting on page 85 of the "**All HRP Policies**" document.

[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).

6. For human subject research that **does NOT qualify for Exempt Self-Determination**, IRB review is required.
    a. Begin the IRB submission process with **Determining the level of risk** involved in your research.

IRB Submission Summary Table:

Non-Human Subjects Research (NHSR) Self-Determination	**Exempt Self-Determination**	**Exempt Research that Requires IRB Approval** **Expedited** **Full Committee**
NOT Human Subject Research	**Human Subject Research**	
UCI IRB Review is NOT Required		**UCI IRB Review Required**
Administrative Determination Submission Required		**IRB Protocol Submission Required**
• **Activities may begin once the self-determination form is completed and submitted. The UCI IRB will not review or approve the submission.** • **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.**		• **Activities may begin once UCI IRB Approval has been granted.** • **EQUIP will conduct routine quality assurance reviews of IRB approved protocols.** • **Minor changes to exempt research do NOT require an amendment. Significant changes to exempt research require UCI IRB review and approval. See HRP website: Protocol Amendments**

7. **All self-determinations and IRB applications must be submitted in Kuali Research Protocols (KRP):**
    a. **Review the "KRP User Guide"** PRIOR to submission.
    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.
    c. When **IRB Review is required**, review the **Protocol Preparation Checklist** to ensure a complete submission.

8. **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.

9. IRB Review & Determinations:
a. The results of the IRB review can be found once logged into the protocol in **KRP**. For review status, refer to the "**Admin Details**" section of KRP for "project status" or "amendment status"
b. Full Committee meeting results are posted by 3 pm, the afternoon of the meeting.
c. Detailed information about IRB Committee review, determinations and considerations can be found in the **IRB Reviewer Desk Reference** document.
d. 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**.**

10. Review your post approval responsibilities

11. 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.

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**
- **IRB Forms**
- **IRB Policies**

IRB Contact Information:

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