UCR IRB–SB Reviewer Guide

Is IRB Review Required?

Research: Does the project involve a systematic investigation which will generate generalizable knowledge?

Yes: Study is research
Then: Are human subjects involved?
Definition: Living individual about whom an investigator conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Yes: Study is research involving human participants
Then: IRB review is required

Application Review by ORI staff, IRB delegate and/or convened meeting

No: Research does not include living human participants
Then: IRB Review not required

No: Project is not research; QA/QI, Program evaluation, etc.
Then: IRB Review not required

Notice of Determination of Activity Letter completed and sent to the researcher/s

Which level of review?

Exempt
Yes: Minimal risk study meeting one of the 6 exempt categories
Then: Issue Exempt determination and ensure consent procedures include the required UCR required elements

Expedited
Yes: Minimal risk study meeting one of the 9 expedited categories
Then: Review can be conducted by ORI staff and/or IRB delegate review

Full Board Review
Yes: Greater than minimal risk
Then: Review will be conducted at a convened IRB meeting following a preliminary review by ORI staff

Main determinations following review:

- Approved (Expedited or Full board)
- Approval with modifications
- Deferral
- Disapproval
- Exempt
- Not Human Subjects Research

Consider Risk…

Definition of Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

UCR Risk Matrix

Group vulnerability: ability to give free & informed consent
Research risk: invasiveness of the research-related procedures

Group vulnerability	Research Risks: Low	Med	High
Low	Exp.(**1**)	Exp.(**1**)	Full (**2**)
Med	Exp.(**1**)	Full (**2**)	Full (**3**)
High	Full (**2**)	Full (**3**)	Full (**3**)

1 = Expedited review; 2 or 3 = Full board review

Risks can include…

- Physical Risks (e.g., bodily contact, administration of a substance)
- Psychological / emotional risks (e.g., feeling uncomfortable or upset)
- Social risks (e.g., economic, loss of status/employability, reputation)
- Legal risks (e.g., arrest or subpoena, recording w/o consent)

Application Review

General Information:

- ✓ Researcher and faculty advisor, if applicable, are listed
- ✓ Funding identified and grant copy included, if needed
- ✓ Additional reviews required (e.g., IBC, SCRO, PRO)

Detailed information about the study is included:

- ✓ Procedures include a clear explanation of how participants will be involved:
  - What participants will be doing
  - Where research will occur
  - How long participants will be involved
- ✓ Lay abstract and hypothesis/research questions are clear
- ✓ Inclusion/exclusion criteria for participant description are detailed
- ✓ Recruitment procedures clearly explained – not by referencing another app
- ✓ Reimbursement/Compensation/Cost identified
- ✓ Consent procedures clearly explained
- ✓ Risks and benefits are identified; researchers should acknowledge even small, remote risks
- ✓ Procedures for mitigating risks are explained
- ✓ Confidentiality procedures outlined; use of encryption software is required for identifiable sensitive data

***If used*, the following are justified:**

- ✓ Vulnerable populations
- ✓ Age, language, gender or ethnicity-related inclusion/exclusion
- ✓ Deception or intentional lack of disclosure – ***may*** require f/b review
- ✓ Waiver or alteration of informed consent

Additional Documents (separate from Application form):

- ✓ Consent and Assent forms (if applicable)
- ✓ Debriefing form (required for Psych Subject Pool or deception)
- ✓ Project roster; training required for lead researcher and faculty advisor for approval to be issued
- ✓ Recruitment materials (e.g., flyers, scripts, emails)
- ✓ Measures (e.g., interview guide, surveys, questionnaires)
- ✓ Access/permission letters for external sites

Important Extras:

- Additional review criteria applicable if funding provided by DOJ, DOD, DOE, ED, or EPA
- Any use of lotteries/raffles/drawings **must** be open to the public and not just participants – use template language
- Researchers travelling internationally should be notified to register their trip with UC Away

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Informed Consent

Required Elements

1. Statement that the study involves **research**, purpose of the study and the expected duration of participation and description of the procedures
2. Reasonably foreseeable risks or discomforts
3. Benefits (*note*: compensation is **not** a benefit)
4. Alternatives identified, if any
5. Confidentiality procedures are provided
6. Compensation/reimbursement
7. Contact information for researchers and ORI
8. Voluntary participation statement
9. If identifiable information or biospecimens are collected, one of the following statements is included:

- Identifiers might be removed from the identifiable private information/biospeciments and that, after such removal, the information/biospecimens could be used for future research or distributed to another investigator for future research without additional informed consent, if this might be a possibility; or
- The information/biospecimens collected, even if identifiers are removed, will not be used or distributed for future research.

Additional Elements – *may* not be required

- ✓ Risks are unforeseeable
- ✓ Termination of participation by the researchers
- ✓ Any additional costs to the participants
- ✓ Consequences of withdrawing
- ✓ Significant new findings
- ✓ Number of participants
- ✓ Biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- ✓ Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- ✓ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

For Exempt studies, UCR required consent elements include:

- ✓ Statement that study involves research conducted by UCR faculty/student
- ✓ Procedures
- ✓ Voluntary participation
- ✓ Contact information for researchers
- ✓ Contact information for UCR IRB

Important Extras

- ✓ Written in group-appropriate reading level
- ✓ Details consistent with application
- ✓ Consent specifically for recordings
- ✓ UCR ORI may access data
- ✓ Funding identified, if any
- ✓ Conflict of Interest identified if relevant
- ✓ Method to provide research results

Waiver or Alteration Consent

Waiving *signed* consent if the study meets the following:

- ✓ It is minimal risk, and
- ✓ It involves no procedures that usually require written consent

OR

- ✓ The principal risk is breach of confidentiality, and
- ✓ The only record linking participants to the research would be the consent document

OR

- ✓ Participants are members of a distinct cultural group or community where signing a form is not the norm,
- ✓ The research presents no more than minimal risk of harm, and
- ✓ Provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

- ***If waiver of signed consent is requested, researchers may be required to provide an information sheet.***
- ***Researchers should document how informed consent was obtained.***

A study is eligible for a waiver or alteration of the *consent process* if it meets the following criteria:

- ✓ It is a minimal risk study
- ✓ The waiver or alteration will NOT adversely affect the rights and welfare of the subjects
- ✓ The research could NOT practicably be carried out without the waiver or alteration
- ✓ If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
- ✓ Whenever appropriate, the participants will be provided with additional pertinent information after participation **OR**
- ✓ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials; **OR**
- ✓ The research or demonstration project is designed to study, evaluate, or examine one or more of the following:
  - Public benefit of service programs
  - Procedures for obtaining benefits or services under those programs
  - Possible changes in or alternatives to those programs or procedures
  - Possible changes in methods or levels of payment for benefits or services

Are the approval criteria met?

45 CFR 46.111 and 21 CFR 56.111

Risk Minimization

- ✓ Risks to participants are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose participants to risk
- ✓ Risks to participants are minimized by using procedures already being performed on the subjects for other purposes
- ✓ Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result

Identifying and Recruiting Participants

- ✓ Selection of participants is equitable

Informed Consent

- ✓ The informed consent process is adequate
- ✓ The documentation of informed consent is adequate

Safety

- ✓ The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants

Privacy and Confidentiality

- ✓ There are adequate provisions to protect the privacy of participants
- ✓ There are adequate provisions to maintain the confidentiality of data

Vulnerability

- ✓ Additional safeguards have been included in the study to protect the rights and welfare of participants vulnerable to coercion or undue influence

Tips for Writing the Review to Researchers

- ➢ Address to both Faculty Advisor and researcher(s)
- ➢ Write directly to the researcher(s) on behalf of IRB-SB
- ➢ Use friendly, collegial tone
- ➢ Use full sentences and not point form
- ➢ Be specific by referencing the sections of concern
- ➢ Comment only on issues that are of concern and avoid remarks that summarize or describe information already in the application
- ➢ Refer to specific guidelines that researchers might find useful in addressing the concerns (e.g., 45 CFR 46, Informed Consent Guide, etc.)
- ➢ When needed, use ORI templated language
- ➢ Include positive comments (e.g., an ethical challenge is handled well)