UCR Research Integrity

IRB Basics

The Who, What, When, Where and How of Human Subjects Research Review

Craig Vaughn & Portia Twidt
Research Compliance Analysts
Office of Research Compliance

Overview

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- Who is the IRB?
- Why is there IRB review?
- When is IRB review needed?
- What needs to be submitted to the IRB?
- How does the IRB review applications?
- Where can I find more resources and information about the UCR IRB?

Who is the IRB?

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- Institutional Review Board (IRB) is charged with the oversight of human subjects research at UCR
  - Currently, one board at UCR
  - The board reviews Socio-behavioral (IRB-SB) & Clinical-biomedical (IRB-CLIN) research
- Mandated to review the ethical acceptability of research on behalf of UCR
- Comprised of faculty, non-scientific and community members
- Administrative support from the Office of Research Compliance (ORC)
  - Website: https://research.ucr.edu/ORC

Why is there IRB review?

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- Required by federal regulations (45 CFR 46)
- History of mistreatment of individuals in research
  - Tuskegee Syphilis study (1932)
  - Willowbrook experiments (1955)
  - Milgram experiment (1961)
  - Tearoom Trade Study (1968)
  - Stanford Prison experiment (1971)
- Belmont Report (1979)
  - Respect for Persons (informed consent)
  - Beneficence (risk/benefit analysis)
  - Justice (equitable selection of participants)
- Common Rule, 45 CFR 46 (1991)
  - Revised Common Rule (January 21, 2019)

Ethical Principles *Belmont*

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Respect for persons –

individual treated as autonomous agent and those with diminished autonomy (vulnerable) are entitled to protection.

Beneficence –

minimize harm; maximize benefits and well being. Obligations of beneficence apply to individuals and society as a whole.

Justice –

fair distribution of benefit and risks.

Applying Belmont Principles

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- Respect/Autonomy
  - Privacy
  - Informed consent
  - Vulnerable populations are protected
- Beneficence/Risk-benefit balance
  - Maximize benefit
  - Minimize harm
  - Employ safeguards
- Justice/Fairness
  - Distribute risk and benefit fairly
  - Ensure people who might benefit are included
  - Avoid placing groups at risk who aren't going to benefit

Why is there IRB review?

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- The purpose of the UCR IRBs is to ensure:
  - The rights and welfare of research participants are adequately protected; and
  - The research is compliant with local, state and federal regulations.

Rules and Regulations

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- The Common Rule
- Vulnerable Subject Regulations
- FDA
- Privacy- HIPAA, FERPA, GDPR
- State Law
- University Policies and Procedures
- IRB Policies and Procedures
- Other states' or countries' laws

When is IRB review needed?

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Definition of Human Subjects Research

Systematic Investigation	• Attempts to answer research questions • Is methodologically driven • Data is analyzed in a disciplined way • Conclusions are drawn from the results
+	
Generalizable Knowledge	• Activities are primarily designed to develop new knowledge or activities as part of a thesis, dissertation, coursework or degree requirements • This can also include knowledge intended to be published or shared outside of the local context
+	

Human Subject	• Living individual(s) about whom an investigator 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

=	
Human Subjects Research	• Requires prior review and approval by an IRB. Contact the Office of Research Integrity to ensure protection of your participants and also to adhere to Federal Regulations surrounding your research

What needs to be submitted?

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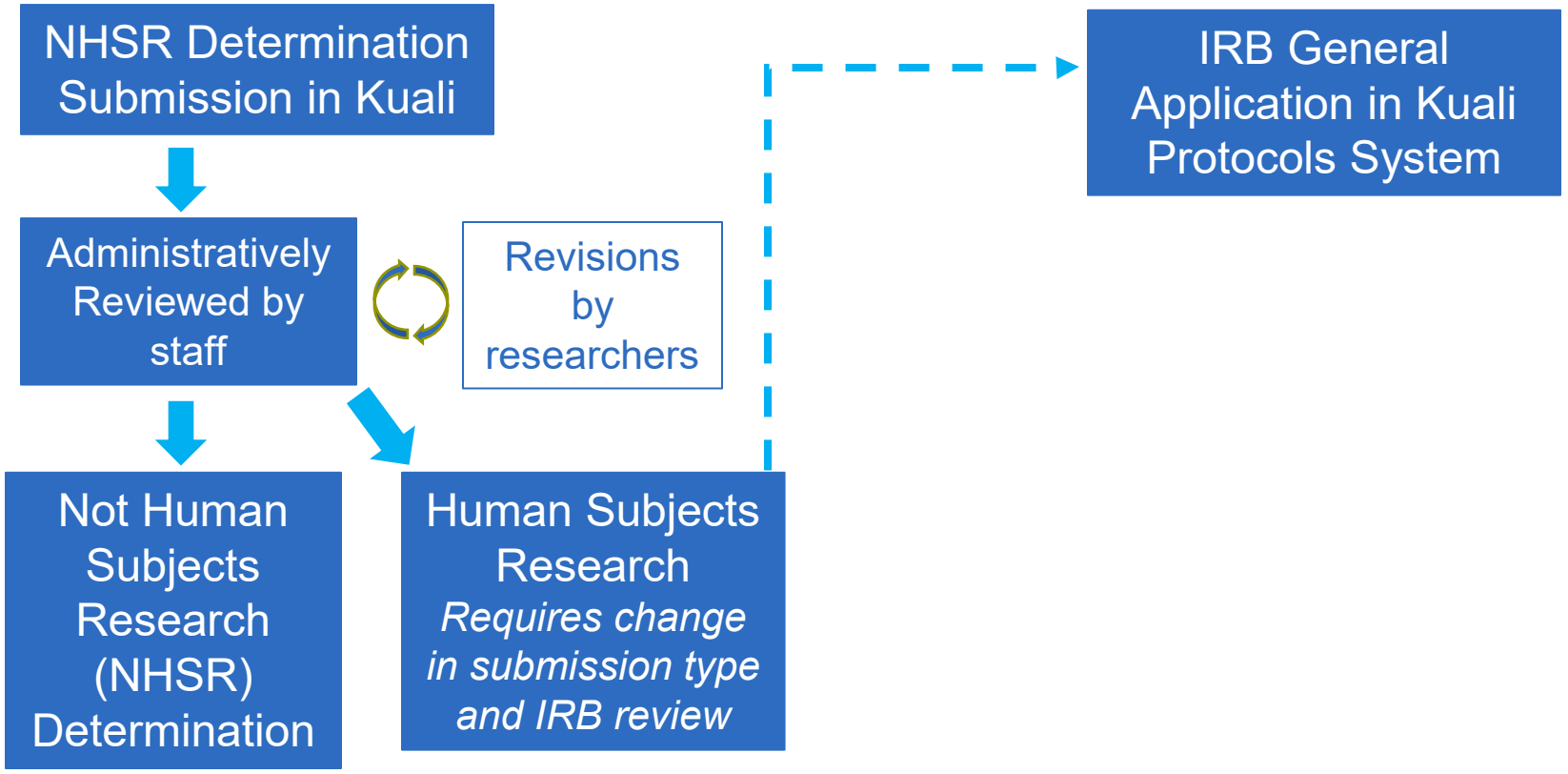
Not Human Subjects Research (NHSR) Determination (Formerly Determination of Activity or DOA) request can be submitted:

- Project is in a gray area (research done for class project)
- Unsure of HSR applicability
- Need formal documentation of a NHSR determination

Submitted in the Kuali system at https://ucr.kuali.co/.



Kuali IRB Protocols – Create and Submit a New Protocol

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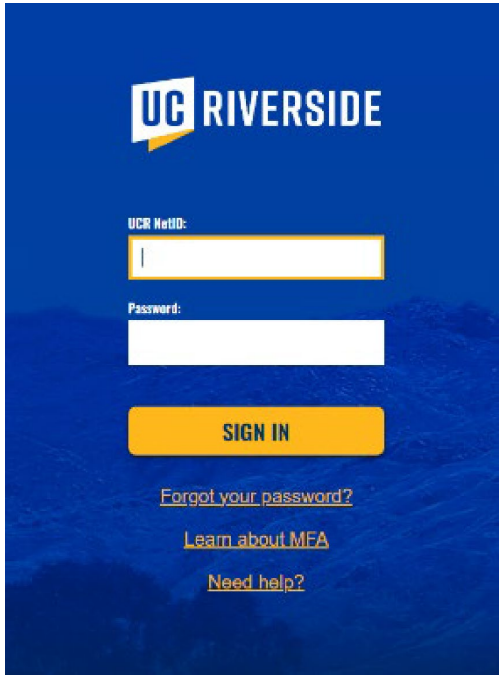
IRB Application in the Kuali Protocols System

- When a project meets the definition of human subjects research, a protocol should be submitted to the IRB for review and approval prior to any human subjects research taking place.
- To submit a protocol to the IRB, login into the Kuali Protocols System with your NetID and password at https://ucr.kuali.co/protocols/portal/protocols
- In the Kuali Protocols System, you can create a protocol submission for IRB review.



How does the IRB review?

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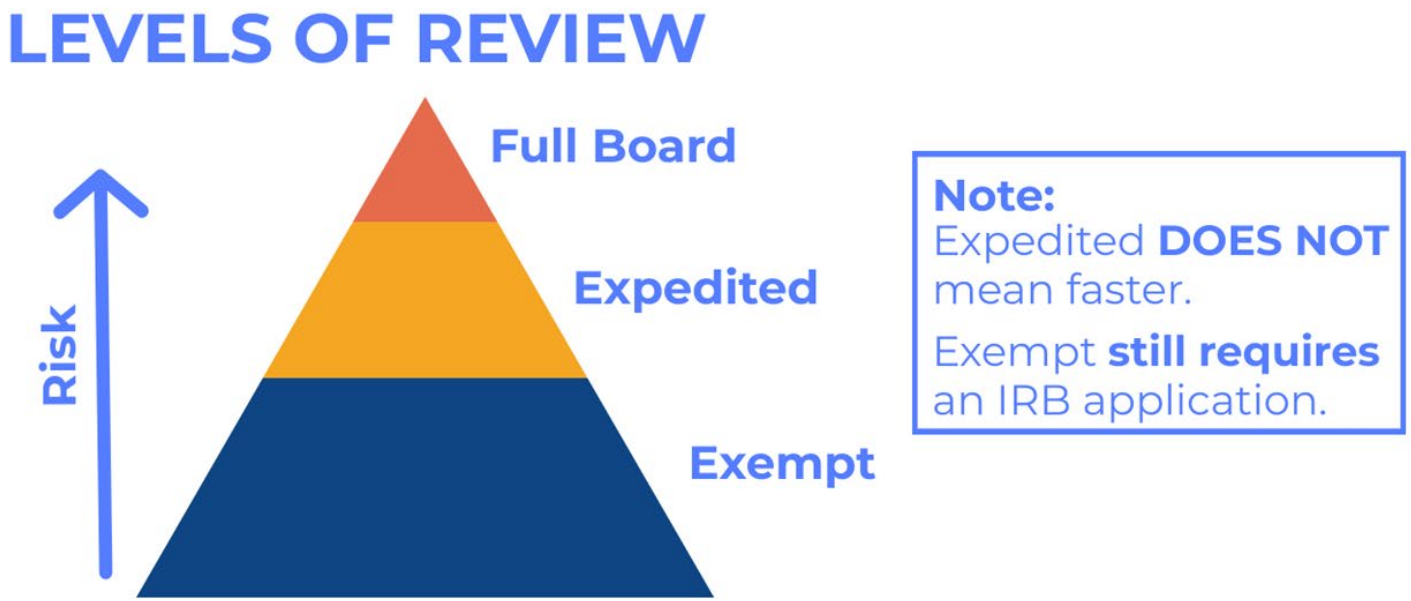
The ***probability and magnitude of harm or discomfort*** anticipated in the research that ***are not greater*** in and of themselves than ***those ordinarily encountered in daily life*** or during the performance of routine physical or psychological examinations or tests.



How does the IRB review?

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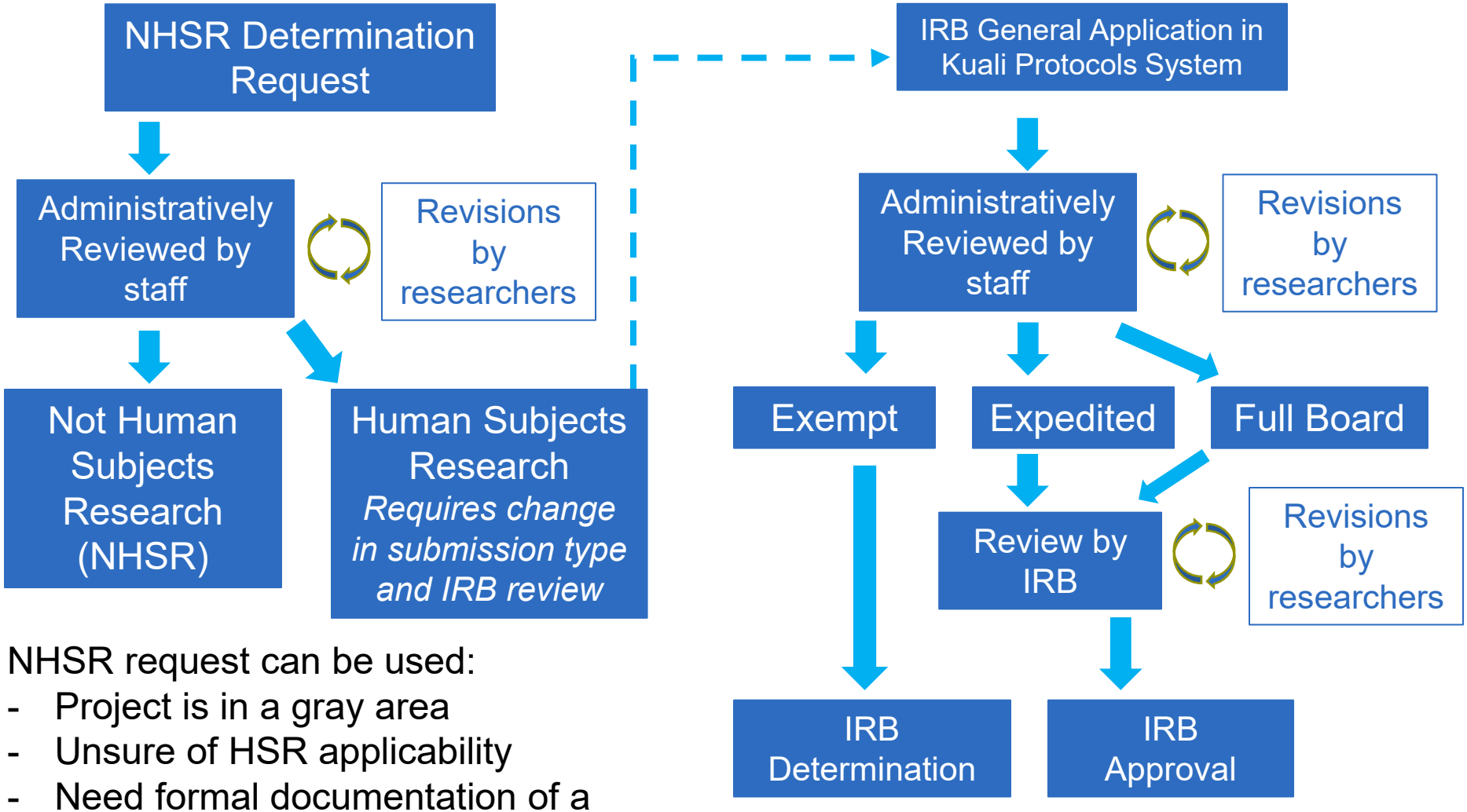

NHSR request can be used:

- Project is in a gray area
- Unsure of HSR applicability
- Need formal documentation of a NHSR determination

Quick Quiz

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What % of new IRB application submitted do you think we reject (i.e., never approve because of an ethical concern)?

A) 50%
B) 30%
C) 10%
D) 1%
E) 0.001%

Questions or Comments?

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Thank you!

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Craig Vaughn, robert.vaughn@ucr.edu

Portia Twidt, portia.twidt@ucr.edu

ORC General Info

irbsupport@ucr.edu