Institutional Review Board (IRB) Process at LMU

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Presentation Goals

1) Describe the goals of the IRB
2) Recall the definition of human subjects research
3) Describe what vulnerable populations are and give examples
4) List the levels of IRB review
5) Explain the elements of informed consent
6) Select the appropriate CITI training

THE BELMONT REPORT

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The *Belmont Report* was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission, created as a result of the National Research Act of 1974, was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with those principles. Informed by monthly discussions that spanned nearly four years and an intensive four days of deliberation in 1976, the Commission published the *Belmont Report*, which identifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects.

Emphasizes three important principles for human subjects research: beneficence, justice, and respect for persons.

Federal Regulations and Policy stemming from Belmont Report

OHRP
Office for Human Research Protections

45 CFR 46 – DHHS Policy for Protection of Human Research Subjects- Subpart A

"The Common Rule" – Revised and implemented on January 21, 2019

The basic policy provides requirements such as the composition and function of the IRB, criteria for IRB approval, informed consent requirements, and definitions.

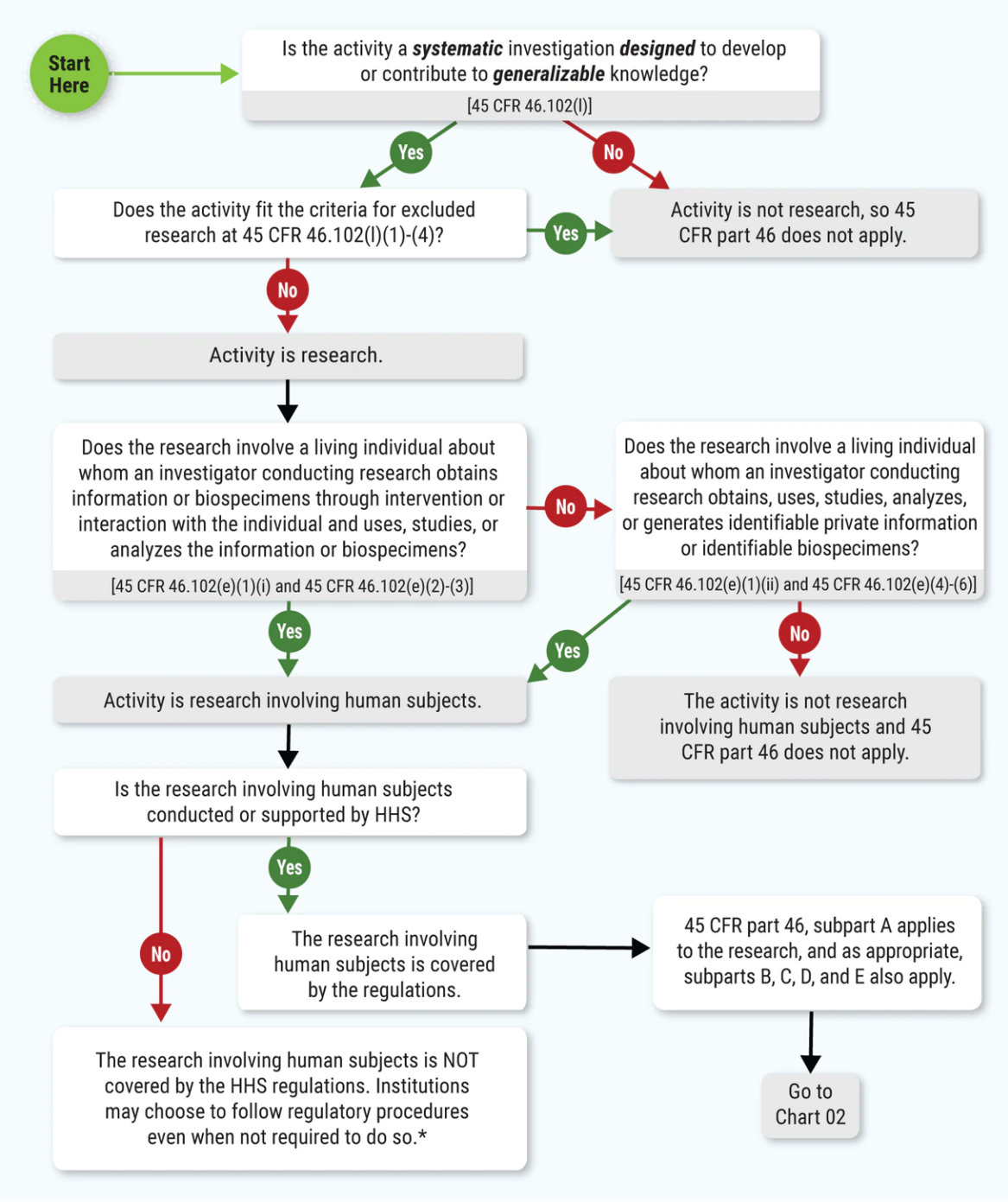
Institutional Assurances of compliance—LMU holds a Federal-wide Assurance agreement with HHS/OHRP

What is an IRB?

- Institutional Review Board (IRB) is a group that has been designated to review and monitor research involving human subjects.
- According to federal regulations, an IRB must contain at least 5 members, at least one who is primarily concerned with scientific areas, at least one who is primarily concerned with non-scientific areas, and at least one who is not affiliated with the institution.
- At LMU, we have twelve faculty members who represent each of the academic units and one community representative (not an LMU employee or affiliate).

What are the goals of the IRB?

- IRB's oversee human subjects research to ensure compliance with federal regulations.
  - Protects research participants
  - Protects researchers
  - Protects LMU
- IRB members guide and advise researchers to design studies that minimize risk



From HHS.gov/ohrp

Human subject means a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction and uses, studies, or analyzes the information or specimens; or obtains, uses, studies, analyzes, or generates identifiable, private information or identifiable biospecimens.

What is meant by the term vulnerable population? (Belmont principle of justice)

- Vulnerable populations include:
  - Children (all minors younger than 18 years of age in most states must also have parental consent)
  - Pregnant people
  - Institutionalized individuals (e.g., prisoners, individuals in group homes, nursing homes, mental institutions)
  - Cognitively impaired individuals

Other considerations may also count as "Vulnerable"

- Language
  - Consent forms may be translated but answering questions may still be limited
- Culture
  - May feel compelled to agree to participate or fear of signing anything
- Educationally, economically disadvantaged
  - Ability to comprehend the research, unduly influenced by payment for participation, literacy
- Transient Cognitive Impairment
- Substance Use
- Health Status
- Students
  - Coercion, unduly influenced by extra credit for example
- Employees
  - Coercion, concerned about consequences

Levels of Review for IRB Protocols (Belmont principle of beneficence)

- **Exempt:** **Minimal risk** for the study participants – reviewed by the chair or designee, quick turnaround time NOTE: Exempt does not mean exempt from review.

- **Expedited:** No more than **minimal risk,** reviewed by the chair and at least one IRB member

- **Full:** **More than Minimal Risk** or vulnerable populations (children, pregnant women, prisoners); longer turnaround time, must be reviewed by full committee and discussed at monthly meeting--allow 4 weeks
- NOTE: Review may take longer if application is not complete.

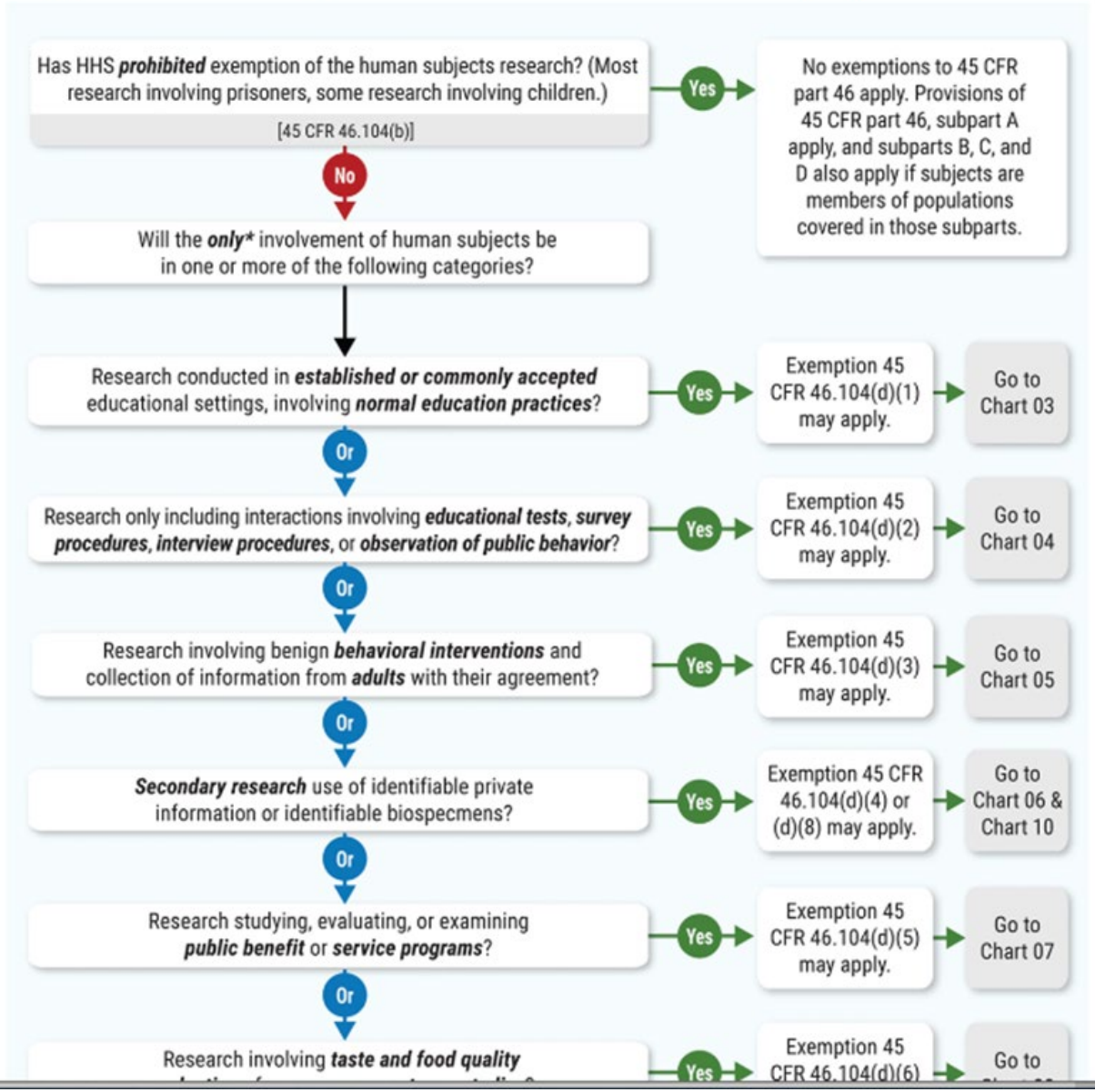
Definition of minimal risk

”probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in daily life or doing the performance of routine physical or psychological examination or tests” 45CFR46

Minimal Risk Considerations

- Anonymous surveys are generally considered minimal risk, but if the questions reveal potentially harmful information AND confidentiality is not maintained, the risk may be greater.
- Administration of surveys or procedures by trained personnel minimizes risk, too.
- Timing may also be important because it reflects participants state of mind or circumstances.

Chart 02: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.104(d)?



Expedited Categories

- Research on drugs or devices for which an investigational new drug or device exemption is not required
- Collection of blood samples from healthy individuals with limits
- Prospective collection of biological specimens by non-invasive means (saliva, swabs, dental plaque, etc.)
- Collection of data by non-invasive procedures routinely employed in clinical practice (MRI, EEG, ultrasound, etc.)
- Research involving materials (data, records, etc.) that have been collected or will be collected solely for non-research purposes
- Collection of data voice, video, digital or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (motivation, identity, language, communication, cultural beliefs , etc.) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (some may be exempt)

Full Review

Full Board: According to 45 CFR 46.110(b), full board review is required of all research studies that are neither exempt, nor subject to expedited review.

- IRB Committee must review and vote at a fully convened meeting.
  - Meeting held once a month.
  - Submissions must be processed at least one week prior to meeting.

- Deception/ Non-disclosure of information to subjects.

- Studies with greater than minimal risk.

- Special/ Vulnerable Populations.

Privacy and Confidentiality

- *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data"* 45 CFR 46.111(a)
- Breaches of privacy and/or confidentiality are the main risk in social-behavioral research or research that is no greater than minimal risk.
- Privacy concerns people (e.g. revealing a subject's participation to others); confidentiality concerns data (e.g. sharing identifiable collected data without permission).

Required elements of informed consent –
BASIC ELEMENTS 45 CFR 46.116(a)
Belmont principle of respect for persons

- *Statement that the study involves research*
- *Reasonably foreseeable risks/discomforts*
- *Reasonably expected benefits*
- *Disclosure of appropriate alternative procedures*
- *Confidentiality of identifiable records (HIPAA)*
- *For high risk, what happens if injured in research*
- *Whom to contact about research, problems, or concerns*
- *Participation is voluntary*, refuse to *participate without penalty,* and *discontinue participation at any time*

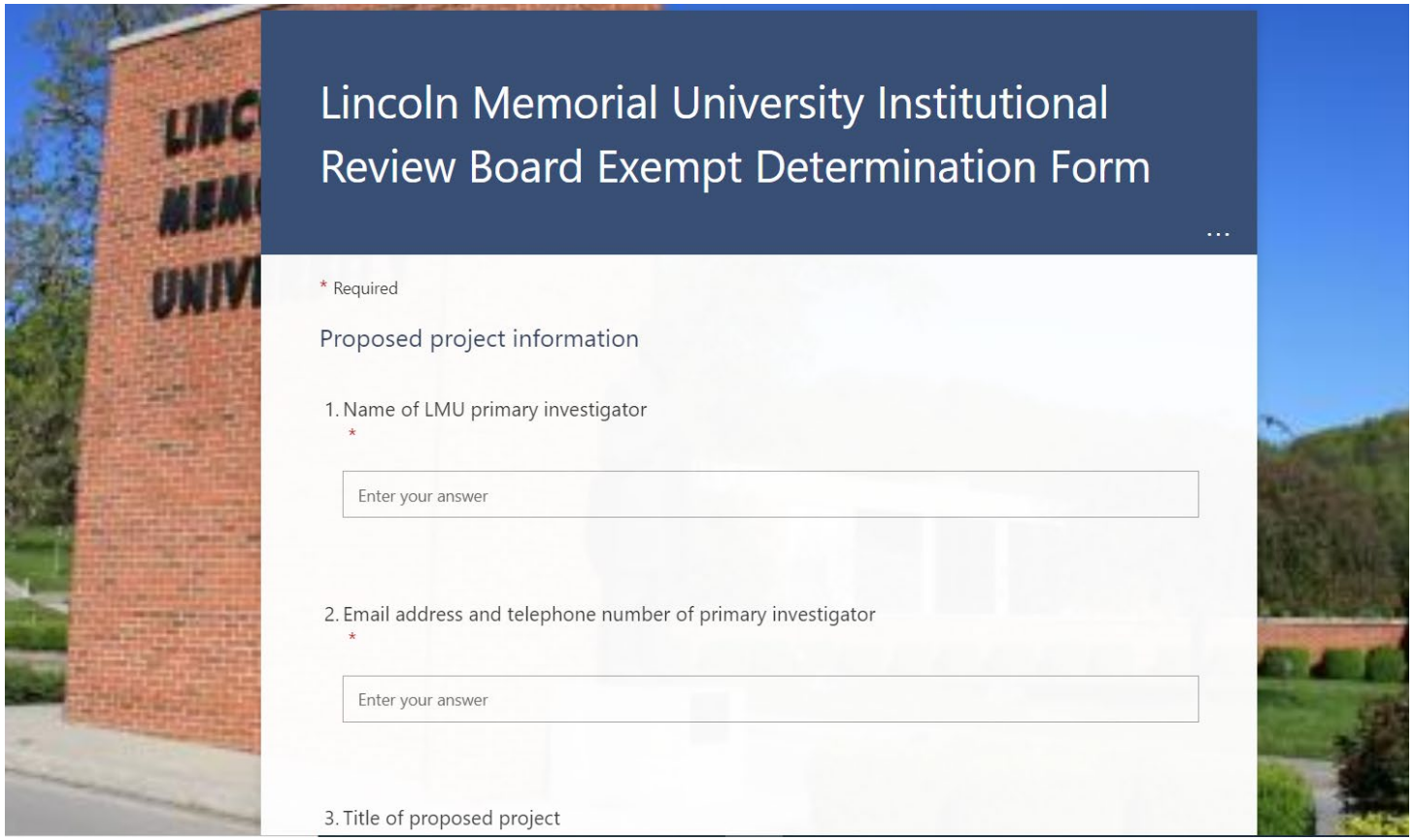
Application Form

https://www.lmunet.edu/orgsp/institutional-review-board-irb/forms

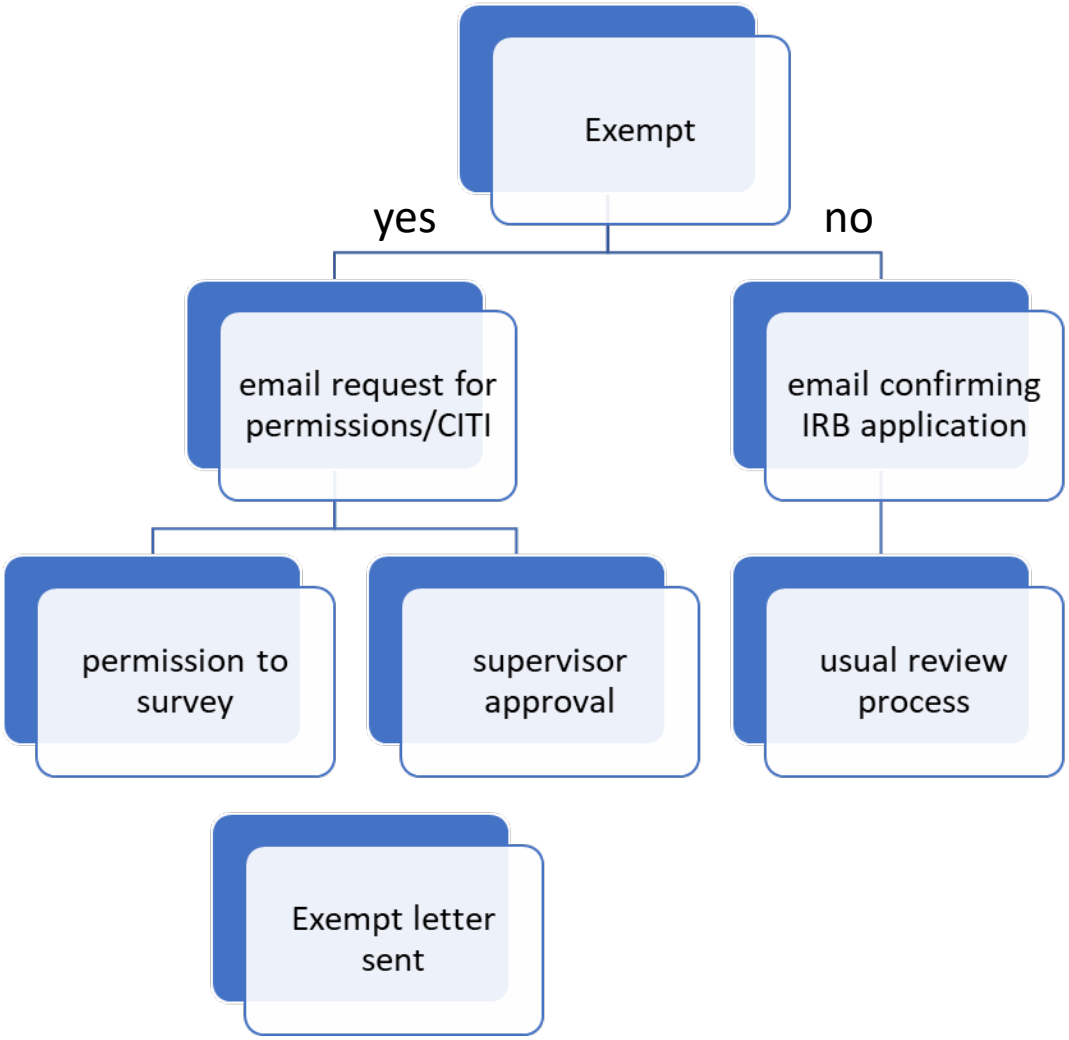
- Project Title
- Type of review—IRB makes final determination
- Project dates—approval date by IRB vs. researcher's planned dates
- Principal Investigator, co-investigators, faculty sponsor, research assistants, with signatures
- IRB Training and Certification dates
- Student/Outside researcher information - Signature of a university sponsor
- Funding/Conflict of Interest statement
- Research statement: purpose of study and/or research question(s)
- Participants—subjects, number of subjects, method of solicitation
- Informed consent (consent and assent forms), method to obtain
- Data & Consent collection methods—data with identifiers, how confidentiality/anonymity will be protected, how and where will the data to be stored
- Methodology details—specifics regarding contact, selection and exclusion, consent and assent process, data instruments (permission or purchase issues), distribution and collection of instruments, location with permission to distribute at school, agency, company
- Risk factors
- Submission of all materials—recruitment flyers and emails, informed consent, data collection instrument(s), letters of permission, debriefing, media to show to participants

Screening Tool

https://forms.office.com/Pages/ResponsePage.aspx?id=hxrv069d30uhG0BBL0orPNEzWcs2sOxOpU_7OE2FXfVUQ1cwUzk2MDdXODVHWUFOT01MRDI0MkxPWC4u



After filling out the screening form



What are Reviewers Looking For? (45 CFR 46.111)

- **Risks** to subjects are **minimized**.
- Risks are **reasonable** in relation to anticipated benefits.
- Selection of subjects is **equitable**.
- **Informed consent** is sought from each subject and is appropriately documented.
- The researcher has adequate **training** and experience and there is not a **conflict of interest**.
- **Privacy** and **confidentiality** of subjects is protected.
- Additional safeguards are included for **vulnerable populations**.
- **Data** collection is **monitored** to ensure subject safety.
- The **research methodology is reasonable** and will accomplish the purpose of the study.
- Subjects are fully **debriefed** if deception used.

IRB Training Requirements

- All persons named on the application (Principal Investigators, Co-PIs, Faculty Sponsors, and Research Assistants) must complete online CITI training and submit proof of completion along with their IRB application (must be updated since January 21, 2019)
- Members of the IRB are also required to complete specialized training modules through CITI and/or the University.
- LMU location: MyLMU - Quicklinks - CITI
- https://about.citiprogram.org/series/human-subjects-research-hsr/?gclid=EAIaIQobChMI_cWy-674-AIVJ2xvBB0oxwvmEAAYAiAAEgK71fD_BwE
- Register to complete the modules for Social-Behavioral-Educational or Biomedical Tracks

Questions