Criteria for IRB Approval

Research Compliance Office

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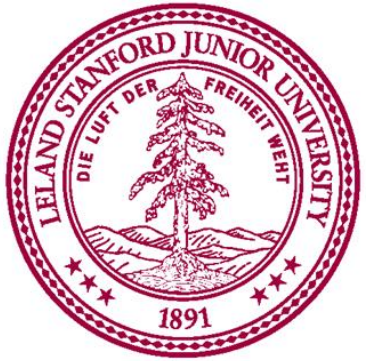

Criteria for Approval

Recommendation of this protocol for approval means that the member has determined that the following criteria have been met under 45 CFR 46.111 (a)(b); 21 CFR 56.111 (a),(b),(c)

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought from each prospective subject
- Informed consent will be appropriately documented
- When appropriate, data collection is monitored to ensure subject safety
- When appropriate, privacy of subjects and confidentiality of data are protected
- When appropriate, additional safeguards are included for vulnerable populations

The IRB member also confirms that, when appropriate:

- Informed consent will be obtained from the participant or the participant's legally authorized representative 45 CFR 46.111(a)(b); 21 CFR 50.20, and, the consent from includes the required elements of consent 45 CFR 46.116 (a),(b); 21 CFR 50.25 (a),(b)
- Informed consent will be documented using the long form consent document 45 CFR 46.117 (a), (b)(1); 21 CFR 50.27 (a)and/or informed consent will be documented using the short form consent document 45 CFR 46.117(a),(b)(2); 21 CFR 50.27 (b)(2).
- If the requirement to obtain a signed consent form will be waived, the protocol includes and justifies protocol specific findings 45 CFR 46.117(c)(1) or 45 CFR 46.117(c)(2); 21 CFR 56.109(c)(1).

Adapted from §45 CFR 46.111(a)(b); 21 CFR 56.111(a),(b),(c)

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1. Risks to Subjects Minimized

- Procedures consistent with sound research design and do not unnecessarily expose subjects to risks, and

- Whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes.

OHRP 45 CFR 46.111/FDA 21 CFR 56.111(a)(b)(c)

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2. Evaluating Risks in Relation to Benefits

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

OHRP 45 CFR 46.111/FDA 21 CFR 56.111(a)(b)(c)

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3. Equitable Selection of Subjects

- Subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

- Diversity, equity, and inclusion within the target population to fairly distribute the burdens and benefits of research. IRB should consider:
  - where and how recruitment is being conducted
  - inclusion for those who do not speak English
  - gender inclusive language in consents such as regarding childbearing risks

OHRP 45 CFR 46.111/FDA 21 CFR 56.111(a)(b)(c)

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4 and 5. Informed consent

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative,
- Informed consent will be appropriately documented or appropriately waived

OHRP 45 CFR 46.111/FDA 21 CFR 56.111(a)(b)(c)

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And When Appropriate

- Data collection is monitored to ensure subject safety
- Privacy and confidentiality of data are protected
- Additional safeguards included for vulnerable populations

OHRP 45 CFR 46.111/FDA 21 CFR 56.111(a)(b)(c)

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Questions?

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