SOP 3.08 – Flexibility Policy

1. Objective
   To describe the situations in which the UNLV Flexibility Policy is utilized in the review, administration, and oversight of research involving human subjects. The goal for the Flexibility Policy is to reduce administrative burden for researchers, IRB chairs and members, and Office of Research Integrity – Human Subjects (ORI-HS) staff.

2. General Description
   The UNLV ORI-HS/IRB has chosen to limit the application of the federal regulations for the protection of human subjects to research that receives federal funding or is federally regulated. Research projects that are outside the scope of these federal regulations are afforded equivalent protections with this Flexibility Policy.

   The Flexibility Policy is limited to research studies that involve no greater than minimal risk to subjects. If a study obtains federal funding or if the risk level of the study changes, the Principal Investigator must inform the ORI-HS. This may require the PI to submit a new proposal for review through the IRB review process. Studies reviewed under this policy remain subject to UNLV’s ORI-HS/IRB policies and review.

Definitions

  Research - is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." Research includes, but is not limited to, surveys and interviews, behavioral investigations, retrospective reviews of data, experiments with blood and tissue, demonstration and service programs, and clinical trials.

  Human Subject - means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or collects identifiable private information. "Human subject" under FDA regulations includes an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A "subject" may be a healthy human or a patient.

  Clinical investigation - means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) or where the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
**Minimal Risk** – the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life, or during performance of routine physical or psychological examinations or tests and any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation.

**Prisoner** - is defined to include any individual involuntarily confined or detained in a penal institution (45 CFR 46.303.c). The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Inclusions to the Flexibility Policy:**
- Studies that involve no greater than minimal risk
- Studies with no federal funding or plans for submitting for federal funding
- Equivalent protections commensurate with risk level

**Exclusions to the Flexibility Policy:**
- Funding (exceptions may apply for non-federally funded research)
- Studies involving clinical interventions
- Studies needing ancillary reviews (radiation safety, biosafety, conflict of interest, School of Medicine Scientific Review Committee, School of Medicine Executive Resourcing Committee)
- Studies using prisoners as subjects
- Studies required to register with ClinicalTrials.gov
- Studies held for FDA inspection (i.e., a clinical investigation involving a FDA regulated drug or device) or studies preparatory to a FDA regulated clinical investigation

**3. Roles & Responsibilities**
Execution of SOP: Principal Investigator (PI)/Research Team Members, Office of Research Integrity – Human Subjects (ORI-HS) Staff, IRB Chairs/Co-Chairs.

**4. Procedures**
The Flexibility Policy establishes a separate review group named Non-Committee Review. Submissions can be made to the Non-Committee Review group with the Non-Committee Proposal Form. In order to qualify, research studies must meet the inclusion criteria but not any of the exclusion criteria listed above.

Subject protections and ethical standards will apply. Standard continuing review will not be required and no study expiration date will be set. Standard federally regulated criteria for informed consent will not be required for studies reviewed under this policy. Studies may include an informed consent process and information sheet equivalent.

Non-Committee Reviews will be conducted by experienced ORI-HS staff members. If the reviewer determines that informed consent is necessary or if a study is modified to contain any of the exclusion criteria.
criteria listed above, the current study must be closed and a new study submitted to proceed through the IRB review process.

5. References
Flexibility Coalition. Retrieved July 9, 2019, from https://oprs.usc.edu/about/initiatives/flexibility-coalition/

Non-committee review proposal form

Non-committee reviewer form