Flexibility Policy

This policy establishes flexibility in review, administration, and oversight of human subjects research. USC will also be encouraging and supporting additional opportunities for flexibility when encountered.

The University of Southern California has chosen to limit the application of the federal regulations for the protection of human subjects to federally funded or federally regulated research. Research projects outside the scope of these regulations will nonetheless be afforded equivalent protections. This Flexibility Policy is limited to studies involving no greater than minimal risk. Should a study approved under the Flexibility Policy obtain federal funding or should the risk level change, it is the responsibility of the Principal Investigator to notify the IRB. Under no circumstances will federally funded or FDA regulated research be reviewed under this policy. The IRB may make exceptions to this policy for funded research that is not federally funded. Studies reviewed under this policy remain subject to USC IRB policies and review. Application of this policy will be at the discretion of the USC Institutional Review Boards (IRBs).

Inclusion and exclusion to this policy are described below.

Exclusions to Policy:

- Studies involving clinical interventions[1]
- Studies necessitating informed consent
- Ancillary reviews required (radiation safety, biosafety, conflict of interest, Cancer Center Clinical Investigations Committee)
- Funding (exceptions may apply for non-federally funded research)
- Research funded or otherwise regulated by a federal agency that has signed on to the Common Rule, including all agencies within the Department of Health and Human Services
- Classified research (research procedures and/or results are legally knowable only by individuals with United States government security clearance)
- Studies with FDA-regulated components
- Projects where a student is paid/supported from a federal training grant or otherwise paid/supported directly from the Faculty Advisor's federal funds
- Studies with contractual obligations or restrictions that preclude eligibility in this policy
- Studies using prisoners as subjects[2]
- Studies seeking or obtaining Certificates of Confidentiality
- Studies required to register to ClinicalTrials.gov

[1] For the purposes of this policy, clinical intervention is defined as one that is intended to change or assess a health-related processes and/or endpoint. Examples include the use of drugs, dietary supplements, devices, blood draws, imaging (e.g., DXA, x-ray), delivery systems (e.g., telemedicine, face-to-face), diet, cognitive therapy, exercise, and any intervention that includes treatment, prevention, or diagnostic strategies.

[2] Incidental incarceration may not require subpart C regulations. The subjects continued participation is under the investigators overall responsibility to protect the rights and welfare of subjects.

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Inclusions to Policy:

- Educational tests, surveys, interviews, and observations of public behavior
- Normal educational practices in established or commonly accepted educational settings that are not likely to adversely impact students' opportunity to learn required educational content, or the assessment of educators who provide instruction
- Benign behavioral interventions[3]
- Behavioral games or tasks
- Studies requiring performance of tasks that incur no risk
- Online surveys, in-person focus groups, and/or interviews involving minors
- Studies of leadership traits of non-public, non-elected officials
- Studies involving focus groups, oral histories, ethnographies,
- Studies utilizing commercially available measurement technology such as eye-tracking
- Medical record reviews where data was extracted from records
- Data analysis of information already collected from court records

Additional inclusions may be found in the section on Subparts B, C, and D

Minimal-risk review:

This policy creates a new approval category not subject to federal regulations that applies to minimal risk research (otherwise known as expedited and exempt). Subject protections and ethical standards will apply. Continuing review will not be required. Informed consent will not be required of minimal-risk studies eligible for the flex policy. However, should the reviewer determine informed consent is necessary; the study should not be flexed.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research 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 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.

Minimal risk studies approved under the Flex Policy will require an amendment if there is a change in risk, funding, or scope.

Research eligible for minimal-risk research does not require continuing review; however, a HIPAA waiver may still be required.

[3] Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing (Common Rule, 2018).

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Protected Categories Eligible for Minimal-Risk Review

Minimal-risk review may be applied to minimal-risk research involving pregnant women, prisoners, or children. The IRB confirms the research qualifies as minimal-risk.

- Subpart B- Pregnant Women, Human Fetuses and Neonates
  The Subpart B regulations for pregnant women and fetuses are not applied when a pregnant adult subject is involved in minimal-risk research or research involving procedures that hold the prospect of direct benefit to the fetus only– paternal consent is not required.

- Subpart C- Incidental incarceration
  The Subpart C regulations for prisoners are not applied when a subject becomes incarcerated during the course of participation in research. The subject's continued participation is part of the investigator's overall responsibility to protect the rights and welfare of subjects.

- Subpart D – Children involved as subjects in research
  The Subpart D regulations are not applied when a minor subject is involved in minimal-risk research, anonymous research– parental consent is not required.

Investigator Obligations: transmitted in determination letter

For any project that qualified for the minimal-risk review, it is the responsibility of the Principal Investigator to report to the IRB:

- Any changes in risk or project scope

- Any changes in funding status. If the PI receives federal funding of a study that originally qualified under this Flexibility Policy, the PI must notify the IRB. The study will no longer be eligible for minimal-risk review. A new application must be submitted for IRB review.

Reporting to Federal Entities:

- Research projects that are not federally funded or federally regulated are not subject to the same federal reporting requirements as federally funded projects which must report to the appropriate federal agency. Studies reviewed under the Flexibility Policy do not have an obligation to report to a federal agency but must adhere to USC reporting policies.

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Monitoring:

- Each year, a portion of studies reviewed under this policy will be reviewed annually to ensure that minimal- risk eligibility is maintained and no funding has been obtained.
- Results of monitoring activities will be archived annually.

Administrative Flexibility

The following additional regulatory flexibilities are afforded to non-federally funded, minimal-risk research as determined appropriate by the IRB.

- Outside institutions determined to be engaged will not be subject to the filing of an IRB Authorization Agreement, unless required by the outside institution. If the outside institution requires an IRB Authorization Agreement, USC will comply with their requirements. Additionally, USC may require an IRB Authorization Agreement at its discretion
- The determination of engagement is at the discretion of the IRB.
- For research that involves a nonaffiliated investigator and/or an outside institution that is considered engaged[4], unaffiliated investigators are required to sign an Unaffiliated Investigator Agreement, but the Institutional Official (IO) signature is not required. The signature of the IRB Director or IRB Chair can substitute the IO signature.
- The IRB Director is designated to sign, on behalf of the IO, requests for Certificates of confidentiality, IRB Authorization Agreements and, Unaffiliated Investigator Agreements.
- Designate IRB staff as Expedited/Exempt reviewers and IRB members
- Empower IRB staff to perform all non-committee functions

[4] An Institution becomes "engaged" in human subjects research when its employees or agents: 1)intervene or interact with living individuals for research purposes, 2) Obtain individually identifiable private information for research purposes, 3) Obtain the informed consent of human subjects, 4) receives a direct HHS award to support such research.