Flexibility Policy

The University of Southern California has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research, the terms of which allow an appropriate level of flexibility for research involving no greater than minimal risk. Unfunded research projects outside the scope of the FWA and reviewed under the flexibility policy will be afforded protections commensurate with risk as determined by the IRB. This policy is limited to unfunded studies involving no greater than minimal risk. Should the funding status of a study reviewed under this policy 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.

All human subjects research projects conducted or supported at USC remain subject to USC IRB policies and review, whether they qualify for this policy or not. When questions of applicability arise, studies will be reviewed on a case by case basis. For additional information, see USC Flex Implementation by Campus.

Inclusion/exclusion of any research project will be at the discretion of the USC Institutional Review Boards (IRBs).

Policy:

This policy applies to research projects that are not funded. Projects that receive federal support are subject to the terms of the USC Federalwide Assurance and are not reviewable under this policy.

This policy creates exempt categories 7 and 8, not found in the federal regulations, for projects that do not directly conform to a specific exempt category according to 45 CFR 46. These projects will be reviewed using an approval process identical to that used for exempt research categories 1-6 under 45 CFR 46.101(b).

This policy also provides three-year approvals for nonexempt unfunded projects that are not FDA regulated involving no greater than minimal risk. These projects will be processed under expedited review according to 45 CFR 46.110 but approval will be valid for three years, rather than one as required in 45 CFR 46.109(e).

Research projects that meet the federal definition for human subject research and exceed minimal risk are subject to the criteria for approval articulated in the regulations at 45 CFR 46 and/or FDA regulations as applicable and do not qualify for review under the flexibility policy.

Flexibility Policy

Mandatory Exclusions to Policy:

- Funding (exceptions may apply for non-federally funded research)
- No-cost extensions
- Projects where a student is paid/supported from a federal training grant or otherwise paid/supported directly from the Faculty Advisor's federal funds
- Federal sponsorship, including federal training grants
- Studies with FDA-regulated components
- Studies with contractual obligations or restrictions that preclude eligibility in this policy
- Studies with clinical interventions
- Studies using prisoners as subjects*
- Studies seeking or obtaining Certificates of Confidentiality

Exempt Categories (not found under 45 CFR 46.101(2) (b)):

Subject protections and ethical standards expected of exempt research will apply to new exempt categories 7 and 8.

- Exempt 7: Non-funded research, involving no greater than minimal risk, that does not conform to a specific exempt category under 45 CFR 46.
  Examples include:
  - Online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk
  - Behavioral games
  - Studies of leadership traits of non-public, non-elected officials
  - Studies requiring performance of tasks that incur no risk
  - Studies involving focus groups, oral histories, ethnographies, or studies utilizing eye-tracking technology (unfunded)

- Exempt 8: Research, involving no greater than minimal risk, where activity is limited to study of existing (*or prospective at IRB discretion*) identifiable data.
  Examples include:
  - Medical record reviews where data was extracted from records
  - Data analysis of information already collected from court records

* 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.

Flexibility Policy

Exempt 8 category does not require continuing review; however, a HIPAA waiver may still be required. Studies that typically fall under expedited category 5 (involving analysis only of already collected data/documents/records) may now qualify for exempt category 8.

All studies regardless of initial risk determination, that are now limited to data analysis and not federally funded, may qualify for exempt category 8.

Extended Approval Period:

- Unfunded studies, involving no greater than minimal risk, and not limited to data analysis may qualify for continuing review every three years. Studies limited to data analysis may qualify for exempt 8.

Flexibility with Subparts B and C

- Subpart B- Pregnant Women, Human Fetuses and Neonates
  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, then paternal consent is not required and the Subpart B regulations for pregnant women and fetuses are not applied. The IRB must determine that the research qualifies as minimal risk.

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

Determination of Engagement:

For research that involves a nonaffiliated investigator and/or an outside institution that is considered engaged, this policy allows for the following:

- 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.

- 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.

Flexibility Policy

Reporting Requirements:

Research projects reviewed outside the scope of the FWA are not subject to the same federal reporting requirements as federally funded projects. For projects conducted under the flexibility policy, the USC IRB follows internal reporting requirements for serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risk to subjects or others.

All USC researchers using human subjects are required to submit their research to the IRB for review and determination.

Changes in Funding Status:

It is the responsibility of the Principal Investigator to report to the IRB changes in funding status:

- If the PI receives federal funding **less than one year into the three-year approval** of a study that originally qualified under this Flexibility Policy, the PI must notify the IRB via an amendment in iStar. The approval period will be decreased from three years to one year and the PI will be required to obtain continuing review by day 364 from the original approval date.

- If the PI receives federal funding **after the first year of a three-year approval**, the PI must notify the IRB and an amendment and continuing review must be submitted. Upon approval, a new review category will be designated (if applicable) and a new expiration date will be calculated by the IRB based on the approval date of the continuing review.

- For any project that qualified for any exempt category, a change in funding must be reported to the IRB.

Monitoring:

- Studies reviewed under this policy will be audited periodically to confirm that the funding status has not changed.
- Funding status change reminders will be sent out annually for three year approvals

Request for IRB notification of change in funding status will be included in all determination letters for studies reviewed under the flexibility policy.