THE UNIVERSITY OF ARIZONA Research & Partnerships

Flexible Review

This Guidance applies to IRB review for research not covered by the Federalwide Assurance (FWA).

Background

The University of Arizona (UA) has elected to limit the scope of its Federalwide Assurance (FWA) to federally funded or supported research, the terms of which allow an appropriate level of flexibility for research are funded from sources other than federal agencies or are unfunded. **Federally funded or supported includes awards to the UA that are made directly by a federal sponsoring agency, sub-federal awards where the UA receives a subcontract issued from a non-federal entity's prime federal award, or any non-federal sponsored research that invokes the code of federal regulations as a condition of award.**

Protections equivalent to the principles of the Belmont Report and respective to the degree of risk will be applied to all projects. Non-federally funded and unfunded research projects fall outside the scope of the FWA and will be reviewed under this guidance and will afford protections commensurate with risk as determined by the Institutional Review Board (IRB).

Purpose

This guidance creates flexible review options for the IRB for projects funded or supported from sources other than federal agencies. This guidance applies to all research under the jurisdiction of the UA IRB.

All human subject research projects conducted or supported at UA remain subject to UA IRB policies and review, whether they qualify under this guidance or not. Inclusion/exclusion of any research project will be at the discretion of the IRB. Should the funding status of a study reviewed under this guidance change, it is the responsibility of the Principal Investigator to notify the IRB.

This guidance does not apply to projects that receive any external funding support as those projects are subject to the UA FWA and will be reviewed according to the policies of the granting agency (except for project updates from July 19, 2019 forward as noted below). Projects that anticipate receiving federal funds, where a grant proposal is pending or planned, are not subject to this guidance and will be reviewed as if they were supported by a federal agency.

Data repositories containing data which are intended to be used to support applications to the Food and Drug Administration (FDA) and industry funded studies are not eligible for review under this guidance.

Mandatory Exclusions from this Guidance

- Federal sponsorship, including federal training grants, and agencies or organizations that have signed on to the Common Rule (http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html)
- Federal 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
- Studies with FDA-regulated components
- Studies with contractual obligations or restrictions that preclude eligibility in this policy
- Studies seeking or obtaining Certificates of Confidentiality

Flexible Review

Flexible Guidance

1) Minimal Risk Research

Research projects or changes in approved research that do not appear on the list of expedited or exempt categories as outlined in the federal regulations for protection of human research will be reviewed as "minimal risk." These projects will not be granted any specific category beyond "minimal risk."

2) Continuing Review Requirements

Effective July 19, 2019, the Human Subjects Protection Progam (HSPP) implemented three burden reducing provisions in the new federal rules. One of the provisions is the removal of a continuing review requirement for minimal risk research that is federally funded or supported. Prior to eIRB implementation, projects were reviewed on a three (3) or five (5) year basis depending on whether the projects would traditionally have fallen into the expedite or exempt categories respectively as identified in the Common Rule. Projects migrated to eIRB that are Minimal Risk will maintain either their three (3) or five (5) year approval period. At next follow-on submission, the IRB will assess if the project is eligible for elimination of Continuing Review all together, as outlined in the regulations and per institutional policy. New Minimal Risk projects approved in eIRB will not receive an expiration date. Researchers are still required to submit protocol modifications as applicable, notify the IRB of any problems or reportable events as outlined in the *Investigator Responsibilities after IRB approval* guidance, and conclude the protocol at its completion.

3) Expansion of Research Involving Children

a) Research projects involving children are subject to the regulations and tiered review standards at 45 CFR 46 Sub Part D. Requirements for assent and parental permission may be altered or waived for reasons other than those outlined in 45 CFR 46.408.

b) Research that would otherwise be subject to the requirements at 45 CFR 46.407 may be handled locally, not through the Secretary of HHS.

c) Online surveys, in-person focus groups, and/or interviews involving minors if the information collected does not place the individual at greater than minimal risk.

d) Unfunded studies that involve children can be classified as Minimal Risk under Flexible Review at the discretion of the IRB.

4) Expansion of Research Involving Prisoners

a) Research projects involving prisoners are subject to the same requirements for review as those at 45 CFR 46 subpart C, with the exception of the requirement for review by the Secretary of HHS cited at 45 CFR 46.306. Unfunded or non-federally funded research is not required to get approval from the Secretary at HHS.

b) Individuals incarcerated during participation in research may continue participation in non-federally funded projects without an IRB re-review with the prisoner representative.

c) The UA HSPP will not consider persons in transitional custody whose liberty is restricted such as half-way houses, electronic monitoring, probation, or house arrest, to meet the federal definition of prisoner. For those individuals, the criteria at 45 CFR 46.111 offer sufficient protection for their level of vulnerability.

d) Data analysis of information collected from court records may be deemed exempt.

5) Expansion of Research Involving Pregnant Women, Human Fetuses and Neonates

a) Research projects involving Pregnant Women, Human Fetuses and Neonates are subject to the requirements at 45 CFR 46 subpart B, with the exception of the requirement at 45 CFR 46.204(d) which requires the research develop "important biomedical knowledge." Social and behavioral research or medical research that does not involve greater than minimal risk are not required to meet the requirement of “important biomedical knowledge.”

b) Neonates of uncertain viability and nonviable neonates may be in involved in retrospective medical chart reviews without requiring the legally effective informed consent of both parents as required at 45 CFR 46.205(b)(2) and (c)(5).

c) Research projects that are funded by sources other than federal agencies, that involve greater than minimal risk, involve physical intervention, and include pregnant women, human fetuses, or neonates will be subject to the requirements of Sub Part B irrespective of the funding source.

6) Determination of Engagement:

Multicenter or multisite research projects involving other “engaged” institutions that are funded outside the federal funding stream are not subject to the same formal inter-institutional agreements or assurance requirements as are federally funded projects. Other forms of communication documenting collaborations are sufficient. 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 Individual Investigator Agreement, but the Institutional Official (IO) signature is not required. The signature of the HSPP Director or IRB Chair can substitute for the IO signature.

- Outside institutions determined to be engaged will not be subject to an IRB Reliance Agreement, unless required by the outside institution. If the outside institution requires an IRB Reliance Agreement, the UA will comply with their requirements. Additionally, the UA may require an IRB Reliance Agreement at its discretion. The determination of engagement is in accordance with the Office for Human Research Protections definition of engagement. In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project

obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. The following two sections apply these concepts. The signature of the HSPP Director or IRB Chair can substitute for the IO signature.

7) Reporting Requirements:

Research projects that fall outside the scope of the FWA are not subject to the same federal reporting requirements as federally funded projects for reporting requirements of serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risk to subjects or others. The UA HSPP does not report those matters to the federal agencies but follows internal reporting requirements.

Archived Flexible Review

The regulatory categories below were archived for any new submissions effective January 21, 2019, with the implementation of the 2018 Common Rule. Projects approved under these archived flexible review options will maintain their status as originally approved, but no new projects will be evaluated under these criteria.

a) **Exempt 7**: Projects that do not conform to a specific exempt category under 45 CFR 46.

Examples include:

- Online surveys, in-person focus groups, and/or interviews involving minors if the information collected does not place the individual at greater than minimal risk
- Behavioral games
- Studies of 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

b) **Exempt 8**: Research, involving no greater than minimal risk, where activity is limited to study of identifiable data.

Examples include:

- Medical or educational record reviews where data is extracted from records
- Data analysis of information collected from court records
- Collection or analysis of audio, video, or digital images