



TITLE: Applying Flex Policies
PURPOSE: Apply flexible review options for non-federally funded and unfunded research projects
RESPONSIBILITIES: HSPP Staff

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 University of Arizona that are made directly by a federal sponsoring agency, sub-federal awards where the University of Arizona 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.

Non-federally funded and unfunded research projects fall outside the scope of the FWA and will be reviewed under this policy and will afford protections commensurate with risk as determined by the Institutional Review Board (IRB).

PROCEDURES:

Mandatory Exclusions

The following studies are **excluded** from flexible reviews discussed in this policy:

- 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>).
- Research being conducted with Veterans Affairs (VA) subjects or data.
- 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 that are FDA-regulated.
- Studies with contractual obligations or restrictions that preclude eligibility in this policy (this includes studies where the UA IRB is serving as IRB of record for an institution that applies the federal rules to *all* research regardless of funding).
- Studies seeking or obtaining Certificates of Confidentiality.
- Other studies at the discretion of the IRB.

New Exempt Categories

New exempt categories 7 and 8, not found in the federal regulations, have been created for projects that do not directly conform to a specific exempt category according to 45 CFR 46.101(b). These projects will be reviewed using an approval process identical to that used for exempt research under 45 CFR 46.101(b).



- Exempt category 7: Projects that do not conform to a specific exempt category under 45 CFR 46. The following lists examples that apply.
 - 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 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
- Exempt category 8: Research, involving no greater than minimal risk, where activity is limited to study of identifiable data. The following lists examples that apply.
 - Medical or educational record reviews
 - Data analysis of information collected from court records
 - Collection or analysis of audio, video, or digital images
 - Studies that are in the data analysis phase can be switched to this new Exempt category during the renewal period

*Exempt category 8 may still require a waiver of consent and HIPAA Authorization.

Expansion of Continuing Review Requirements

Two-year approvals can be granted for projects 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 two years, rather than one as required in 45 CFR 46.109(e). Studies limited to data analysis may qualify for exempt 8.

The following lists studies that are **excluded** from expansion of continuing review requirements outlined in these procedures:

- All new studies are required to have a one-year approval for their first year.
- Studies that have a reportable item (F224) submitted within the last year.
- Studies with reported noncompliance or complaints.
- Other studies at the discretion of the IRB.

MATERIALS:

- Flexible Guidance

REFERENCES:

- 45 CFR §46.110
- 45 CFR §46.101(b)
- 45 CFR §46.109(e)