

Extended Approval Policy for Nonmedical Human Subjects in Research

Stanford University has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research by “unchecking the box” on its FWA. This will allow an appropriate degree of flexibility by extending the approval period for nonfederally sponsored research involving no more than minimal risk (as defined by 45 CFR 46.102) to participants in nonmedical studies. Research projects reviewed under the Extended Approval Policy will be afforded protections commensurate with risk as determined by the IRB.

All human research projects conducted or supported at Stanford remain subject to Stanford IRB policies and review, whether they are reviewed under this policy or not. When questions of applicability arise, studies will be reviewed on a case by case basis.

Inclusion/exclusion of any research project will be at the discretion of the Stanford Research Compliance Office.

Policy

This policy extends IRB approvals to a (3) three-year approval period for nonmedical human subject research involving no more than minimal risk that has no federal sponsorship. The policy does not apply to exempt research, which has an approval period for the life of the project.

- These research projects will be processed according to 45 CFR 46.110, except approval will be valid for three (3) years, rather than one (1) as stated in the federal regulations.
- Annually, a reminder notice will be sent to PDs asking whether any of the following changes have occurred:
 - changes in study procedures not previously reported to the IRB
 - increase in risks;
 - adverse events that have not yet been reported to the IRB; or
 - addition of federal funding.
- If none of the aforementioned changes have occurred, no submission to the IRB is required and the protocol can continue. If one or more of the changes have occurred, a Continuing Review application must be submitted and approved in order for the protocol to continue.
- If the protocol is no longer active, the PD will be asked to close the protocol.

The IRB reserves the right to make exceptions to this policy. Projects that receive federal support in whole or in part, or that involve greater than minimal risk, are subject to the full terms of the Stanford FWA and cannot be reviewed under this policy.

Examples of exclusions from this Policy are:

- Federal sponsorship, including federal training and program project grants
- Student projects when the faculty sponsor uses federal funding for the student’s project
- Federal no-cost extensions
- Studies with clinical interventions or FDA-regulated components
- Studies with contractual obligations or restrictions that preclude eligibility in this policy, i.e. the nonfederal sponsor or funder of the research require annual review.

- Studies seeking or obtaining Certificates of Confidentiality

It is the responsibility of the PD to report to the IRB changes in funding or sponsoring status that involve federal agencies.

Monitoring

- A random sample of studies processed under this policy will be reviewed periodically to confirm that the funding status has not changed to federally sponsored, the level of risk has not increased to more than minimal, and that any changes made to the protocol have been reported to the IRB prior to implementation.
- Reminder notices will be sent out annually to researchers requesting that they address whether changes have occurred regarding study procedures, increase in risks, adverse events, or addition of federal funding.

Reporting Requirements

Research projects outside the scope of the FWA are not subject to federal reporting requirements. For projects conducted under the Extended Approval Policy, the Stanford IRB follows internal reporting requirements for serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risks to participants or others, as described in Stanford's Human Research Protection Program (HRPP) Manual, Chapter 3, Sections 3.9-3.11.