Stanford University has chosen to limit the scope of its Federalwide Assurance (FWA) to federally sponsored research by “unchecking the box” on its FWA on 1/31/2011. This has allowed an appropriate degree of flexibility by extending the approval period for non-federally sponsored research involving no more than minimal risk (as defined by 45 CFR 46.102) to researchers conducting medical human subject chart review studies. Research projects reviewed under the Extended Approval Policy will be afforded protections commensurate with risk as determined by the IRB. This policy will be effective on 3/1/2013 for medical human subject chart review studies.

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 medical human subject chart review research involving no more than minimal risk that has no federal sponsor. 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 notice will be sent to PDs asking whether any of the following have occurred:
  - increase in risks;
  - adverse events that have not yet been reported to the IRB; or
  - addition of federal sponsor(s).
- If none of the aforementioned has occurred, no reply or submission to the IRB is required and the protocol can continue. If one or more of the above have occurred, a Continuing Review application must be submitted and approved in order for the protocol to continue.
- Changes that do not involve added risks or added federal sponsor(s) should continue to be submitted on a Modification application, as needed, during the 3 year approval period.
- If the protocol is no longer active, the PD will be asked to close the protocol.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 are federally sponsored, 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:

- Federally sponsored projects, including federal training and program project grants
- All VA studies
- 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 requires 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.
- 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 a federal sponsor.

**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.