

<b>Wayne State University Institutional Review Board</b>	
<b>Subject</b>	<b>Flexible Review and Oversight of Research Not Covered by Federalwide Assurance</b>
<b>Form Date</b>	March 15, 2016
<b>Approvals</b>	March 15, 2016

## **Background**

Wayne State University limited the scope of its Federalwide Assurance (FWA) to federally funded research beginning March 15, 2016. Limiting the scope of the FWA allows for an appropriate level of flexibility for review and oversight of research projects without compromising protection of human participants. Research projects that present no more than minimal risk to human participants are eligible for flexible review and oversight. Federally sponsored studies, projects with FDA-regulated components, projects with prisoner participants, and projects with contractual obligations or restrictions that require adherence to federal regulations are not eligible for flexible review and oversight.

## **Policy**

This policy describes flexible review and oversight for eligible research projects that are under the purview of the Wayne State University Institutional Review Board (WSU IRB). Wayne State University applies commensurate protections for research projects that are eligible for this policy. Research projects that present no more than minimal risk to human participants are potentially eligible for flexible review and oversight. Federally sponsored studies, projects with FDA-regulated components, projects with prisoner participants, and projects with contractual obligations or restrictions that require adherence to federal regulations are not eligible for flexible review and oversight.

Examples of research projects that are ineligible include:

- Federally sponsored research projects
- Federal training and program project grants
- Student projects supported by a faculty sponsor's federal funding
- Veterans Affairs (VA) projects
- Federal no-cost extensions
- FDA-regulated projects
- Data repositories containing data intended to support applications to the FDA
- Clinical trials involving interventions
- Projects with prisoner participants
- Projects where non-federal sponsors require annual review
- Projects that will obtain Certificates of Confidentiality

If a project approved under flexible review later becomes ineligible (i.e. federal funding is obtained, risks become more than minimal), it is the responsibility of the Principal Investigator (PI) to report these changes to the WSU IRB. A project that becomes ineligible must follow all federal research regulatory requirements.

All human participant research projects conducted or supported at Wayne State University and/or affiliated institutions remain subject to WSU IRB policies and review, whether they qualify for this policy or not. Eligibility of any research project for flexible review and oversight is at the discretion of the Wayne State University Office of Research Compliance.

### **Exempt Flexible Review Categories**

Projects that are eligible for flexible review may apply for an exemption under two additional exempt categories, WSU IRB Exempt Categories 7 and 8. Ethical standards and participant protections expected of exempt research will apply to WSU IRB Exempt Categories 7 and 8. Exempt research must present no more than minimal risk to human participants.

WSU IRB Exempt Category 7: Research with adults and/or minors involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, behavioral games, tasks or observation of public behavior, unless: (i) information obtained is recorded in such manner that human participants can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

WSU IRB Exempt Category 8: Research involving no direct interaction or intervention with human participants that is limited to the study of identifiable data and it is not feasible to obtain consent from participants. If Protected Health Information (PHI) will be used, a HIPAA Waiver of Authorization is still required.

### **Criteria for Non-Exempt Flexible Review**

A project cannot be approved by non-exempt flexible review unless the following criteria are met:

- Risks to participants are no more than minimal
- Risks to participants are minimized
- Risks to participants are reasonable in relation to anticipated benefits
- Selection of participants is equitable
- Research plan makes adequate provision for monitoring
- When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights of vulnerable participants

## **Extended Approval Period for Non-Exempt Projects**

Projects eligible for flexible review and oversight may qualify for continuing review up to every three years. Exempt studies do not require continuing review. Request for IRB notification of change in funding status will be included in all determination letters for studies reviewed under the flexibility policy.

## **Research with Participants Incarcerated During Participation**

If research participants become incarcerated after enrolling in projects eligible for flexible review and oversight, federal prisoner research regulations (45 CFR 46 Subpart C) do not apply. In addition, the project does not require IRB review with a prisoner representative when individuals are incarcerated after study enrollment.

## **Pregnant Women, Fetuses and Neonates**

Research projects eligible for flexible review and oversight involving pregnant women, fetuses and neonates are subject to the federal 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."

## **Reporting Requirements**

Research projects eligible for flexible review and oversight are not subject to the same federal reporting requirements as federally sponsored projects. For projects conducted under this policy, the WSU 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.

## **IRB Procedures**

Unless specific to research within the scope of the FWA, all procedures outlined in other WSU IRB policies apply to research eligible for flexible review and oversight. Submission requirements, reviewer assignment, WSU IRB documentation, and approval/exemption procedures will be processed by the IRB Administration Office in the same manner as research within the scope of the FWA, unless otherwise indicated in this policy.

Research projects approved using a flexible review process will be audited periodically to confirm that the project is still eligible for flexible review and oversight. Request for IRB notification of change in funding status will be included in all determination letters for studies reviewed under the flexibility policy.