Policy Change: Non-Federal Exemption Categories
September 1, 2013

Description of Policy Change
The Department of Health and Human Services has identified certain categories of research involving human subjects that qualify for exemption from certain federal regulations applicable to research. At the University of Utah, the IRB makes federal exemption determinations according to 45 CFR 46.101.

This policy change proposes five additional non-federal exemption categories, which may be applied to non-federally supported or otherwise non-federally regulated studies. These five categories were created based upon commonly accepted, minimal risk research practices that were originally delineated in 45 CFR 46.110 for receiving the expedited IRB review procedure.

In order to qualify as “non-federally supported or otherwise non-federally regulated,” a study must meet the following criteria:
   a) Research is not subject to FDA regulations;
   b) Research is not federally funded;
   c) Research is not contractually or otherwise subject to federal research requirements, including but not limited to research conducted under the Department of Veterans Affairs or under an NIH Certificate of Confidentiality;
   d) Research does not involve prisoners as participants;
   e) Research meets the University’s ethical standards governing the conduct of the research, including appropriate provisions for the protection of privacy and confidentiality when identifiable and coded information are used.

The full extent of this policy is described in the following policy/guidance documents:
• IRB SOP 401b: Research Activities Exempt from IRB Review
• Investigator Guidance Series: Exempt Research

What this Policy Changes Means for Research at the University of Utah
Under the new policy, many studies that were once considered as non-exempt, minimal risk studies will now qualify for exemption. The difference in process is shown in Table 1.

It is anticipated that this policy change will result in a decreased number of continuing review and amendment applications. This, in turn, will reduce the workload for the IRB.
The University of Utah IRB has policies to ensure that all research determined to be exempt under a non-federal exemption category adheres to principles of sound research design and ethics, as follows:

- The University of Utah IRB is authorized to make exemption determinations, not individual investigators.
- IRB review of exempt research will ensure that the following is true of all qualifying proposals:
  - The research poses no more than minimal risk to participants.
  - The selection of participants is equitable.
  - There are adequate provisions for maintaining the privacy and confidentiality of participants.
  - If there are interactions with participants, there is a consent process that will disclose such information at:
    - That the activity involves research.
    - A description of the procedures.
    - That participation is voluntary.

Table 1: Comparison of processes for non-exempt and exempt studies that are minimal risk

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<thead>
<tr>
<th>Process for a Non-Exempt Minimal Risk Study</th>
<th>Process for an Exempt (Minimal Risk) Study</th>
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<tr>
<td>1. Investigator completes full new study application.</td>
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<tr>
<td>2. IRB review and approval according to Criteria for IRB Approval of Research.</td>
<td>2. IRB review an exemption according to criteria for IRB exemption of research.</td>
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<td>4. Investigator submits a continuing review application to the IRB every 1-2 years.</td>
<td>4. Investigator is not required to submit a continuing review application to the IRB for the lifetime of the study.</td>
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<td>5. Investigator submits all minor and substantive changes via amendment applications to the IRB.</td>
<td>5. Investigator submits all substantive changes via amendments applications to the IRB. The exemption determination will be revoked if a substantial change causes the study to no longer qualify for exemption. The study will then follow the requirements for a non-exempt study (left).</td>
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<td>6. Investigator submits all possible unanticipated problems to the IRB via a report form.</td>
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<td>7. Investigator submits all possible serious or continuing non-compliance to the IRB via a report form.</td>
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<tr>
<td>8. Investigator closes the study with the IRB via a final project report.</td>
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Justification for Policy Change

This change is allowable by federal regulation and the DHHS Federal-Wide Assurance. The University of Utah maintains a Federal-Wide Assurance (FWA00003745) with the Department of Health and Human Services, which requires that the federal regulations be applied to all federally-supported research at the University of Utah. Within the FWA, the University of Utah has elected to apply comparable standards to all other research that is not federally supported or otherwise non-federally regulated.

The University of Utah IRB has policies to ensure that all research determined to be exempt under a non-federal exemption category adheres to principles of sound research design and ethics, as follows:
The name and contact information for the investigator.
- The research is otherwise conducted in an ethical manner which does not adversely affect the rights and welfare of the participants.

All of the non-federal exemption categories represent commonly accepted, minimal risk research practices. Because the non-federal exemption categories are based upon the “expeditable” research categories described in federal regulation (45 CFR 46.101), it is widely accepted that the research activities represented by the non-federal exemption categories pose no more than a minimal risk to participants.

Ongoing monitoring of exempt research is still performed by the IRB. Though exempt projects are not required to receive continuing review, substantive changes, unanticipated problems, and serious/continuing non-compliance must still be reported to and evaluated by the IRB. Given the low risk of exempt research, these are appropriate monitoring mechanisms to ensure protection of human subjects.

A non-federal exemption category was successfully implemented as a demonstration project at the University of Michigan. In September 2007, the University of Michigan IRB implemented a new, non-federal exemption category and reports that there has been no increased risk to subjects or non-compliance from the change. The University of Michigan also reports a reduction in IRB workload. The University of Utah has similar and comparable methods for ensuring the protection of human subjects in exempt research and both institutions have received accreditation from the Association for Accreditation of Human Research Protection Programs (AAHRPP). More information about the University of Michigan Demonstration Projects can be viewed here: http://www.hrpp.umich.edu/initiative/demonstrations.html.

Evaluation of this Policy Change
The impact of this policy change will be evaluated as follows:
- Annual analysis of continuing review and amendment data will occur to determine the effect on IRB workload.
- Education and outreach to investigators and study teams will occur to ensure compliance with exemption policy and receive feedback on the process.
- Monitoring of the number of problems and events reported to the IRB for exempt studies to determine if there is concern for non-compliance with exemption policy.