

STATEMENT OF PRACTICE

Flexibility Initiative: Exemption 2A

Effective: *March 12, 2014*

Revised: *May 1, 2015*

I. STATEMENT OF PRACTICE

Under the current federal regulations for human subjects research, Exemption Category #2 is defined as:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: ,,

- Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects

AND

- Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. [45 CFR 46.101\(b\)\(2\)](#)

Some studies under the oversight of IRBMED employ research designs that involve a minimal risk, non-invasive intervention such as viewing a video, reading a story, playing an economic game, using a computer program, using an experimental tool (eg, a robot arm or mechanical object), or being exposed to stimuli such as sound, color, or light, followed by data collection via a survey, interview, test, or observation. Data may also be collected by automated or researcher observation; for example, a computer may record objective data such as how long a subject views each screen in a program, or a researcher may subjectively “rate” how comfortably/readily a subject manipulates a device.

OHRP’s position on Exemption #2 is that it cannot be applied to projects that involve an intervention of any kind in conjunction with a survey, interview, test, or observation, regardless of the risk associated with the project.

II. PROCESS

Utilizing the flexibility of the regulations and in [collaboration with IRB-HSBS](#), IRBMED proposes a new U-M [demonstration project](#): Exemption 2A. This demonstration project will expand the definition of Exemption 2 to **minimal risk research with adults** that involves a **non-invasive** intervention followed by data collection via survey, interview (including focus groups), test, observation, and/or recording of physiological measurements.

Non-invasive inventions include, but are not limited to:

- Reading a story or vignette
- Playing an economic game
- Using a computer program or website
- Watching a video
- Using a robot arm or mechanical object, if it remains outside of the body
- Being exposed to stimuli such as color, light or sound (within safe limits)

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To qualify for this expanded definition of Exemption 2, the study must pose **no more than minimal risk** to subjects and may **not** include any of the following:

- Federal funding or federal training grants (direct or prime sponsorship)
- FDA regulated components
- Sponsor or other contractual restrictions
- Clinical interventions (including clinical behavioral interventions)
- [Minors](#) as subjects
- [Prisoners](#) as subjects
- Receipt of an NIH issued [Certificate of Confidentiality](#) to protect identifiable research data

Initial or Scheduled Continuing Review applications meeting the criteria cited above will be reviewed by the IRB to determine that subject protections are equivalent to those required by federal regulations. If equivalent protections are in place, and there are no additional extenuating circumstances, the IRB can issue the new Exemption 2A by following the standard exempt (initial and transitional) procedures. All other regulatory requirements pertaining to exemptions remain unchanged.

III. Resources

- [45 CFR 46.101\(b\)\(2\)](#)
- [45 CFR 46.401\(b\)](#)
- U-MIC Presentation:
<http://medicine.umich.edu/medschool/sites/medicine.umich.edu.medschool/files/exemptions.ppt>
[x](#)
- U-M Exemption categories: <http://research-compliance.umich.edu/operations-manual-activities-subject-hrpp#UMcategories>