Overview of Changes

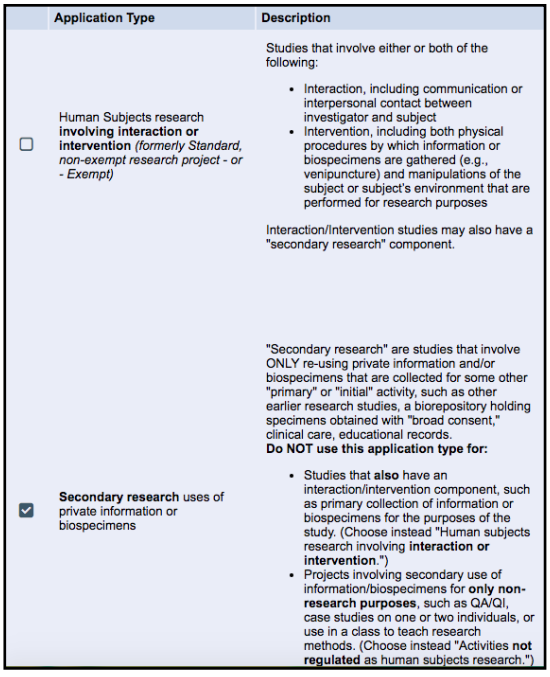
U-M is piloting **some** of the 2018 Common Rule enhancements to evaluate the new and updated business processes and the IRB application changes prior to the implementation of the federal regulations. 2018 Common Rule regulations (e.g., new exemption definitions, continuing review changes) will apply to **non-federally funded human subjects research only**. However, the IRB application changes will be visible and utilized by all new and In Progress (pre-submission) studies.

This document provides a description of changes included in the eResearch Regulatory Management 4.3 release on June 11, 2018, to support the pilot and the future Common Rule implementation.

Major Changes

I. New Application Type Page

U-M is streamlining the Application Type options in section 1-1. Specifically:



	Application Type	Description
☐	Human Subjects research **involving interaction or intervention** *(formerly Standard, non-exempt research project - or - Exempt)*	Studies that involve either or both of the following: • Interaction, including communication or interpersonal contact between investigator and subject • Intervention, including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes Interaction/Intervention studies may also have a "secondary research" component.
☑	**Secondary research** uses of private information or biospecimens	"Secondary research" are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other "primary" or "initial" activity, such as other earlier research studies, a biorepository holding specimens obtained with "broad consent," clinical care, educational records. **Do NOT use this application type for:** • Studies that **also** have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead "Human subjects research involving **interaction or intervention**.") • Projects involving secondary use of information/biospecimens for **only non-research purposes**, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead "Activities **not regulated** as human subjects research.")

Application Type Page (section 1-1)

- The *Exempt Human Subject Research* application type was retired. Exemption questions and exemption review path options are embedded within the application type associated with the exemption category.
- The *Standard* application type was renamed "Human subjects research involving interaction/intervention." This application type is used for non-exempt research or for exempt research qualifying for exemptions 1, 2, 3, 5, and 6.
- The *Secondary Use* application type was renamed "Secondary research uses of private information or biospecimens." This application now routes **all** secondary use studies through the correct IRB review/determination path (i.e., Not Regulated, Exempt 4, or Full IRB Regulated Secondary Use), eliminating the need for study teams to self-identify the required level of review.

Note: All other application types (e.g., *Not Regulated*, *Requesting Review by a Non-UM IRB*, etc.) remain unchanged and continue to be options in section 1-1.

Impacts of the pilot on existing applications

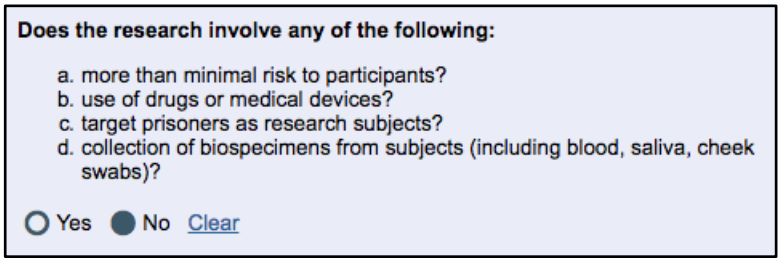
Standard studies that are In-Progress *(Pre-Submission)* will have their answers pre-populated when converted to the research involving the interaction/intervention Application Type.

Existing *Exempt* studies **will not be** converted to the new "interaction/intervention" Application Type. Future amendments will be permitted for **administrative changes only** (i.e., for personnel changes or to record new funding for the project). If changes are needed to the exempt specific questions in Section 5-3 or Section 12, then terminate the study and submit a new application.

II. Exemption Changes

New "exemption screener" in the interaction/intervention Application Type

A new "exemption screener" appears upon selection of the interaction/intervention Application Type.



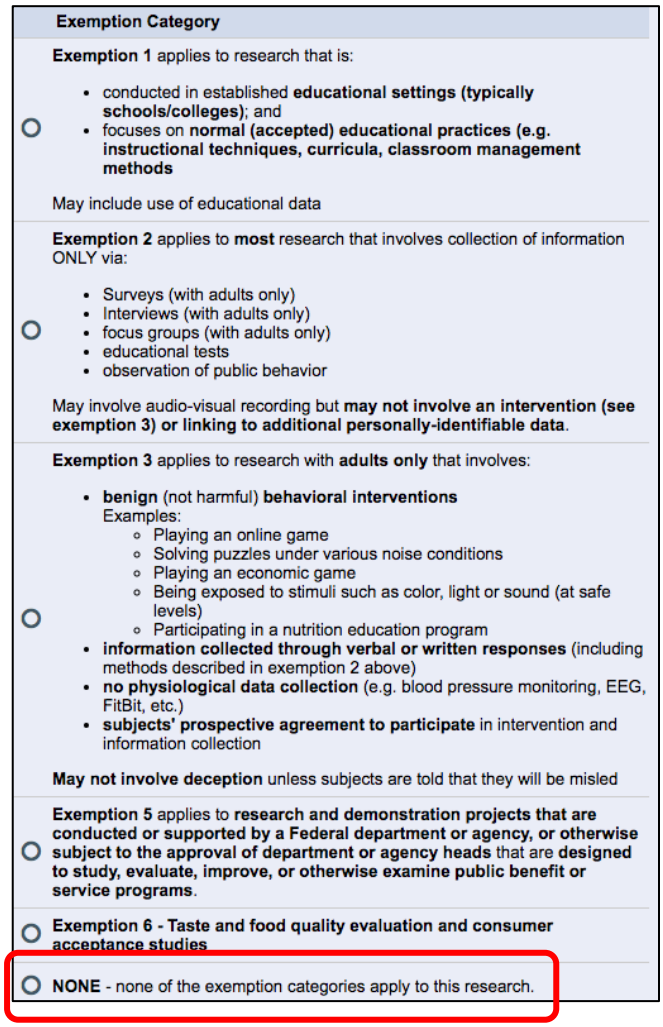
Selecting "Yes" routes the application for full (comprehensive) IRB review or expedited review.

Selecting "No" displays the list of Exemption Category options from which to select.

Existing *Standard* studies will be updated to display the new "exemption screener" question. At the next amendment, this page will be required.

Pilot instructions for federally-funded exempt studies

Exemption Category Page



Exemption Category

○ **Exemption 1** applies to research that is:

- conducted in established **educational settings (typically schools/colleges)**; and
- focuses on **normal (accepted) educational practices (e.g. instructional techniques, curricula, classroom management methods**

May include use of educational data

○ **Exemption 2** applies to **most** research that involves collection of information ONLY via:

- Surveys (with adults only)
- Interviews (with adults only)
- focus groups (with adults only)
- educational tests
- observation of public behavior

May involve audio-visual recording but **may not involve an intervention (see exemption 3) or linking to additional personally-identifiable data**.

○ **Exemption 3** applies to research with **adults only** that involves:

- **benign** (not harmful) **behavioral interventions**
  Examples:
  - Playing an online game
  - Solving puzzles under various noise conditions
  - Playing an economic game
  - Being exposed to stimuli such as color, light or sound (at safe levels)
  - Participating in a nutrition education program
- **information collected through verbal or written responses** (including methods described in exemption 2 above)
- **no physiological data collection** (e.g. blood pressure monitoring, EEG, FitBit, etc.)
- **subjects' prospective agreement to participate** in intervention and information collection

May not involve deception unless subjects are told that they will be misled

○ **Exemption 5** applies to **research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads** that are **designed to study, evaluate, improve, or otherwise examine public benefit or service programs**.

○ **Exemption 6 - Taste and food quality evaluation and consumer acceptance studies**

○ **NONE** - none of the exemption categories apply to this research.

If your study is/will be **federally funded AND** includes **deception** and/or **identifiable and sensitive information**, it *does not* qualify for Exemption 2 or Exemption 3. In these cases, select **NONE.**

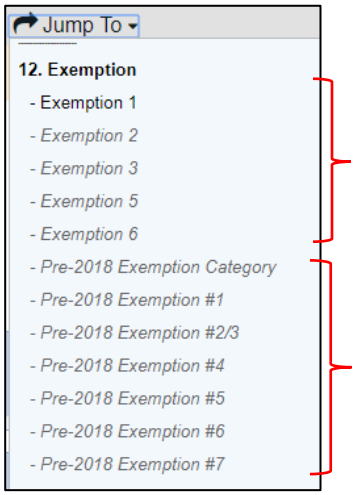
When the Common Rule changes become effective (expected implementation on January 19, 2019), these exemptions will also apply to federal studies.

New Exemption category detail pages

The exemption category detail pages (section 12) were updated to reflect the Common Rule changes. **Note**: A disqualifying response to an exemption question reroutes to the next applicable question in the full review path rather than being returned to select a different Application Type.

As existing exempt IRB applications were not be converted to the new "interaction/intervention" Application Type, the **Jump To** menu displays both sets of detail pages. This facilitates navigation within current exempt applications.

Jump To menu



New ability to issue Exempt Self-Determination on qualifying studies

Self-determination means that the Principal Investigator is permitted to issue a system-generated exemption determination letter based on responses to key questions within qualifying human subjects exemption categories. The IRB does not review self-determined projects. Investigators may choose not to apply self-determination but, instead, choose to submit a study for an IRB determination of exemption.

This process will be similar to the one currently available for some Not Regulated projects. The **Generate Exempt Self-Determination Letter** activity, will be available from the Study Workspace or the End of Application page. Once the activity is completed, the application will be in the state of **Exempt Self Determination**.

Note: The IRBs will be auditing all federally-funded exemptions during the pilot to ensure appropriate use of the self-determination option.

III. Informed Consent Changes

Section 10, Informed Consent, was reorganized to help investigators select the correct informed consent category: With signature, without signature (waiver of documentation), Waivers of informed consent, or Other. This reorganization applies to the sections for adults and for children.

In most cases, selections prior to June 10, 2018 will display and do not need re-answering. In some cases, questions 10.1 and/or 10.2 must be fully re-answered, as these cases have answers that could not be directly converted.

IV. No Continuing Review Required

Non-federal, minimal risk studies may now qualify for No Continuing Review. Qualifying studies will be given a No Continuing Review determination, and these studies will no longer have an option to create a new Continuing Review.

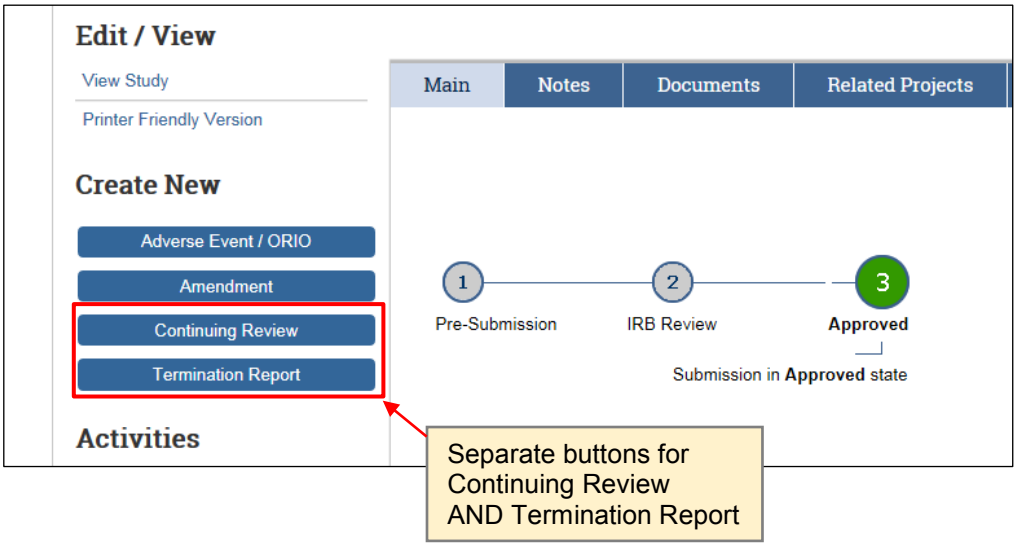
If Continuing Review is not required, then a study workspace message will display on the application's main tab: **No Continuing Review Required. However, Amendments and AE/ORIOs are required when applicable.**

V. Termination

A new **Termination** process in the Study workspace will allow the Principal Investigator (PI) or Faculty Advisor to close approved or exempt studies upon completion of the research. See the Creating a Termination Report step-by-step procedure for more details.

Previously, study termination was initiated through the SCR process. See the updated Creating a Scheduled Continuing Review step-by-step procedure.

Study Workspace



VI. Updated External Sponsor Information (section 2)

External Sponsor questions were removed from Section 2, and are now indicated by linking a related Proposal Approval Form (PAF) or Unfunded Agreement (UFA) from eResearch Proposal Management (eRPM). See the Adding a PAF or Internal Sponsor step-by-step procedure. Certain PAF and UFA data will be imported and displayed in eRRM. This data will display in both the application and in the Related Projects tab.

A new required question was added: 2.4 Is there any other financial or non-financial sponsorship or support not covered in the sections above?