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 (section 1-1)
   • Impacts of the pilot on existing applications

II. Exemption changes
   • New "Exemption screener" in the interaction/intervention application type
   • Pilot instructions for federally-funded exempt studies
   • New exemption category detail pages
   • New ability to issue "Exempt Self-determination" on qualifying studies

III. Informed Consent changes (section 10)

IV. No Continuing Review Required for expedited studies

V. Termination

VI. Updated External Sponsor Information (section 2)

I. New Application Type Page

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

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.

![Exemption Screener](image)

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**

<table>
<thead>
<tr>
<th>Exemption Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemption 1 applies to research that is:</td>
<td>- conducted in established educational settings (typically schools/colleges) and focuses on normal (accepted) educational practices (e.g. instructional techniques, curricula, classroom management methods)</td>
</tr>
<tr>
<td>Exemption 2 applies to research that involves collection of information ONLY via:</td>
<td>- surveys (with adults only) - interviews (with adults only) - focus groups (with adults only) - educational tests - observation of public behavior</td>
</tr>
<tr>
<td>Exemption 3 applies to research with adults only that involves:</td>
<td>- benign (not harmful) behavioral interventions</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Exemption 6 - Taste and food quality evaluation and consumer acceptance studies.</td>
<td></td>
</tr>
</tbody>
</table>

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

```
12. Exemption
  - Exemption 1
  - Exemption 2
  - Exemption 3
  - Exemption 4
  - Exemption 5
  - Exemption 6
  - Pre-2018 Exemption Category
    - Pre-2018 Exemption #1
    - Pre-2018 Exemption #2
    - Pre-2018 Exemption #3
    - Pre-2018 Exemption #4
    - Pre-2018 Exemption #5
    - Pre-2018 Exemption #6
    - Pre-2018 Exemption #7
```

*New Exemption 1 – 6 detail pages*

*Pre-2018 Exemptions 1 - 7  detail pages*

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). 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?