Revised Common Rule: Implementation Plan at Emory

LATEST INFORMATION
Topics to Cover

- eIRB changes for Common Rule
- What studies are required to transition?
- What other studies are eligible?
- What is the process to transition?
Topics to Cover

- New Informed Consent Requirement
- Information for studies submitted or edited between 1/1 and 1/20/2019
- What happens next?
- Guidance in IRB Website
You will be able to tell if your study is under the Revised Common Rule by checking the “Common Rule Version” information under the main study history.
Studies created BEFORE January 1, but still in Pre-Submission, will see this message after clicking “Edit Study”

After this the study will be under the Revised Common rule.
eIRB

Studies created BEFORE January 1 and not further edited will see the following when they click “Submit”

You will Cancel, then “Edit Study” to fix errors caused by the transition, then resubmit.

After this the study will be under the Revised Common rule.
You will notice other changes we have made to align to the Revised Common Rule.

This example shows a revised population for individuals with impaired decision-making capacity (vs. the old terminology of cognitively impaired).
Definition information has been modified as well.

This example shows the updated information under “Type of Research” section.
IRB staff will determine if your new study is FDA regulated or DOJ-funded

- If so, we manually revert study back to pre-2018 Rule

- Parts of 2018 Rule will still apply if federally-funded
  - E.g. new informed consent elements; public posting of consent form
  - So, use our latest consent template in all cases
What studies are required to transition?

- Non-FDA regulated, non-Department of Justice (DOJ) supported studies which are...
  - In long term follow up or data analysis only as of the last continuing review, or
  - Secondary analysis of identifiable data or biospecimens under waiver of consent/HIPAA (data not going to be submitted to the FDA)
  - ...And have no international sites, or significant history of compliance issues
What other studies are eligible?

- Non-FDA, Non-DOJ, minimal risk studies may be eligible to transition to the revised common rule. However, transitioning may not represent a benefit for you if:
  - You are planning to finish your study (close out) in the next year, especially if you are enrolling subjects and would need to revise your consent per the Revised Common Rule.
What other studies are eligible?

- What is a more than minimal risk study?
  - “Involves activities with an anticipated probability and magnitude of harm or discomfort that is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (45 CFR 46)

- How do you know whether your study is minimal risk?
  - The risk level of your study appears in the main study workspace. Also indicated by “Expedited Approved” status.
What is the process to transition?

**Studies required to transition**

Transition will occur 45 to 30 days before study expiration

- Do not submit continuing review
- Submit an amendment (AM) with attestation form, stating how much longer study will likely remain open
- The study will not require continuing review in the future

**Study Team-Requested Transition**

Transition should occur 45 to 30 days before study expiration

- Submit a continuing review (CR) application as usual
- Submit an amendment (AM) with attestation form, stating when the study will close (approximate date)
- Include revised ICF to include new elements, if still enrolling subjects
New Informed Consent Requirements

- All studies submitted or edited after January 1st will need to use our new template.
- The new template starts with a checklist to be used by study team at initial review.
- The purpose is to make sure the informed consent contains all the required basic and additional elements required in the Revised Common Rule.
- Separate the checklist into a separate document for submission (copy/paste).
### ICF Checklist

#### Checklist for Study Teams

**Instructions**
- The purpose of this form is to make sure that all required elements of consent from the revised common rule are included in your informed consent document.
- This form needs to be completed and submitted separately with your consent forms.
- Copy and paste the chart below to a different Word document, and delete it from the consent template (that should start with the conclusion presentation). We will not stamp the checklist.
- One checklist can apply to all consent forms of the study.

#### BASIC ELEMENTS OF INFORMED CONSENT

<table>
<thead>
<tr>
<th>Statement</th>
<th>YES</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Statement that the study involves research</td>
<td></td>
<td></td>
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<tr>
<td>2. Explanation of the purpose of the research</td>
<td></td>
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<tr>
<td>3. Expected duration of participation</td>
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<td>4. Description of the procedures</td>
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<tr>
<td>5. Identification of research procedures vs. non-research</td>
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<tr>
<td>6. Description of any reasonably foreseeable risks or discomforts</td>
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<tr>
<td>7. Description of any benefits to the subject or to others that may be reasonably expected from the research</td>
<td></td>
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<tr>
<td>8. Disclosure of appropriate alternative procedures or courses of treatment</td>
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<tr>
<td>9. Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the research staff, IRB, sponsor, their representatives, and possibly the FDA or OHRP.</td>
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<td></td>
</tr>
<tr>
<td>10. For research involving more than minimal risk, a statement that emergency medical care will be arranged for a study-related illness or injury, and an explanation of whether funds are set aside to pay for this care and/or compensation, and if so by whom (e.g., sponsor, subject, insurer), language must not be inflammatory.</td>
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<tr>
<td>11. An explanation of whom to contact for pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject</td>
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</tr>
<tr>
<td>12. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.</td>
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<td></td>
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<tr>
<td>13. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:</td>
<td></td>
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</tr>
<tr>
<td>13.1 A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.2 A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Studies created or edited between 1/1 and 1/20/2019

- Your study will be reviewed under the new Common Rule
- Make sure you use our new consent templates posted on our website
- If your study is non-FDA, non-DOJ regulated:
  - We will screen your study, but not send for review until after January 21, 2019
  - Log a comment if urgent need for review prior to that date
- If your study is FDA-regulated we will review as usual, but use our latest consent template
The eIRB system will automatically move all studies created or edited after January 1st to the Revised Common Rule.

- If your study is FDA regulated, the IRB staff will put your study back to the old Common Rule status in the system.

- You will not need to do anything else! After January 21st you should expect to see your studies approved as usual.

- The IRB will roll out other QA/QI procedures for studies that do not require continuing review anymore, so stay tuned!
Here are some guidance documents we have put together to help our investigators transition to the revised common rule:

- Guidance and Attestation form for the Transition of Studies approved before January 21, 2019 to the Revised Common Rule
- Emory IRB Detailed Guidance: [Revised Common Rule at Emory University](#)
- Chart: [Which studies and How to transition studies to revised common rule](#)
Contact us!

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Happy Holidays