2018 Common Rule Conversion Instructions & Guidance

Does my study have to convert?

Yes. Conversion will apply to all studies approved prior to January 21, 2019 EXCEPT emergency use and center/ administrative grant submissions.

"Conversion" refers to two different types of changes and these changes may take place either simultaneously or at different time points, depending upon the nature of the research:

1. Conversion to the updated RAMS-IRB Smartform – a streamlined, protocol-like submission form
2. Transition to the 2018 Common Rule (if eligible) to take advantage of the new, burden-reducing provisions

ALL studies will convert to the updated RAMS-IRB Smartform, but only eligible studies will transition to the 2018 Common Rule.

Overview of the RAMS-IRB Smartform changes Overview of the 2018 Common Rule changes

The following studies are currently ineligible to transition to the 2018 Common Rule:

- Department of Justice studies (i.e. funded, supported, or regulated by this agency)
- FDA regulated studies (i.e. a clinical investigation of a drug, medical device, or other test article)

FDA and DoJ studies will be required to convert to the updated RAMS-IRB smartform and to update the study's consent documents. However, they will not be eligible to be reviewed under the 2018 Common Rule until these departments/agencies adopt or harmonize with the 2018 Common Rule. The IRB will notify investigators when these studies become eligible to be transition to the 2018 Common Rule.

Eligible VCU IRB studies will be reviewed in accordance with the 2018 Common Rule during the IRB's review of either an initial submission or a conversion amendment.

	FDA regulated studies	Department of Justice supported studies	All other VCU IRB studies
Studies approved by the IRB before 1/21/19	Not eligible to transition; *Reviewed under the Pre-2018 Common Rule until notified that are eligible to transition*		Will transition to the 2018 Common Rule during the study's conversion amendment
Studies approved by the IRB after 1/21/19			Initial submissions will be reviewed under the 2018 Common Rule

When does my study have to convert?

The first amendment a study CREATES after the RAMS-IRB patch (during the week of January 22-25, 2019) will automatically be the study's conversion amendment.

This conversion process is part of the design of RAMS-IRB and cannot be changed.

- **External IRB** studies that submit amendments to the VCU IRB will also automatically convert to the updated RAMS-IRB Smartform.
    - External IRB studies that do not otherwise submit an amendment to the VCU IRB will be contacted separately by IRB Reliance staff about conversion later in 2019.
- Studies that were determined to be **exempt PRIOR to January 21, 2019** will convert when and if they submit their next amendment to the IRB.
- **Non-exempt studies** that do not otherwise need to submit an amendment to the IRB will be receive an emailed conversion notice.
    - Conversion notices will be automatically emailed by RAMS-IRB on a rolling schedule 6 months prior to the study's expiration date.
    - Notices will be sent beginning in **March 2019** for studies that expire in September 2019.

Investigators are asked to convert according to this schedule when possible so that the IRB and its reviewers can manage the volume of submissions it receives.

- The conversion notice schedule was set in order to allow time for the submission and review of the conversion amendment prior to any continuing review notices being sent.
- Some studies that previously required expedited review – or even full board review – may qualify for exemption under the 2018 Common Rule and will no longer require continuing review.
- Other expedited studies that previously required continuing reviews will be eligible to submit status update reports instead of continuing review submissions.

<table>
<tr><th colspan="3">Conversion Schedule</th></tr>
<tr><td rowspan="1">Existing Studies</td><td>… approved by the IRB
before January 21, 2019</td><td>➢ Full Board and Expedited studies will convert to the updated Smartform via a conversion amendment either: when the study's next amendment is created OR when an amendment is created in response to an emailed conversion notice (whichever comes first)
➢ Exempt studies will convert to the updated Smartform at the time of the study's next amendment (the conversion amendment)
➢ External IRB studies will convert at the time of the study's next amendment or at a separate time later in 2019</td></tr>
<tr><td rowspan="3">New Studies</td><td>… in development
on January 21, 2019</td><td>… will need to be revised on the updated Smartform before being submitted.
Investigators will want to review their entire submission for accuracy and answer the newly added questions.</td></tr>
<tr><td>… submitted but not approved
on January 21, 2019</td><td>… will be returned to investigators to be revised on the updated Smartform.
Investigators will want to review their entire submission for accuracy and answer the newly added questions.</td></tr>
<tr><td>… created after
January 21, 2019</td><td>… will use the updated Smartform.</td></tr>
<tr><td rowspan="3">Amendments</td><td>… in development on
January 21, 2019</td><td>… will not convert to the updated Smartform</td></tr>
<tr><td>… submitted but not approved on
January 21, 2019</td><td>… will not convert to the updated Smartform</td></tr>
<tr><td>… created after
January 21, 2019</td><td>… will use the updated Smartform.
For existing studies approved by the IRB prior to January 21, 2019, the first amendment CREATED after that date will automatically be the study's conversion amendment.</td></tr>
<tr><td colspan="3">Continuing Reviews and Reports are unaffected as they use different forms.</td></tr>
</table>

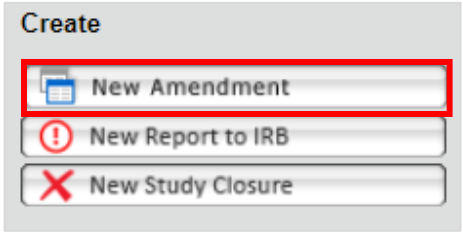
What are the benefits of converting my study?

1. The RAMS-IRB smartform has been given a new look and feel to make submissions more user-friendly and to function more like a protocol.
2. The 2018 Common Rule offers burden-reducing benefits
    - Many expedited studies will no longer require continuing review submissions
    - The new rule expands the scope of research that is exempt from IRB review. Some studies which previously required expedited review – or even full board review – may qualify for exemption under the new rule
    - Certain studies will no longer require grant congruency review.
3. Investigators and study staff whose studies convert to the 2018 Common Rule not need to operate under and maintain compliance with two sets of regulations.

How do I create a conversion amendment?

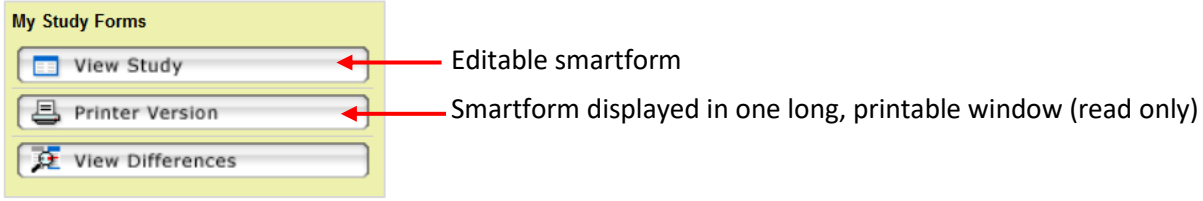
1. Update the RAMS-IRB Smartform

1. Create an amendment – instructions are available here: How do I submit an amendment to change my study?



2. Read through the entire smartform to verify the accuracy of all responses and familiarize yourself with the organization of the updated smartform.

    ✓ *Tip: One easy way to review your submission is to read the Printer Version in one tab of your internet browser and have the editable smartform open in another tab of your browser so that you can make edits as you read.*



3. Answer the newly added questions. In the smartform, click “Hide/Show Errors” to show a list of all the new required questions in the smartform. You can then click the page links to jump to those specific pages. If you have additional changes you’d like to make at this time, make those revisions too.

4. Upload revised consent documents (see conversion instructions below).

   Tip: Remember to stack revised documents on top of the previously approved versions – instructions are available here: How do I submit an amendment to change my study?

5. Remember to click “Save” before exiting the smartform.
6. Submit the amendment to the IRB.

List of new questions added to the main pages of the RAMS-IRB Smartform

Note: Other new questions that are specific to only certain types of studies that are not included.

Organization of pages in the updated RAMS-IRB Smartform

2. Update the Study’s Informed Consent Documents

All adult consent documents that are currently being used or may be used in the future must be updated.

- This includes all consent documents used with adult participants, legally authorized representatives (LAR), and/or parents of child participants, regardless of what a specific study may have named the document.

  Examples of consent documents that must be converted include but are not limited to: informed consent forms, parental permission forms, LAR consent forms, consent scripts, pre-screening consent documents, and any other consent documents used with adult participants.

- Assent forms and exempt information sheets do not need to be updated.

- In anticipation of the FDA and Department of Justice (DoJ) regulations being harmonized with the 2018 Common Rule, VCU’s institutional policies require that all FDA and DoJ studies update their consent documents to include the 2018 Common Rule consent requirements (i.e. the key summary and new elements of informed consent) unless a robust justification is provided and accepted by the IRB.

  The 2018 Common Rule consent requirements in no way contradict the existing FDA/DoJ consent requirements.

Consent documents do NOT need to be updated in the following situations:

1. If the entire study is no longer accruing and will not reopen to accrual
2. If one or more arms/phases of the study is no longer accruing and will not reopen to accrual, that particular consent document does not need to be updated. However, all consent documents for arms/phases that are still accruing must be updated.
3. If you think your study will qualify for exemption under the 2018 Common Rule. However, if the IRB finds your study does not qualify for exemption, you will be required to update your consent documents.
4. If an applicable consent document is already compliant with the 2018 Common Rule because the study was initially submitted after March 1, 2018. The document must already contain the new consent elements and key summary section (if applicable)

To update your consent documents, read and follow these instructions to avoid doing unnecessary work:

Instructions on how to update existing consent documents

Template language needed to update existing consent documents

Four new consent elements

Key summary section for biomedical consent documents

Key summary section for social-behavioral consent documents

Humanitarian Use Device studies must make only one revision to their consent documents: At the end of the first sentence, "4,000 individuals" should be revised to be "8,000 individuals":

> *"You are being asked to consider treatment involving the use of a Humanitarian Use Device (HUD), which is a medical device intended to benefit patients in the treatment or diagnosis of a disease that affects or is manifested in fewer than 8,000 individuals in the United States per year."*

How long will it take the IRB to approve my conversion amendment?

Please allow at least 2 months for the review and approval of your conversion amendment.

- Currently, the approximate time from receipt by the IRB until the first IRB review comments are sent to investigators (excluding departmental and scientific review) is 3-4 weeks for single reviewers (exempt/expedited) and 1-2 weeks for committee reviews (full board).
- However, the IRB is anticipating that there will be a higher than usual volume of submissions during the next months, which will lead to longer timelines.

If you have an important deadline or need, log a Public Comment to the assigned IRB Coordinator for your study after you submit your amendment. Explain what your need is, and we will do our best to work with you.

What can I do to help the conversion process go smoothly?

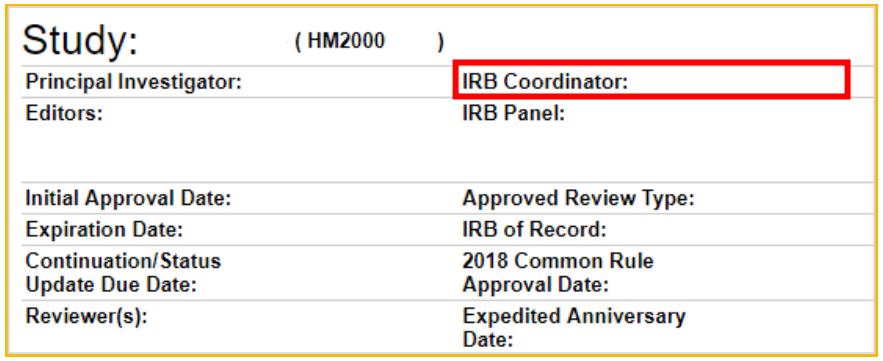
The better the quality of the amendment submission, the faster the review. Rushed submissions tend to have longer review times and require more rounds of revisions.

Here are some tips to help the conversion process go smoothly and quickly:

- Educate yourself about the 2018 Common Rule so that you're familiar with the changes - 2018 Common Rule Information is available here
- Read and follow the instructions that are provided on the page above about how to convert
- Allow sufficient time to create the conversion amendment so that you can do your best work
- Proofread the RAMS-IRB smartform and consent documents prior to submission to make sure your submission accurately reflects your research
- Respond promptly if and when changes are requested or if the IRB contacts you with questions
- Contact the IRB Coordinator assigned to your study if you are unsure about something – the IRB staff are regulatory experts and can advise you on exactly what to do for your particular study.

Whom can I contact with questions?

» Contact the IRB Coordinator assigned to your study - This will be the best person to answer your questions.



» Or contact ORSP at 828-0868 or at ORSP@vcu.edu