2018 Common Rule: Consent Form Conversion

START

You must convert your consent form to meet the 2018 Common Rule Standards if:

1. You received a notice to convert your study,
2. Your study was approved by the VCU IRB before 3/1/2018, AND
3. The study is still accruing participants or might reopen to accrual

Do Convert

* Adult consent documents
* Parental Permission documents
* Verbal or phone scripts to obtain consent/parental permission

Don't Convert

* Assent forms
* Exempt Information Sheets
* Consent documents that will no longer be used
* Consent documents that are already compliant with the 2018 Common Rule Standards

FAQ's

Q. What if the study sponsor won't let me convert to the 2018 Common Rule?

A. Format the Key Information section and new consent elements as a VCU-specific cover page

Q. Will I have to re-consent current or past participants?

A. Only if you add new information that could change someone's decision about whether to participate.

Q. What about my translated consent documents?

A. You will need to obtain a new translation that matches the revised English consent document.

Q. Does this apply to FDA and DoJ studies?

A. Yes, these agencies plan to harmonize with the 2018 Common Rule.

Step 1

Find and download your approved consent document(s) from RAMS-IRB:

- Navigate to the Documents tab
- Click 'View' next to the consent form
- Click the History hyperlink
- Click on the Word (.doc) file under the stamped PDF file to download

Step 2

Will the following 6 sections of your consent document(s) fit on 3½ pages or less?

1. Purpose
2. Procedures
3. Risks and Discomforts
4. Benefits
5. Alternatives
6. Voluntary Participation (excl. withdrawal instructions)

YES

A. Re-order the sections of the consent document to be in the following order:

1) Voluntary Participation (excluding withdrawal instructions)
2) Purpose and Description of Study
3) Procedures
4) Alternatives
5) Risks and Discomforts
6) Benefits

B. Add the new elements of consent

NO

A. Add a new Key Information section as the first section of the consent document

B. Add the new elements of consent

Templates for the new Key Information Section & New Elements of Consent are available on the ORSP website!

Look under "Conversion Resources."

Contact ORSP

ORSP@vcu.edu

804-828-0868

research.vcu.edu/human_research

wp.vcu.edu/humanresearch

Step 3

Proofread and edit the entire consent document:

- Does the content still make sense in its new order?
- Is the language understandable to a lay reader?
- Does it contain all the information a reasonable person would want to know about the study?