

GUIDANCE: CONVERTING STUDIES TO UTRMS-IRB	
NUMBER	VERSION DATE
HRP-UT980	10/08/2020

UT Research Management Suite – IRB (UTRMS-IRB) Study Conversion Guidance for Researchers

This document contains an inventory of action items you will need to complete when you submit your first continuing review in the UT Research Management Suite – IRB Module (UTRMS-IRB) to convert your study from IRBaccess to the UTRMS-IRB.

This conversion process will be starting in October 2020 for all expedited and exempt studies currently approved in IRBaccess. We request, at time of your next continuing review or progress report due on or after October 1, 2020, that you submit the “**Modification and Continuing Review**” action in UTRMS-IRB.

*It is strongly recommended that you begin this conversion process **at least 3-4 weeks prior** to your current study approval end date.*

When you log in to the UTRMS-IRB, you will be able to see a shell protocol created for your current study in IRBaccess. This shell protocol contains basic information about your study that was copied from IRBaccess to UTRMS-IRB. You will need to update the SmartForm to have a complete copy of your study details in the UTRMS-IRB. Additionally, you will be required to upload the most recent versions of all study documents (proposal, supplemental proposal forms, consent forms (in Word Doc format), recruitment materials, study measures, surveys, site letters, etc.).

Note: If your full board or expedited study was originally approved prior to January 21, 2019, additional changes to study documents will be required to transition your study to the New Common Rule. You will be required to submit an updated proposal using the required HRP-UT901 – Template IRB Proposal Standard Submission and any supplemental proposal forms applicable to your study. The required templates can be accessed in the UTRMS-IRB Library or on the [IRB Submission Forms](#) page. Additionally, please see the Informed Consent Changes section (below) for additional information on the required changes needed to transition your study. If you have any questions about this transition, please reach out to the IRB staff via email at irb@austin.utexas.edu.

[Step-by-Step Overview of Converting Studies to UTRMS-IRB.](#)

1. Update proposal as required (see below for additional information)
2. Download all most recently approved study documents from IRBaccess.
3. Navigate to [UTRMS-IRB](#) and find the study you will be converting (Tip: the study number in UTRMS-IRB will be the same study number in IRBaccess, without the dashes).
4. Open the study by clicking on the study title – this will take you to the study workspace.
5. Click on **Create Modification/CR/Closure**

Approved

Entered IRB: 8/12/2020 11:40 AM
 Initial approval: 8/12/2020
 Initial effective: 8/12/2020
 Effective: 8/12/2020
 Last updated: 8/12/2020 11:42 AM

Next Steps

View Study

Printer Version

Create Modification/CR/Closure

Report New Information

- a. Choose “Modification and Continuing Review” as the purpose of the submission.
- b. Select “Other parts of the study”
 - i. *Note:* To list current and new study team members, also choose “Study team member information”

Modification / Continuing Review

Continuing Review / Study Closure Information

Modification Summary

Modification Details

Editing: STUDY00000211-MODCR01

Modification / Continuing Review / Study Closure

*** What is the purpose of this submission?** ?

Continuing Review/Study Closure

Modification / Update

Modification and Continuing Review

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information

Other parts of the study

Active Modification For This Study	Modification Type
Active Modification And Continuing Review For This Study Modification and Continuing Review #1 for Study Test - KC Aug5	Modification Type Other parts of the study Study team member information

- c. Click **Continue**
- d. Continuing Review/Study Closure Information: Complete the Continuing Review information

Modification / Continuing Review

Editing: STUDY00000211-MODCR01

Go to forms menu Print Help

Continuing Review / Study Closure Information

Continuing Review / Study Closure Information

Modification Summary

Modification Details

- * Specify enrollment totals at this investigator's sites:**
- * Specify enrollment totals at this investigator's sites since last approval:**
- * Specify enrollment totals study-wide:**
- Research milestones: (select all that apply)**
 - Study is permanently closed to enrollment OR was never open for enrollment
 - All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
 - Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - Remaining study activities are limited to data analysis
 - Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
- * Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?**

Yes No [Clear](#)
- Check the items that are true since the last IRB approval for all sites involved in the study:** (initial review or last continuing review)
 - NO subjects experienced unexpected harm
 - Anticipated adverse events have NOT taken place with greater frequency or severity than expected
 - NO subjects withdrew from the study
 - NO unanticipated problems involving risks to subjects or others
 - NO complaints about the study
 - NO publications in the literature relevant to risks or potential benefits
 - NO interim findings
 - NO multi-center trial reports
 - NO data safety monitoring reports
 - NO regulatory actions that could affect safety and risk assessments
 - NO other relevant information regarding this study, especially information about risks
 - In the opinion of the PI, the risks and potential benefits are unchanged
 - All modifications to the protocol have been submitted to the IRB
 - All problems that require prompt reporting to the IRB have been submitted

Exit Save Continue

- i. *Note:* Only attach supporting documents if appropriate for the Continuing Review, general study documents will be attached later in the process.
- e. Modification Summary: Summarize the Modifications: Include “Convert study from IRBaccess to UTRMS-IRB”

Modification / Continuing Review

Editing: STUDY00000211-MODCR01

Go to forms menu Print

Modification Information

Continuing Review / Study Closure Information

Modification Summary

Modification Details

- Study enrollment status:**
 - No subjects have been enrolled to date
 - Subjects are currently enrolled
 - Study is permanently closed to enrollment
 - All subjects have completed all study-related interventions
 - Collection of private identifiable information is complete
- Notification of subjects: (check all that apply)**
 - Current subjects will be notified of these changes
 - Former subjects will be notified of these changes

Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.
- * Summarize the modifications:**

Convert study from IRBaccess to UTRMS-IRB

- i. *Note:* If you will be making modifications to the currently approved research, provide a brief summary if any additional changes.

- ii. *Note:* If your study was originally approved prior to January 21, 2019 and you need to update your protocol and consent form to comply with the new common rule, add the following (as applicable to your research) to the Summarize the Modifications section:
 "Update consent forms to new common rule (as required):
 1. Add key information section to consent form.
 2. Add information regarding future use of data/bio-specimens.
 3. Add information regarding commercialization.
 4. Add information regarding disclosure of clinically relevant information.
 5. Add information regarding whether research will involve whole genome sequencing to consent form."

For more information on the common rule transitions see the "Informed Consent Document Changes for New Common Rule" section below.

- f. Click **Continue** - you will then be directed to the overall study SmartForm. Follow instructions on updating the SmartForm in the table below.

The screenshot shows the 'Basic Study Information' section of a SmartForm. On the left is a navigation menu with items: Basic Study Information (highlighted), Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, Drugs, Devices, and Local Site Documents. The main content area contains the following questions and input fields:

1. * Title of study: [Text input field]
2. * Short title: [Text input field]
3. * Brief description: [Text area]
4. * What kind of study is this?:
 - Multi-site or Collaborative study
 - Single-site study
 - [Clear](#)
5. * Will an external IRB act as the IRB of record for this study?:
 - Yes
 - No
6. * Local principal investigator:
 - Kristen Crabtree [Dropdown menu]
7. * Does the local principal investigator have a financial interest related to this research?:
 - Yes
 - No
 - [Clear](#)
8. * Attach the protocol:
 - [+ Add](#)
 - Document

- g. Once the SmartForm is updated (following instructions in the table below), Click **Finish** and on the study workspace, Click **Submit** to submit the Modification and Continuing Review action.

Manual Changes Required on UTRMS-IRB SmartForm

Although all active studies will be converted into the new system, there will be a handful of manual changes you will have to make when you submit your first Modification and Continuing Review in UTRMS-IRB. An inventory of these changes is listed below.

#	Manual Conversion Component	Description of change
1	Basic Study Information	<ol style="list-style-type: none"> 1. Confirm title of study is accurate, make changes if needed. 2. Confirm short title is accurate, make changes if needed 3. Brief description: include a brief description of your study 4. What kind of study is this: confirm response is correct, if not, update as needed. 5. Will an external IRB act as the IRB of record: If relying on UT IRB, selection will default to "No." If you are moving the study to an external IRB for review, select "Yes." 6. Local principal investigator: Confirm PI is correct, update if needed. 7. Does the local PI have a FCOI: confirm and modify if needed 8. Attach the protocol: Attach the UT proposal template (Standard Submission, Exempt, Secondary Use, or HUD proposal)
2	Study Funding	Update the funding sources as appropriate.
3	Local Study Team Members	Add research personnel and modify roles as needed. Be sure to include all research personnel engaged in human subjects research.
4	Study Scope	<ol style="list-style-type: none"> 1. Study involve drug, biologic, or supplement: update response as needed – select "Yes" if the study involves a drug/biologic/supplement and complete the additional drug smart form pages. 2. Study involve investigational device or HUD: update response as needed – select "Yes" if the study involves an investigational device or HUD and complete the additional device/HUD smart form pages.
5	Local Research Locations	Update to include research locations (e.g., Dell Children's Medical Center, Austin Independent School District, etc.).
6	Local Site Documents	<ol style="list-style-type: none"> 1. Consent forms: Upload Word Document copies of all currently approved consent, assent, and parent permission forms, as applicable. 2. Recruitment materials: Upload copies of all recruitment materials 3. Other attachments: Upload copies of all other study materials including supplemental proposal documents, sponsor protocols, measures, surveys, interview guides, site letters (e.g., Seton Site Approval Tool confirmation, school district letters, etc.), and other study related materials as appropriate.

Protocol Template Changes

With the launch of UTRMS-IRB, the IRB office is also implementing new protocol/proposal templates and supplemental proposal forms. The research team converting current protocols/proposals to the new template should be able to copy/paste most of the text information and can complete the rest of the form by simply checking boxes (instructions appear at the top of each template document). All expedited and full board studies originally approved prior to January 21, 2019 will be required to convert their existing study proposals into the new proposal template and applicable supplemental proposal forms.

For all expedited and full board studies originally approved after January 21, 2019, it is strongly recommended that you convert the study proposal to the new templates as they are built to be more collaborative (can use track changes and make comments).

Informed Consent Document Changes for New Common Rule

Studies that were originally approved prior to January 21, 2019 will need to transition to the New Common Rule. This transition is likely to affect informed consent document/parental permission forms as additional elements are now required in some instances. See below for an outline of changes that may need to be made to the current informed consent document/parental permission forms. Please update your consent forms as needed and submit the revised consent forms with your Modification and Continuing Review submission in UTRMS-IRB.

I. Key Information

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. The key information section is required for consent forms with 4 or more pages.

Researcher Action:

Insert the following at the beginning of the consent form and revise to include study applicable information:

“Things you should know:

- The purpose of the study is to **[briefly describe study purpose]**.
- In order to participate, you must be **[briefly describe eligibility criteria]**
- If you choose to participate, you will be asked to **[do what, when, where, and how]**. This will take **[state period of time]**.
- Risks or discomforts from this research include **[briefly describe most likely risks or state that the risks involved in this study are not greater than everyday life]**.
- The possible benefits of this study include **[provide a description of potential benefits to subjects or state that there is no direct benefit for participating in this study]**.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.”

II. Future Use

Notice of future use of identifiable private information or identifiable biospecimens.

Researcher Action:

Update consent form to state whether de-identified information or biospecimens could be used for future research without additional consent. Add **one** of the following:

Option 1:

“We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers may include information that can directly identify you. Researchers will not contact you for additional permission to use this information.”

Option 2:

“We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you.”

Option 3:

“The data or samples that we will collect about you will not be shared with any other researchers.”

III. Commercialization

If applicable, include a statement that identified or de-identified biospecimens may be used for commercial profit and whether the subject will share in the profit or not. Only include one of the following if you are collecting biospecimens as part of your research procedures.

Researcher Action:

Update consent form to state whether or not a subject will share in commercial profit. Add **one** of the following:

Option 1:

“Your samples may be used for commercial profit and there is no plan to share those profits with you.”

Option 2:

“Your samples may be used for commercial profit and there are plans to share those profits with you. **[Explain profit sharing plan]**”

IV. Clinically Relevant Research Results

If applicable, include a statement whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

Researcher Action:

Update consent form to state whether or not the results will be disclosed and under what conditions. Add the following, if applicable:

“As part of this study, we may learn medically relevant information about you. If we learn something that you and your doctor did not know, we will **[describe process to relay health information]**.”

V. Whole Genome Sequencing

If applicable, for research involving biospecimens, include a statement that the research will or might include whole genome sequencing.

Researcher Action:

Update consent form to state that whole genome sequencing may occur (consider that sequencing may take place in the future if specimens are to be shared). Add **one** of the following:

Option 1:

“The samples collected during this research may have genetic information created from them. The researchers do not plan to sequence your whole genome from this sample.”

Option 2:

“The samples collected during this research may have genetic information created from them. The researchers plan to sequence your whole genome from this sample. **[Explain what genetic information will be used, generated, or obtained].**”

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from his research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by and all employers with 15 or more employees must follow this law.

Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it prohibit discrimination on the basis of a genetic disease or disorder that you already know about.”