eIRB Annual Updates – FAQs

1. **What are Annual Updates in eIRB?**

   IRB continuing review is not required for **some** minimal risk research initially approved by the IRB on or after **January 21, 2019**. This includes **some** more than minimal risk research where the remaining activities are limited to analysis of identifiable data/biospecimens or the collection of follow up information. Additionally, studies relying on an external IRB are not required to undergo Continuing Review by the UTSW IRB.

   While Continuing Review (CR) may not be required for some studies, the HRPP still requires an Annual Update (AU) for these studies. The Annual Updates will allow the HRPP to monitor progress and ensure studies are closed in a timely manner.

   NOTE: If a study was initially approved by the IRB prior to January 21, 2019 and was determined to require continuing review, continuing review is still required to remain compliant. Additionally, all FDA-Regulated research is required to undergo continuing review.

2. **Is the Annual Update Form as long as the Continuing Review Form in eIRB?**

   No. The AU form is simplified and includes between 8-14 questions depending on your study activity in the past year. Reliance studies may have an additional 3 questions. *See the bottom of this FAQ for samples of the AU forms.*

3. **Who reviews and accepts Annual Updates?**

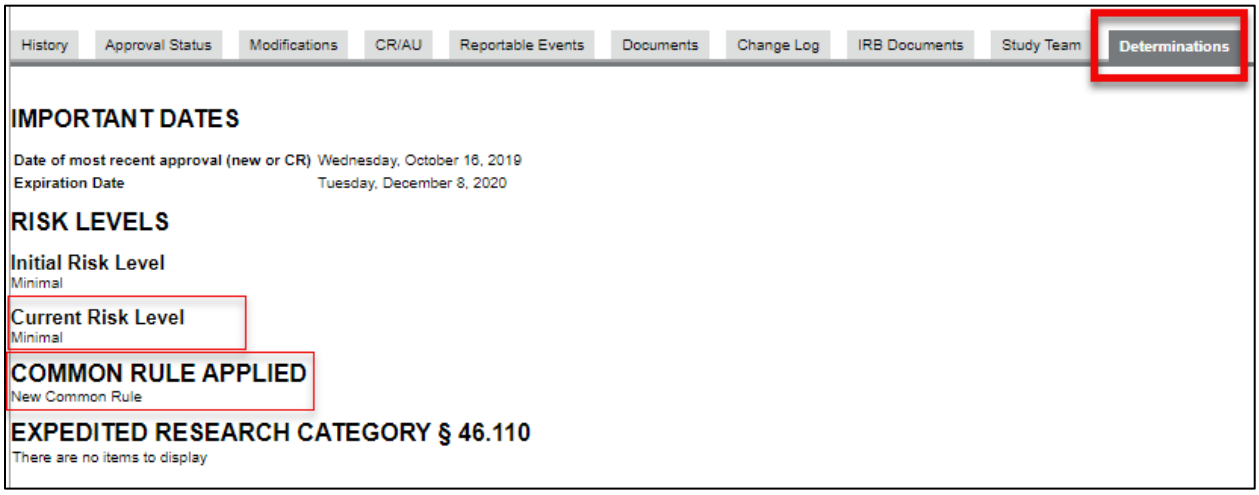
   Annual Updates are reviewed and accepted administratively within the HRPP Office. Annual Updates **will not** be reviewed by the IRB.

4. **How will I know if I need to submit a CR or AU?**

   Refer to eIRB. Notifications will be sent from eIRB notifying you to submit either an Annual Update or Continuing Review. The system will only allow for the correct type of submission to be created in eIRB.

   Studies with a "Review Type" of *Relying on a Non-UT Southwestern IRB* will submit an AU. You may also refer to the "Determinations" tab in eIRB. AU is required for the following:

   - Common Rule Applied = New Common Rule *AND* Current Risk level = Minimal (as below)



5. Will my study look different in eIRB if it qualifies for Annual Updates?

Yes.

The eIRB system will now reflect CR/AU to include both Continuing Reviews and Annual Updates. When your study is nearing expiration, the system will notify you that an Annual Update is due. If a study reaches its expiration date, the status will change to “Annual Update Overdue” (instead of “Expired”).

6. Can research continue when the state changes to “Annual Update Overdue”?

Yes.

While you may continue your research activities in this state without regulatory violations, you should submit the Annual Update as soon as possible. Studies which have not submitted the AU timely are at risk of suspension or termination. If you are unable to submit the AU timely, contact the HRPP office to ensure the study is not closed.

Sample AU Forms (actual questions highlighted)

Minimal Risk, Revised Common Rule AU:

1.0 Study Status

*** 1.1 Recruitment of new subjects (Select one)**
No participants/specimens/data have been enrolled/collected at this site to date

This response is system generated and not editable

*** 1.1.1 Special Protocol Type:**
This study requires an Annual Update instead of Continuing Review (it is externally reviewed by non-UTSW IRB, or minimal risk and non-FDA regulated per Revised Common Rule)

View: LITE 12.0 Annual Update

12.0 Annual Update

12.0 Annual Status Report

*** 12.1 Since the last review (initial or annual update), how many subjects have you either: enrolled (consented); and/or otherwise included in this research (e.g., waived consent)?**
12

*** 12.2 How many total subjects have been enrolled/included in this research since the study started?**
12

*** 12.3 Summarize your study's progress toward achieving the objectives of the study.**
summary

12.4 Funding source and/or cooperating organization(s):

Federal Grant Information

Agency	Grant Number
There are no items to display	

Other External (Non-Federal) Information

Supporting Entity	Supporting Mechanism
There are no items to display	

*** 12.4.1 Has the funding source changed?**
Yes **No**

*** 12.5 Have any non-English speaking participants been enrolled since the last review?**
Yes **No**

*** 12.6 Taking into consideration all experiences and safety-related information, have any problems (AE or non-AE) occurred (locally or externally if multi-center) since the last IRB review?**
Yes **No**

*** 12.7 Have there been any *deviations* (major or minor) from the currently-approved protocol initiated by the investigator, study staff, or study subjects (i.e. procedures/labs done outside the window, missed visits, procedures/labs not conducted, discrepancies in medication inventories)?**
Yes **No**

View: LITE 14.0 Final Page

14.0 Final Page

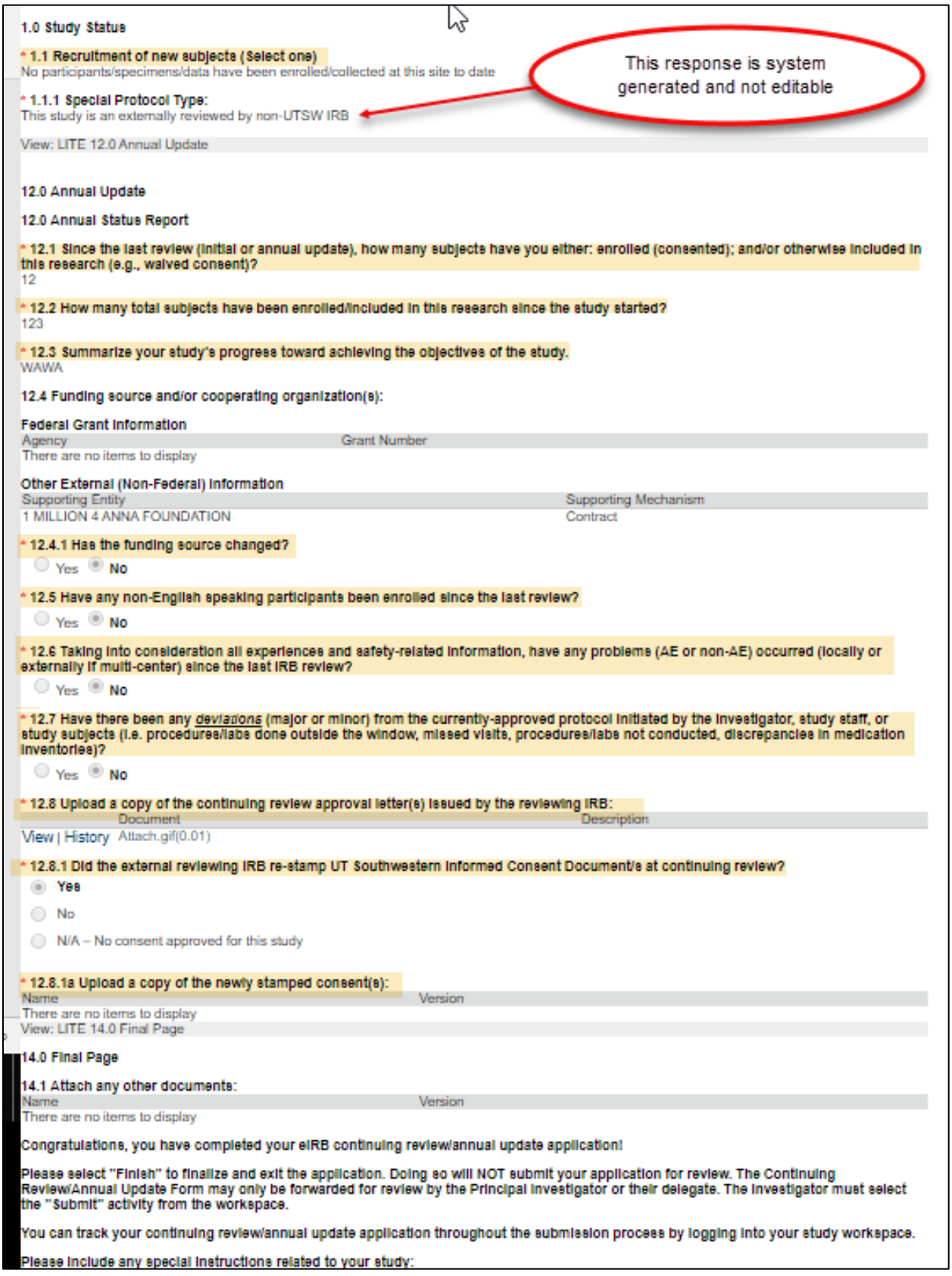
14.1 Attach any other documents:

Name	Version
There are no items to display	

Congratulations, you have completed your eIRB continuing review/annual update application!

Please select "Finish" to finalize and exit the application. Doing so will NOT submit your application for review. The Continuing Review/Annual Update Form may only be forwarded for review by the Principal Investigator or their delegate. The investigator must select the "Submit" activity from the workspace.

Relying on Non-UTSW IRB AU:



1.0 Study Status

* 1.1 Recruitment of new subjects (Select one)
No participants/specimens/data have been enrolled/collected at this site to date

* 1.1.1 Special Protocol Type:
This study is an externally reviewed by non-UTSW IRB

View: LITE 12.0 Annual Update

12.0 Annual Update

12.0 Annual Status Report

* 12.1 Since the last review (initial or annual update), how many subjects have you either: enrolled (consented); and/or otherwise included in this research (e.g., waived consent)?
12

* 12.2 How many total subjects have been enrolled/included in this research since the study started?
123

* 12.3 Summarize your study's progress toward achieving the objectives of the study.
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12.4 Funding source and/or cooperating organization(s):

Federal Grant Information

Agency	Grant Number
There are no items to display	

Other External (Non-Federal) Information

Supporting Entity	Supporting Mechanism
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* 12.4.1 Has the funding source changed?
Yes No

* 12.5 Have any non-English speaking participants been enrolled since the last review?
Yes No

* 12.6 Taking into consideration all experiences and safety-related information, have any problems (AE or non-AE) occurred (locally or externally if multi-center) since the last IRB review?
Yes No

* 12.7 Have there been any *deviations* (major or minor) from the currently-approved protocol initiated by the investigator, study staff, or study subjects (i.e. procedures/labs done outside the window, missed visits, procedures/labs not conducted, discrepancies in medication inventories)?
Yes No

* 12.8 Upload a copy of the continuing review approval letter(s) issued by the reviewing IRB:

Document	Description
View | History Attach.gif(0.01)	

* 12.8.1 Did the external reviewing IRB re-stamp UT Southwestern Informed Consent Document/s at continuing review?
Yes
No
N/A – No consent approved for this study

* 12.8.1a Upload a copy of the newly stamped consent(s):

Name	Version
There are no items to display	

View: LITE 14.0 Final Page

14.0 Final Page

14.1 Attach any other documents:

Name	Version
There are no items to display	

Congratulations, you have completed your eIRB continuing review/annual update application!

Please select "Finish" to finalize and exit the application. Doing so will NOT submit your application for review. The Continuing Review/Annual Update Form may only be forwarded for review by the Principal Investigator or their delegate. The investigator must select the "Submit" activity from the workspace.

You can track your continuing review/annual update application throughout the submission process by logging into your study workspace.

Please include any special instructions related to your study: