IMPORTANT IRB updates for Einstein researchers

All studies currently under AEHN IRB oversight will transition to Jefferson IRB oversight and Jefferson's iRIS system according to the following schedule:

Go-live of new and new reliance studies to be submitted in iRIS	Jan 20
Final submission deadline for AEHN IRB for continuing reviews and modifications that require Full Board review.	Feb 1
Last AEHN IRB meeting to review continuing reviews and modifications that require Full Board review **and** last day for expedited continuing reviews and modifications to be approved by AEHN staff.	Feb 17
Suspension of Cayuse system. (Cayuse will remain active for read-only queries.)	Feb 18
Go-live for all expedited transactions to be submitted in iRIS.	Feb 18
Deadline for completion of full transactions from Feb 17 AEHN IRB meeting	Feb 28
Go-live of continuing reviews and modifications requiring full review to be submitted in iRIS.	March 1

Find information within this document on the following:

NEW STUDIES

1. Effective 1/20/23, **all** new studies must be submitted in iRIS.

2. The research team must submit an electronic copy of the following to Mary Klein for all new studies being submitted to the TJU IRB and non-TJU IRB (ie, WIRB, Advarra, etc) for review:

a) Study protocol-	TJU template can be found here: https://research.jefferson.edu/clinical/personnel/human-research/irb-forms.html
b) Draft consent form, if applicable-	TJU template can be found here: https://research.jefferson.edu/clinical/personnel/human-research/irb-forms.html
c) Research staff listing	AEHN form can be found here: Users:\SHARED\IRB_Forms
d) COI/PHS forms for each person listed on the study.	AEHN form can be found here: Users:\SHARED\IRB_Forms

3. Once the admin review is completed by AEHN, you will get authorization to submit the study in iRIS.
    - See previous communication or the TJU Office of Human Research website for more information on training and gaining access to iRIS: https://research.jefferson.edu/clinical/personnel/human-research.html

4. Please note that all staff listed on a study must complete the TJU Required CITI training which includes the following:
    1. AEHN's Human Research Protections modules or TJU's Biomedical or Social Behavior Research modules, (depending on the type of research you are conducting)
        a. Once your AEHN's Human Research Protections modules expire OR if you have never completed AEHN CITI, then you must do TJU's Biomedical Research or Social Behavior modules.
    2. Good Clinical Practice
    3. Conflict of Interest

    - You must update your affiliated institution to Jefferson, if not done already, and "add" any of the applicable courses above, if they are not displayed.

    - Please direct any CITI related questions to Kathleen Avender, CITI IRB Training Coordinator at *Kathleen.Avender@jefferson.edu*

Currently Active Studies

Because Cayuse cannot effectively migrate existing study records from the AEHN Cayuse system into iRIS, you will need to create and submit a new study application in iRiS for each of your active studies. **These applications will not receive formal IRB review**.

The purpose of this activity is to establish your studies in the system. Once submitted, your study will be administratively processed and you will receive an email notification when this has been completed.

In the study application, be sure to answer the following question in section 4.0:

4.5 Was this study previously approved or authorized by the AEHN/Einstein IRB? If yes, please indicate the AEHN/Einstein IRB number below. This number will replace the IRISID number for this study.

Answering this question will ensure that your study is identified as a currently approved AEHN study with the correct AEHN IRB number.

Once your study is established in iRIS, you can proceed to submit transactions for that study.

Continuing Reviews and Annual Check-Ins for currently active studies approved by AEHN IRB

Effective 3/3/23, Continuing Reviews and Annual Check-Ins for existing studies previously approved by the AEHN IRB must be submitted in iRIS.

1. The research team must submit an electronic copy of the following to Mary Klein for all Continuing Reviews and Admin Check-Ins.

a) Research staff listing	AEHN form can be found here: Users:\SHARED\IRB_Forms
b) COI forms for each person listed on the study. *note that PHS verification forms are not required to be submitted.	AEHN form can be found here: Users:\SHARED\IRB_Forms

2. Once the admin review is completed by AEHN, you will get authorization to submit the Continuing Review or Annual Check-In in iRIS.

3. Please note that all staff listed on a study must complete the TJU Required CITI training. See New Studies, #4.

Modifications
for currently active studies approved by AEHN IRB

Effective 3/3/23, modifications that include changes in staffing for existing studies previously approved by the AEHN IRB must be submitted in iRIS.

1. The research team must submit an electronic copy of the following to Mary Klein for all Modifications that include changes in staffing.

a) Research staff listing	AEHN form can be found here: Users:\SHARED\IRB_Forms
b) COI or PHS forms for each person being added on the study.	AEHN form can be found here: Users:\SHARED\IRB_Forms

2. Once the admin review is completed by AEHN, you will receive authorization to submit the modification in iRIS.

3. Please note that all staff listed on a study must complete the TJU-required CITI training. See New Studies, #4.

Study Closures
for currently active studies approved by AEHN IRB

Effective 3/3/23, Study Closures for existing studies previously approved by the AEHN IRB must be submitted in iRIS.

1. The research team must submit an electronic copy of the following to Mary Klein for all Study Closures.

a) Research staff listing	AEHN form can be found here: Users:\SHARED\IRB_Forms
b) COI forms for each person listed on the study. *note that PHS verification forms are not required to be submitted.	AEHN form can be found here: Users:\SHARED\IRB_Forms

2. Once the admin review is completed by AEHN, you will get authorization to submit the Study Closure in iRIS.

Continuing Reviews for currently active studies approved under an external IRB (ex., WCG, Advarra)

Effective 1/20/23, annual check-ins for existing studies previously approved under an external IRB must be submitted in iRIS.

For continuing reviews approved by WCG/Advarra/NCI CIRB, a copy of the approval letter is required. It is to be submitted in iRIS via the External IRB Annual Check-in form.

For continuing Reviews approved by all other external IRBs, a copy of the approval letter and annual report that was provided to the IRB of Record must be submitted in iRIS via the External IRB Annual Check-in form.

1. The research team must submit an electronic copy of the following to Mary Klein for all Continuing Reviews..

a) Research staff listing	AEHN form can be found here: Users:\SHARED\IRB_Forms
b) COI forms for each person listed on the study. *note that PHS verification forms are not required to be submitted.	AEHN form can be found here: Users:\SHARED\IRB_Forms

2. Once the admin review is completed by AEHN, you will receive authorization to submit the Continuing Review or Modification in iRIS.

3. Please note that all staff listed on a study must complete the TJU-required CITI training. See New Studies, #4.

Modifications for currently active studies approved under an external IRB (ex., WCG, Advarra)

Effective 1/20/23, personnel changes for studies under external IRB must be submitted in iRIS.

All other modifications to studies under external IRBs should be submitted to the external IRB.

The research team must submit an electronic copy of the following to Mary Klein for all Modifications that include changes in staffing.

a) Research staff listing	AEHN form can be found here: Users:\SHARED\IRB_Forms
b) COI or PHS forms for each person being added or removed from the study.	AEHN form can be found here: Users:\SHARED\IRB_Forms

1. Once the admin review is completed by AEHN, you will receive authorization to submit the Continuing Review or Modification in iRIS.

2. Please note that all staff listed on a study must complete the TJU Required CITI training. See New Studies, #4.

Other information

Signing Authority
The submitter is responsible for identifying and assigning the appropriate signatories to the iRIS application, typically the local departmental chair and the departmental administrator. Jefferson IRB relies on the research team to correctly identify its signatories, as per Jefferson IRB policy.

Accessing iRIS from off-site
The DUO app is used by all Jeffersonians to gain access to Jefferson systems requiring log-in. If you do not currently have DUO installed on your phone, go to the app store and download.

You will need to go through a short setup process to verify your identify. Then, when you go to log-in to iRIS, the system will verify your identify by either sending you a text or calling you with a temporary password which you type into the DUO log-in screen on your computer. Once your identify is verified, you can then proceed to iRIS to log-in using campus key and password.

You can access the DUO instructions at: Einstein Researchers (jefferson.edu)

What are Jefferson IRB office hours?
Our office hours are 9-5, Monday-Friday.

Where can I find additional information, tip sheets, instructions, and contact information on the following:
1. https://research.jefferson.edu/clinical/personnel/human-research.html
2. Confluence web site.(must be on campus to access).

Who can I contact with questions?

You can contact the Director or Associate Director of the Office of Human Research with questions:

Walter Kraft, MD
Director, Office of Human Research
215-503-0203
Walter.Kraft@jefferson.edu

Kyle Conner, MA, CIP
Associate Director
Office of Human Research
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