Kevin

HUMAN RESEARCH ADVISORY COUNCIL

SUNY Downstate IRB Updates

Forms, data use, policy, training, AI guidance, and ancillary review requirements

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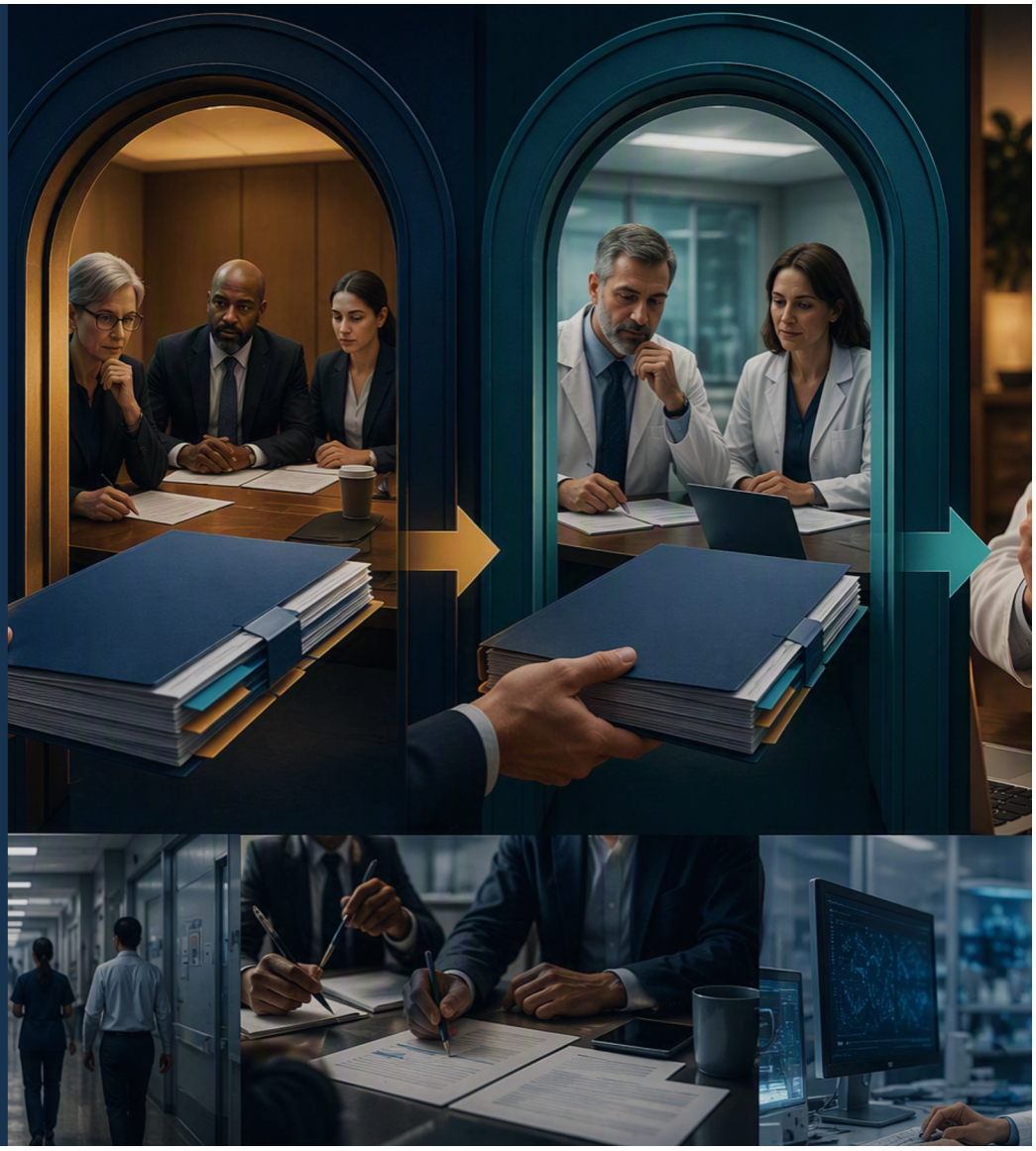
Investigator and study team briefing

Generative AI tools were utilized to assist in drafting portions of this presentation. The content has been independently reviewed, verified, and approved by the presenter for accuracy and completeness.



AT A GLANCE

What changed

1 Forms

11-A4 and 11-A4Q discontinued; use 11-4C for applicable determinations

2 TriNetX Data

TriNetX confidentiality, eligibility, and project-specific requirements

3 Waivers

New Forms 8-19A and 8-19B

4 Governance

IRB-01, COI procedure, Kings County, and AI guidance

5 Unfunded Clinical Research

Step 7B ancillary review clarified for certain clinical research

6 Submission steps

Step 11 finalized and Step 18 updated

SUBMISSION FORM UPDATE

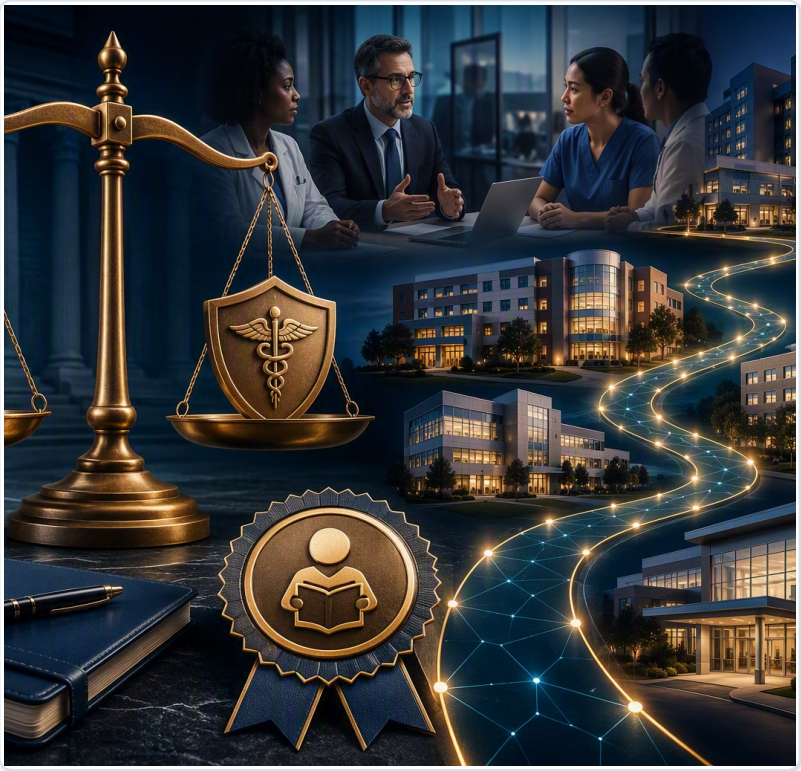
Forms 11-A4 and 11-A4Q are discontinued

Effective workflow

For IRB determinations of “Not Research” or “Not Human Research,” submit Form 11-4C.

Do not use legacy Forms 11-A4 or 11-A4Q for new submissions.

Purpose: streamline operations and reduce avoidable form confusion.



DATA PRIVACY AND ACCESS

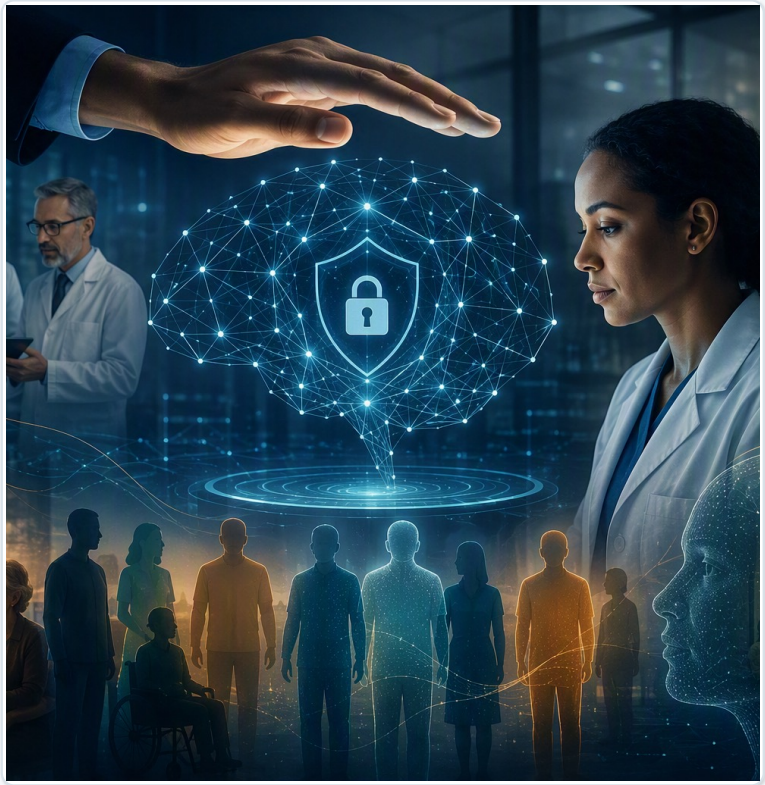
TriNetX data requirements:

1. **Confidential:** do not share data outside authorized Downstate users or the TriNetX license terms. Follow policies governing data privacy, security, and appropriate use.

2. **Eligible access:** limited to individuals with a Downstate-paid appointment or an active appointment confirmed by Student Affairs or GME.
Excluded access: research volunteers, volunteer faculty, visitors, and similar affiliates.

3. **CITI Training:** Responsible Conduct & Export Control

4. **IRB Applications:** Each new project involving TriNetX data requires a separate IRB application. Submit Form 11-4C for access to de-identified data. Submit applicable IRB application to access identifiable Tri-Net-X data, depending on study type: Form 11-A1, A2, or A3.



Requirements language has also been added to Step 11.

FORMS 8-19A AND 8-19B

Updated waiver and alteration request forms

The revised forms incorporate waiver and alteration options permitted under the HIPAA, Common Rule, and FDA regulations, including parental or legal guardian permission and child assent, when applicable.

Form 8-19A

Dynamic PDF for one or more selected waiver or alteration types. Relevant regulatory sections are generated based on the investigator's selections.

Form 8-19B

Typically used for retrospective chart reviews and similar minimal-risk research seeking consent and/or HIPAA waiver or alteration.

The applicable criteria are built into the forms.

WAIVER FORM SELECTION

Choose the form that matches the request

FORM 8-19A

- **Consent waiver or alteration**
- **Public benefit/service program waiver**
- **Leftover anonymous specimens for an IVD study**
- **Waiver of consent documentation**
- **Parental or legal guardian permission**
- **Planned emergency research consent waiver**
- **Child assent waiver**
- **HIPAA waiver or alteration**

FORM 8-19B

Typically used for retrospective chart reviews and similar minimal-risk research when requesting:

- Waiver or alteration of informed consent
- HIPAA waiver or alteration
- Or both requests together

Use the form-specific criteria provided in the PDF.

POLICY AND SUBMISSION PROCESS

Policy IRB-01 and Step 11 are updated

POLICY IRB-01

The updated policy is posted on the Policies and Guidance website.

A summary of revisions and a version comparison report are also available.

Some updates were based on recommendations from CARE-Q certification, FDA Audit, and RF Central Office Internal Audit

Form 11-4C / Step 11

The finalized form includes digital signatures. It is required for all non-human research and all non-research projects carried out by residents and may be required for others by a Department or College/School.

Required for TriNetX access requests involving activities that are not human research (de-identified data).

See Steps 11 and 11A for full submission details.

New procedural updates

COI training and reporting

A new IRB procedure for COI disclosures and training requirements is posted in the IRB Guidance for Investigators section.

Changes required based on NEW Downstate COI Policy and New MyResearch COI Module.

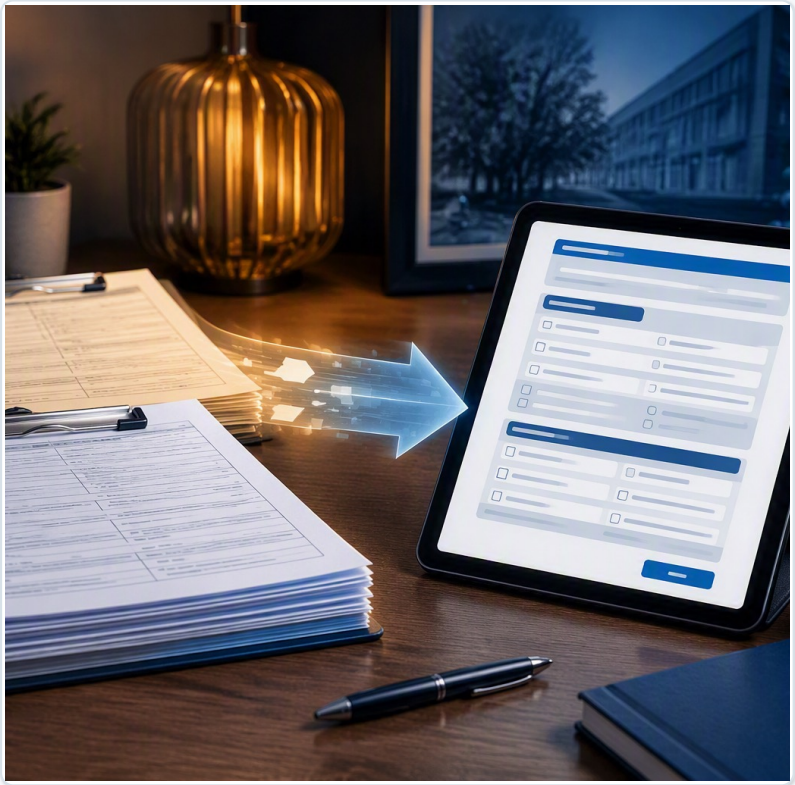
Will integrate with upcoming MyResearch IRB and IACUC modules.

Kings County research

Step 18 has been updated to include clarifications and new requirements for Kings County research.

All submissions involving Kings County research must be shared with the Kings County Research Office.

Review the applicable guidance before preparing or revising the IRBNet package.



New artificial intelligence guidance

New resources & New AI Steering Committee.

Framework for Review of Clinical Research Involving AI

Practical guidance on algorithmic bias, adaptive learning, security, privacy, human oversight, regulatory decisions, study stages, and ethical considerations.

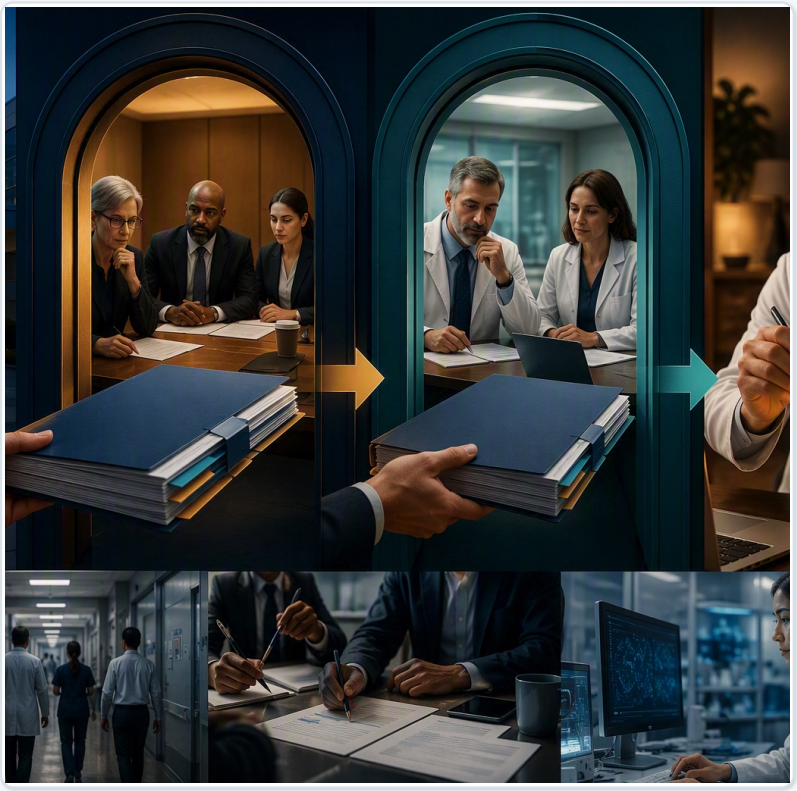
The Downstate IRB will use the framework when reviewing human research that uses AI.

Statewide DeepSeek ban

A separate SUNY memorandum addresses the statewide ban of the DeepSeek AI application.

Downstate AI Steering Committee Ancillary Review

- IRB Issues Conditional Approval Letter.
- PI submits IRB Letter with AI Steering Committee request to HELP@downstate.edu
- PI submits AI approval to IRB for final IRB approval.
- If AI Steering Committee requires modifications, the PI must submit an amendment to the IRB.



Step 7B: ancillary review before IRB approval

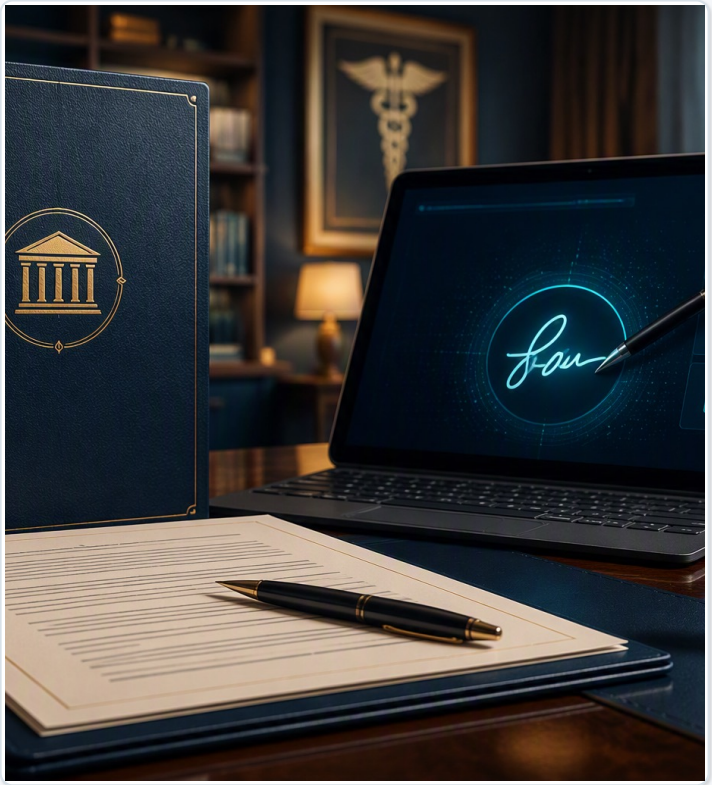
UHD and/or DHP ancillary review is required for certain unfunded clinical research before IRB approval, including:

- Medical device trials requiring an IDE
- Drug or biologic trials requiring an IND
- Clinical trials deemed more than minimal risk
- Clinical research involving bedside infusions, pregnant women, fetuses, children, or cognitively impaired adults
- Clinical research prospectively enrolling UHD or DHP patients or using their resources, except when the sole interaction/intervention is a survey or obtaining consent

PI submits the following to the IRB, which forwards to Hospital Committee and DHP, as applicable:

- Form 7B
- Research Budget – outline research costs and financial support
- Cover letter detailing costs, % effort/labor for paid investigators, signed by Department Chair, PI, and Department Administrator. Dean must sign if Department Chair is PI.

If funded and supported by UHD or DHP, approval from each applicable organization is required.



INVESTIGATOR ACTION CHECKLIST

Before the next submission

Use current forms	Remove legacy 11-A4/11-A4Q copies and use the finalized 11-4C where applicable.
Confirm data access	Verify TriNetX eligibility, confidentiality limits, and project-specific requirements.
Select the correct waiver form	Use 8-19A for broader combinations or 8-19B for the typical retrospective/minimal-risk use case.
Review updated requirements	Check IRB-01, COI guidance, Step 18, AI resources, and Step 7B as applicable.

Use the IRB submission and Policy and Guidance webpages as the source of current forms and instructions.