SUNY Downstate IRB & Privacy Board

Pilot Form 11-4C: Checklist for IRB Acknowledgment of a SELF-DETERMINATION of "Not Research" or "Not Human Research" and Attestation of Institutional Compliance

(Pilot Version 07.18.2025)

PURPOSE: Downstate Residents are required to submit this checklist, along with the IRBNet registration form and any necessary agreements, to the IRB office via IRBNet for any non-research or non-human research activities, as delineated in Section 2 below. Other members of the Downstate workforce may also use this checklist if required by their Department or College/School, instead of Forms 11-A4, 11-A4Q, or 11-10.

INSTRUCTIONS: Please follow these steps to complete and submit this form:

1. **Download and save the fillable PDF form to your computer (e.g., your desktop).**

2. **Open the form using Adobe Acrobat Reader (free download at: https://get.adobe.com/reader/).**

3. **In Adobe Reader, go to the Tools menu and select Fill & Sign.**

4. **Click Select a file, then open the form you saved.**

5. **Complete all required fields on the form. Double-check that any pre-filled information is correct. Consult Downstate Policy IRB-01 or the IRB with any questions.**

6. **Save the completed form with an appropriate file name to your computer.**

7. **Log in to IRBNet (IRB Electronic Application Process) and upload your completed form along with any required attachments. For more information, see the Downstate IRB Electronic Submissions Website or IRBNet guidance, or send an email to IRB@downstate.edu**

   a. Log into IRBNet (www.IRBNet.org) with your registered Downstate email and password. Request an account and affiliate with SUNY Downstate if you do not have one.

   b. Create a "New Project", enter project title, and add Project Lead (as PI).

   c. Click "Designer". Under project documents, use "Attach New Document to upload all required forms and materials. Start the wizard to include the IRBNet Registration Form and include all Project Staff on this electronic form.

   d. Share the Project with all who need to e-sign the document. Each person will need their own IRBNet account to e-sign, if they do not sign this form.

   e. **ALWAYS** share the project with the Department Chair/Dean so they may track it in IRBNet, even if they sign below.

   f. Each person must sign as noted in Section 1.

   g. All Project Staff should sign IRBNet to attest to the information noted in Section 5, or they can sign an additional statement and this can be attached in IRBNet.

8. **Obtain all signatures on this form or share the IRBNet submission for e-signatures.**

Section 1: Project Lead and Project Information

Project Lead Name:

Faculty Mentor Name:
(Required for Students and Residents; otherwise, indicate N/A)

House Staff Quality Council Name:
(If applicable for some Resident projects; otherwise, indicate N/A)

Residency Program Director
(Required for Resident Projects; otherwise, indicate N/A)

Department Chair/Dean Name:

Department or College/School:

Project Title:

Project Staff: List all other Project Staff on page 7, or check box if none: ☐

Type of Project: (check more than one box, if applicable)

- ☐ Quality or Performance Improvement/Program Evaluation
- ☐ Case Report/Case Series (may be up to three individuals for either)
- ☐ Educational or Scholarly Activity
- ☐ Administrative Data Analysis
- ☐ Process Monitoring
- ☐ Evidence-Based Practice Activity
- ☐ Health Care Operations Activity
- ☐ Analysis of TriNetX Agregate/De-identified Data
- ☐ Secondary Use of De-identifed Data (or Coded Data with no link to a key to code)
- ☐ Other Institutional Activity (describe below):

Section 2: Brief description of project or activity:

When submitting a request for a "not research" determination, it is advisable to use terms such as "project" or "project staff" instead of "research," "human research," "study," or "investigator." However, the terms "research," "study," and "investigator" may be applicable when referring to "research" that is classified as "not human research." ***Failure to follow this guidance will cause the IRB to request corrective actions before acknowledging the request.***

A project description (or protocol) typically includes: 1) A brief background outlining the purpose of the project, 2) A detailed account of planned activities, 3) The methods and locations of implementation, 4) A timeline, 5) Information on what data will be accessed or collected, 6) Details regarding whether the project team will access or record identifiable information, 7) Plans for data use, and 8) Any data sharing arrangements between sites, specifying if the data will include identifiable or protected health information. Where possible, sharing de-identified or coded data between sites is preferred.

Provide the description of project or activity below,
or alternatively, check this box if attached as a separate document: ☐

Provide a list of all software used for this project (or indicate N/A):
Reminder: All software used for Protected or Sensitive data must be approved by Downstate Information Technology

Section 3: Protected Health Information

Does this project involve Protected Health Information (PHI)? YES ◯ NO ◯

If YES, attach a copy of all project personnel's HIPAA training certificates.

Protected Health Information (PHI) refers to any individually identifiable health details, in any form, related to an individual's past, present, or future physical or mental health or condition. It encompasses data containing HIPAA identifiers that connects health details to an individual (CFR §160.103).

Examples of PHI:

- Name, address, date, or medical record number when linked to health information
- Medical records, test results, billing records
- Health insurance numbers, appointment schedules
- Health information linked to any of the 18 HIPAA identifiers (see Downstate HIPAA-6 policy)

Section 4: Project Status Checklist

*Please select either box 1A **or** 1B (**but not both**), as well as box 2 below, to validate each statement accordingly.*

◯ **1A. Not Research.** This project **does not qualify as research**:

Research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." (45 CFR 46.102(l))

If checked, provide a brief justification why this project is NOT designed to develop or contribute to generalized knowledge or not a systematic investigation (check all that apply):

- ☐ Findings will only be used to evaluate or improve an internal process, internal program, internal service, internal curriculum, or internal operation
- ☐ Findings will only be used for internal decision-making
- ☐ Findings apply to case report/small series describing unique clinical findings
- ☐ Findings will be limited to inform possible implementation at this site
- ☐ Findings are limited to accreditation, license, or regulatory requirements of this site (e.g., The Joint Commission)
- ☐ Other (describe below):

The following disclaimer, or a comparable statement will be included in all publications or presentations: This project was designated as "not research" by the project team and this determination was acknowledged by the SUNY Downstate Health Sciences University IRB and Privacy Board.

---OR---

◯ **1B. Not Human Research.** This project qualifies as "research" (as defined above) but does **not involve human subjects** (as defined below).

Caution: Do not check 1B if the project involves PHI.

Human subject means “a living individual about whom an investigator obtains (i) data through intervention *(physical procedures or manipulations of the subject or the subject’s environment performed for research purposes)* or interaction *(communication or interpersonal contact between investigator and subject)* with the individual, or (ii) identifiable private information *(private information about an individual for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information)*.” [45 CFR 46.102(e)(1)]

The following disclaimer, or a comparable statement will be included in all publications or presentations: The project team determined that this project does not constitute human research, and this assessment was acknowledged by the SUNY Downstate Health Sciences University IRB and Privacy Board.

--AND--

Please select box 2 to validate the statement accordingly.

☐ **2. Not Regulated by FDA as a Clinical Investigation.** This project is **not considered a clinical investigation involving an FDA-regulated drug, device, or biologic**, as defined below:

Clinical investigation means “any experiment that involves a test article and one or more human subjects, and that is subject to requirements for prior submission to the FDA.” [21 CFR 50.3(c), 21 CFR 56.102(c)]

Note: A medical device regulated by the FDA may include laboratory tests and/or software, including certain use of artificial intelligence (AI) and large language models (LLM), including Software as a Medical Device or Software in a Medical Device. Consult the Downstate IRB or FDA regulations for guidance. For AI projects, refer to the MRCT Framework for Review of Clinical Research Involving AI, to confirm the use of AI is not FDA regulated.

Section 5: Attestation

By signing below (or in IRBNet), the following is confirmed:

Project Status: This project is not human subjects research nor an FDA-regulated clinical investigation; IRB approval is not required.

Team Training: All residents have viewed the Resident Orientation IRB training module. All project staff, including the lead, are listed on page 7 of this form. If protected health information (PHI) is involved, all staff have HIPAA training, and certificates are included in IRBNet.

Data Use, Privacy, and Security: The project follows applicable Downstate, Research Foundation, and Kings County policies on information security, HIPAA, and cloud data security policies. Protected and sensitive data will only be used on Downstate approved platforms. DeepSeek AI is not permitted on Downstate devices. No sensitive or private information is entered into AI tools or other software, unless approved by Downstate Information Services. The project is not subject to European Union General Data Protection Regulation (GDPR) or other international/ non-NY privacy laws.

Agreements and Documentation: All necessary agreements (e.g., Data Use, Material Transfer) have been signed by the authorized Downstate representative and included in IRBNet.

IRB Submission: All information in this form and IRBNet is complete and accurate. The IRB Staff is not liable for errors or omissions; Project Lead will correct any identified issues. Any follow up requests for an official IRB determination letters must be submitted via IRBNet with Forms 11-A4, 11-A4Q, or 11-10.

Accountability: Project Staff understand that false or misclassified submissions can lead to corrective actions, discipline, loss of publication, reporting, and disqualification from future research or funding.

Signatures may be provided in ink, Adobe signature, or electronically within the IRBNet submission.

NOTE: The Project Lead is not required to have "PI Status." The Project Lead, Mentor, House Staff Quality Council, and Residency Project Director may sign the IRBNet submission electronically as an "Other Signatory," instead of physically signing this form below. Caution: The form will need to be printed, if collecting some ink signatures and will no longer be editable.

Project Lead: **Date:**

Faculty Mentor: **Date:**

House Staff Quality Council: **Date:**

Residency Program Director: **Date:**

Department Chair or Dean: **Date**

Section 5: Attestation (continued from previous page):

Name of Additional Project Staff :	Signature:	Date: