SUNY Downstate IRB & Privacy Board

FORM 8-19A: Request for Waiving the Requirements of Informed Consent, Parental/Legal Guardian Permission, Child Assent, or HIPAA Waiver/Alteration[1]

(Version 03.19.2026)

⚠ IMPORTANT – READ BEFORE COMPLETING THIS FORM

⚠ *To avoid losing your data or experiencing technical issues, make sure you complete the form using Acrobat Reader, NOT in your web browser (such as Chrome, Safari, Edge, or Firefox), and NOT with "Preview" on a Mac.*

⚠ *This form is a dynamic, interactive PDF that uses Adobe PDF JavaScript to handle required fields and validation. It works properly only with the latest version of Adobe Acrobat Reader.*

⚠ **Adobe Reader/Acrobat is the ONLY way to complete this form. Tips to avoid common errors:**

DO NOT complete the form online in a web browser such as Chrome, Safari, Edge, or Firefox
DO NOT complete the form inside Box preview.
DO NOT use Apple "Preview" on a Mac. This may cause "invisible data" where the form looks empty to the IRB.
DO NOT submit a scanned or flattened copy.
DO NOT forget to save before closing.

⚠ *These issues may disable required form functions and delay IRB review.*

⚠ Need Help? Watch this 3- minute video: How to Download and Fill Out a PDF Form Using Adobe Acrobat Reader

REQUIRED STEPS TO COMPLETE THIS FORM:

Step 1 – Download the Master Form File

A. Right-click the form link and select "Save Link As..." or click the Download icon (↓)
B. Save the file directly to your Desktop or Documents folder.
C. Close the browser tab immediately to ensure you do not accidentally start typing there.

Step 2 – Open with Adobe Acrobat Reader (or Adobe Acrobat)

A. If needed, download Adobe Reader for free at: https://get.adobe.com/reader/
B. Locate the file you just saved on your computer.
C. Right-click the file and select "Open With "→ "Adobe Acrobat Reader". Look for the red Adobe icon.
D. Mac Users: Do NOT use Apple Preview. It will corrupt your entries and prevent the IRB from seeing your=data.

Step 3 – Use the Interactive Features

- This form uses Skip Logic. Select your waiver types in Section 2, and the appropriate questions will automatically appear.
- If the required boxes do not appear after you click them, you are likely in a web browser or Preview—stop and restart from Step 1.
- CAUTION: If you uncheck a box, the corresponding section will hide again. Any data entered in a hidden section may be cleared.
- Separate waiver requests may be submitted for each IRB submission if needed. (e.g., separate wavier for a unique study population, follow up waiver request from IRB)
- Save the file periodically as you work and before sending to PI for signature.

Step 4 – PI Signs Attestation (instructions in Section 4)

Step 5 – Save and Submit to IRB

1 AI-Assisted Development Disclosure: This form was developed with drafting assistance from generative artificial intelligence tools, including ChatGPT, Google Gemini, and Microsoft Copilot. All content, regulatory citations, and requirements have been independently reviewed, validated, and formally approved by the SUNY Downstate Institutional Review Board (IRB) and Privacy Board. The IRB retains full authority and responsibility for the accuracy and implementation of this document.

Section 1: Basic Information

A. Principal Investigator/Project Lead:

B. Project Title:

C. Funding source[2] (provide name of funding sponsor or indicate if the research is unfunded):
Note: Other funding requirements might exceed the required criteria specified within this form. All requirements must be met for the IRB to approve a waiver.

D. Describe the populations, groups, or arms (e.g., all study participants, healthy controls, adults, parents, children, patients screened from medical record, specific study arm, population, or group) for which this waiver request form pertains. If needed, use a separate waiver request form or describe the relevant group in the sections on the following pages.

E. Describe the information to be collected under this waiver, if applicable or indicate N/A:

F. Provide the date range of records to be reviewed under this waiver, if applicable or indicate N/A:

G. Does the research access, use, or disclose **Protected Health Information (PHI)** from a HIPAA-covered entity? (SELECT ONE OPTION, AS APPLICABLE FOR THIS REQUEST)

- ◯ 1) YES. Will obtain a signed **HIPAA Authorization** before using or disclosing PHI. **No HIPAA Waiver/Alteration** is requested. DO NOT check box "H" in "Section 2" of this form.
- ◯ 2) YES. This request is for a **HIPAA Waiver**. Check box "H" in "Section 2" of this form.
- ◯ 3) YES. This request is for a **HIPAA Alteration**. Check box "H" in "Section 2" of this form.
- ◯ 4) YES. This request is for a **Partial HIPAA Waiver** for recruitment/screening purposes, prior to obtaining signed HIPAA Authorization during enrollment. Check box "H" in "Section 2" of this form.
- ◯ 5) **NO PHI** access, use, or disclosure. No HIPAA documentation required. DO NOT check box "H" in "Section 2" of this form.

H. Does the research follow the requirements of the **Common Rule, FDA, or Both**? (SELECT ONE)

- ◯ 1) **Common Rule** (e.g., federal funded/supported research, unfunded non-FDA regulated research)
- ◯ 2) **FDA** (e.g., Clinical Investigation involving a drug, biologic, or device)
- ◯ 3) **Both** (e.g., FDA regulated clinical investigation that is federally funded). If both, the research must satisfy the provisions of both the FDA and Common Rule regulations.

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2 Other funding requirements might exceed the required criteria specified within this form. All requirements must be met for the IRB to approve a waiver. Contact the funding agency or review the regulations from the funding agency for additional information and consult with the IRB, as needed. For example, the VA, DOD, DOE, and BOB have rules and regulations that exceed the Comon Rule and FDA requirements.

Section 2: Waiver and Alteration Selection

How to Use This Interactive Form: This form utilizes conditional logic to streamline your application. Please start by selecting the types of waivers or alterations you are requesting in the table below. Once selections are made, generate the form and the corresponding section(s) will automatically appear for you to complete. If a section is not relevant to your request, it will remain hidden to simplify your submission.

Check the box for the type of Waiver or Alteration requested:
(Multiple boxes may be requested, as applicable to the request)

- ☐ **A1: General Waiver/Alteration and/or FDA regulated Minimal Risk Clinical Investigation[3]**
- ☐ **A2: Waiver Concerning a Public Benefit/Service Program**
- ☐ **B: Waiver to Use Leftover Anonymous Specimens** (FDA regulated In Vitro Diagnostic Device Study)
- ☐ **C: Waiver of Parental Permission in Common Rule Regulated Research**
- ☐ **D: Waiver of Documentation (signature) of Consent for Common Rule Regulated Research**
- ☐ **E. Waiver of Documentation (signature) of Consent for FDA Regulated Research**
- ☐ **F. Waiver of Informed Consent for FDA Regulated Planned Emergency Research**
- ☐ **G: Waiver of Child Assent**
- ☐ **H: HIPAA Waiver, Partial HIPAA Waiver, or HIPAA Alteration**

NOTE: MUST check box "H" for any activity, including exempt research, that accesses, uses, or discloses Protected Health Information (PHI) from a HIPAA-covered entity and for a "partial HIPAA waiver" for recruitment screening. A HIPAA Waiver it is not required for a) Healthcare Operations Activities[4] that are not research, research certified as Preparatory to Research[5], obtaining a Limited Data Set under a required Data Use Agreement,[6] for obtaining de-identified[7] data, or for conducting certified decedent research[8]. For complete details, please see corresponding footnotes below.

GENERATE CLICK "GENERATE," AFTER CHECKING ABOVE BOXES, TO SHOW SECTIONS

MODIFY CLICK "MODIFY" TO MODIFY BOX SELECTIONS (SECTION DATA NOT REMOVED)
NOTE: If revisions are required by the IRB after signing, right-click the signature field and select 'Clear Signature' to allow new signature and date after the form is edited.

RESET CLICK "RESET" TO RESET ENTIRE FORM & START OVER (ALL DATA & SIGNATURES REMOVED)

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3 FDA regulations do not have a separate provision to waive parental permission that parallels the Common Rule (45 CFR 46.408(c)). Investigators requesting a waiver of parental permission for FDA-regulated research should select A1 and justify how the investigation meets the minimal risk criteria.
4 45 CFR 164.501 "Health care operations" includes quality assessment, improvement activities, and protocol development where the activity is conducted by the covered entity for its own internal business purposes rather than to develop or contribute to generalizable knowledge.
5 Note: This form is for Waivers and Alterations of HIPAA Authorization. If you only require access to medical records for Preparatory to Research purposes (e.g., to design a protocol or estimate the number of potential research participants) without recording or removing PHI, please use the separate Research Certification for Reviews Preparatory to Research available on the Downstate HIPAA Web-Site.
6 Refer to Downstate HIPAA Privacy Policies and Procedures website for Policy HIPAA-27: Use of Limited Data Sets and the corresponding Data Use Agreement (DUA)Template for more information.
7 Refer to Downstate HIPAA Privacy Policies and Procedures website for Policy HIPAA-6: De-Identification of Information.
8 Refer to Downstate HIPAA Privacy Policies and Procedures website for Policy HIPAA-28: Used and Disclosures for Research Purposes and the Researcher Certification for PHI of Decedents.