

## SUNY Downstate IRB & Privacy Board

### FORM 8-19B: Request for Waiving Informed Consent or HIPAA Waiver/Alteration<sup>1</sup>

(Version 03.19.2026)

*NOTE: This form is typically used for retrospective chart reviews and other types of research when requesting a waiver of informed consent requirements and/or HIPAA Waiver/Alteration. See Form 8-19A for other waiver options.*

#### **⚠ 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 – PI Signs Attestation (instructions in Section 4)**

##### **Step 4 – Save and Submit to IRB**

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<sup>1</sup> 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<sup>2</sup> (provide name of funding sponsor or indicate if the research is unfunded or indicate "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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<sup>2</sup> 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 Common Rule and FDA requirements.

## Section 2: Waiver and Alteration Selection

**Check the box for the type of Waiver or Alteration requested:**

(Multiple boxes may be requested, as applicable to the request)

DO NOT Select option A1 for Exempt IRB applications that follow the Common Rule only

DO check option A1 for FDA regulated research or non-Exempt Research.

**NOTE: Please use Form 8-19A for other types of waivers.**

### **A1: General Waiver/Alteration and/or regulated Minimal Risk Clinical Investigation<sup>3</sup>**

If Checked, complete Section A1.

### **H: HIPAA Waiver, Partial HIPAA Waiver, or HIPAA Alteration**

If Checked, complete Section H.

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 is not required for a) Healthcare Operations Activities<sup>4</sup> that are not research, research certified as Preparatory to Research<sup>5</sup>, obtaining a Limited Data Set under a required Data Use Agreement,<sup>6</sup> for obtaining de-identified<sup>7</sup> data, or for conducting certified decedent research<sup>8</sup>. For complete details, please see corresponding footnotes below.

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<sup>3</sup> 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.

<sup>4</sup> [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.

<sup>5</sup> 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](#).

<sup>6</sup> 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.

<sup>7</sup> Refer to [Downstate HIPAA Privacy Policies and Procedures website](#) for Policy HIPAA-6: De-Identification of Information.

<sup>8</sup> 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.

**A1. General waiver requested for research that follows the Common Rule and/or FDA Exception from Informed Consent Requirements for Minimal Risk Clinical Investigations.<sup>9</sup>**

Please provide and confirm the following details to request IRB approval for a waiver of the process (requirement) of informed consent or to request a waiver of specific element(s) of informed consent:

1. This request is to:
  - a) waive the requirements of consent for **adult participants** (e.g., consent process or required elements)
  - b) waive **adult consent/parental permission AND child assent** (e.g., a retrospective review of adult and pediatric records). *NOTE: See FORM 8-19A, Section C or G for other types of waivers of parental permission or child assent.*
  - c) waive ONLY **child assent** (based on consent waiver criteria), **FOR NON-FDA REGULATED RESEARCH**. Will obtain parent or guardian permission. *NOTE: See FORM 8-19A, Section G for other types of waivers of child assent.*
2. The research does not involve non-viable neonates<sup>10</sup>
3. The research is not funded by the Department of Defense (DOD), or DOD funded research does not involve an intervention or interaction with a human being as an experimental research participant (10 U.S.C. 980).<sup>11</sup>
4. The research does not involve student education records protected by Family Educational Rights and Privacy Act (FERPA) and the research does not involve student surveys dealing with sensitive topics Pupil Rights Protection Act (PPRA) in Education Department (ED) funded programs.<sup>12</sup>
5. For Common Rule regulated research, the research is a) not conducted under an HHS Secretarial Waiver for Planned Emergency Research OR b) does not involve prisoners, fetuses, pregnant people, or human in vitro fertilization if conducted under the HHS Secretarial Waiver for Planned Emergency Research<sup>13</sup>
6. This waiver does not apply to Employee Health records or Student Health records.
7. The research involves no more than minimal risk<sup>14</sup> to the research participants, for the following reasons (use protocol specific information to justify the request):

8. The research or clinical investigation could not practicably be carried out without the requested waiver or alteration, for the following reasons (use protocol specific information to justify the request):

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<sup>9</sup> [45 CFR 46.116\(f\)\(3\)](#) and [21 CFR 50.22](#)

<sup>10</sup> [45 CFR 46.205\(c\)\(5\)](#)

<sup>11</sup> For Department of Defense (DoD) funded research, the IRB cannot waive the requirement for informed consent if the research involves an intervention or interaction with a human being as an experimental subject ([10 U.S.C. § 980](#)).

<sup>12</sup> If this research involves student education records or surveys on sensitive topics in Department of Education-funded programs, additional parental consent requirements apply under Family Educational Rights and Privacy Act (FERPA) ([20 U.S.C. § 1232g](#) or [34 CFR Part 99](#)) and Pupil Rights Protection Act (PPRA) ([20 U.S.C. § 1232h](#) or [34 CFR 98.1](#)) that the IRB cannot waive. Additional parental consent requirements apply that the IRB cannot waive. FERPA requires a "signed and dated" written consent; a waiver of documentation is not permitted for the release of Personally Identifiable Information (PII) from education records.

<sup>13</sup> [45 CFR 46.101\(i\)](#); [61 FR 51531 \(October 2, 1996\)](#). Under the authority of [45 CFR 46.101\(a\)](#), the Secretary of HHS established the "Emergency Research Consent Waiver" for a strictly limited class of research. This waiver is explicitly inapplicable to research involving prisoners ([Subpart C](#)) and research involving fetuses, pregnant people, and human in vitro fertilization ([Subpart B](#)).

<sup>14</sup> Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102\(j\)](#) & [21 CFR 50.3\(k\)](#)



## H. HIPAA Waiver or Alteration<sup>51, 52</sup>

Please provide and confirm the following details to request IRB (or Privacy Officer) approval for a HIPAA Waiver or Alteration. Provide the information below to justify the request and check all criteria to confirm eligibility.

This waiver is being requested to permit the use or disclosure of Protected Health Information (PHI) for research purposes without a written (signed) participant HIPAA Authorization. This research intends to access, use, or disclose only the minimum necessary<sup>53</sup> PHI for research activities. This section applies to both full waivers of authorization, partial waivers of authorizations, and alterations (modifications), such as waiving the requirement for a signature when obtaining verbal authorization, as applicable and indicated below.

1. This waiver does not apply to Employee Health records or Student Health records.
2. Type Requested (select one option below, a,b,or c, and answer corresponding questions):
  - a. **Full HIPAA Waiver** of HIPAA Authorization. No HIPAA Authorization will be obtained (e.g., retrospective chart review).
  - b. **Partial HIPAA Waiver** of HIPAA Authorization. PHI will be accessed prior to consent/HIPAA Authorization (e.g., screening/recruitment purposes). A HIPAA Authorization will be obtained at the time of enrolling research participants.
    - i. If Partial HIPAA Waiver:
      - a) Check to confirm the following: 1) PHI will be accessed solely to identify and contact potential research participants, 2) Only authorized study personnel will access PHI, and 3) no PHI will be retained if the individual declines participation.
      - b) Describe recruitment procedures:
  - c. **HIPAA Alteration** of HIPAA Authorization: HIPAA Authorization will be obtained but with modified elements. This is a request to waive one or more of the required elements of the HIPAA Authorization form (e.g., signature). If checked, include description of waived element(s) below:
3. Privacy Rule Justifications (Required for all waivers/alterations):
  - a. **Minimal Risk to Privacy:** Describe why the use/disclosure involves no more than a minimal risk to the privacy of individuals:

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51 HIPAA is the abbreviation for [Health Insurance Portability and Accountability Act of 1996](#). More information about the act is available on the US Department of Health and Human Services [Health Information Privacy website](#).

52 [45 CFR 164.512\(i\)\(2\)\(ii\)](#). The Privacy Rule allows for the waiver or alteration of authorization if the IRB or Privacy Board finds that the research meets three specific criteria: (A) the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals; (B) the research could not practicably be conducted without the waiver; and (C) the research could not practicably be conducted without access to and use of the PHI.

53 [45 CFR 164.514\(d\)](#) defines the "Minimum Necessary" standard. See HIPAA-15: Minimum Necessary Guidelines on the [Downstate HIPAA Privacy Policies and Procedures website](#).

## H-page 2

- b. Practicability (Research): Explain why the research could not practicably be conducted without obtaining individual HIPAA Authorization:
  
  - c. Practicability (Access): Explain why the research could not practicably be conducted without access to and use of the PHI (i.e., why the PHI is necessary).
4. The PHI is limited to the minimum necessary<sup>54</sup> requirements to meet the research objectives. Explain how minimum necessary was determined:
5. Data Protection Plan:
- a) Access Control: List individuals/entities with access to the PHI:
  
  - b) Storage: Describe how data will be secured (e.g., encryption, locked cabinets):
  
  - c) Provide the plan to protect identifiers from improper use and disclosure:  
(Include applicable safeguards such as encrypted storage, limited access, secure servers, audit controls, role-base access controls, multi-factor authentication, certificate of confidentiality, data use agreement, etc.)
  
  - d) Provide **either (item 1 or item 2, not both)** the plans for destruction **or** justification for retention of identifiers (select one):
    1. Provide a plan to destroy identifiers at the earliest opportunity (after data retention period):

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<sup>54</sup> [45 CFR 164.514\(d\)](#) defines the "Minimum Necessary" standard. See HIPAA-15: Minimum Necessary Guidelines on the [Downstate HIPAA Privacy Policies and Procedures website](#).



#### Section 4: Principal Investigator Attestation

**By signing below, I certify that the information in this request is complete and accurate. I agree to conduct this research in accordance with the IRB-approved protocol and application materials, Downstate policies, and all applicable federal, state, and local regulations.**

As the **Principal Investigator**, my signature below attests to the following:

1. **Regulatory Compliance:** I certify that the information provided in this application is complete and accurate. I agree to conduct this research in full compliance with the approved protocol and all applicable federal, state, and local regulations, including the Common Rule (45 CFR 46), FDA regulations (21 CFR 50 and 56), and the HIPAA Privacy Rule (45 CFR 164).
2. **Privacy & Confidentiality:** I will maintain the confidentiality of all data collected and ensure that Protected Health Information (PHI) is accessed, used, and disclosed only as authorized by law or by the IRB/Privacy Board.
3. **HIPAA Assurance:** When section I is completed, the PHI requested meet the minimum necessary<sup>56</sup> standard. Adequate safeguards are in place to protect confidentiality. I provide written assurance that PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted.
4. **Reporting Requirements:** I agree to submit Reportable Events to the IRB within required reporting timeframes. Any potential privacy violation, potential information (data) security violation, incident, or breach, will immediately be reported to the IRB, Privacy Officer, and Information Security Officer, as outlined in IRB policy.
5. **Record Retention:** I will maintain all required research records for the period required by law or institutional policy.

#### How to Digitally Sign This Form

**Step 1:** ⚠ IMPORTANT: **Download and open this form in Adobe Acrobat Reader before signing. Do not sign the form in your web browser.**

**Step 2:** It is recommended that an unsigned copy of the form be saved, so that it can be edited if the IRB recommends changes.

**Step 3:** Scroll to the signature section and click directly on the red **“Sign Here”** tab in the signature box. When prompted, select **“Sign with a Digital ID,”** and apply your certificate-based Digital ID. If you do not have a Digital ID, Adobe will prompt you to Configure New Digital ID.

⚠ **Do NOT** certify or lock the entire document. Certifying the document will make it Read-Only and prevent corrections or the required IRB signature. **Do NOT** sign the next IRB review section (next page) of this form or it will be returned for correction and may cause delays in the review.

After signing your designated field only, save the form and submit to IRB.

**Principal Investigator Signature:**

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<sup>56</sup> 45 CFR 164.514(d) defines the "Minimum Necessary" standard. See HIPAA-15: Minimum Necessary Guidelines on the [Downstate HIPAA Privacy Policies and Procedures website](#).

**THE SECTION BELOW IS FOR INTERNAL (IRB) USE ONLY, WHEN BOX H IS CHECKED**

**Section 5: Downstate IRB and Privacy Board Review & Certification of HIPAA Waiver/Alteration<sup>57</sup>**

Only an IRB Member or Privacy Officer may sign this section. If approval criteria are not met, the form will be sent back to the PI for revision.

1. The Downstate IRB and Privacy Board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:<sup>58</sup>
  - a. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    - i. An adequate plan to protect the identifiers from improper use and disclosure.
    - ii. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    - iii. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.
  - b. The research could not practicably be conducted without the waiver or alteration; and
  - c. The research could not practicably be conducted without access to and use of the protected health information.
2. Type Requested (select one):
  - a. Full HIPAA Waiver
  - b. Partial HIPAA Waiver
  - c. HIPAA Alteration
3. Approval Review Type (select one):
  - a. Full Board
  - b. Expedited procedure

**IRB Member or Privacy Officer Signature:**

*REMINDER: After signing, please save with reviewer notes. The IRB Administrator will publish this with the IRB approval letter to make it available to the study team.*

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<sup>57</sup> This documentation satisfies the requirements of [45 CFR §164.512\(i\)\(2\)\(iii\)](#).

<sup>58</sup> [45 CFR 164.512\(i\)\(2\)\(ii\)](#)