# Application for Waiver of Authorization and/or Consent

## Submission Instructions

Our website provides full instructions on submitting applications to the IRB: <http://irb.med.nyu.edu/esubmission> Please contact the IRB office at 212 263-4110 with any questions.

## Administrative Information

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study# | - | Date of this request | |  | | |
| Study Title |  | | | | | |
| Role | Name | | Kerberos ID/Email\*\* | | Phone | Fax |
| Principal Investigator |  | |  | |  |  |
| Contact Person |  | |  | |  |  |

## Request

In order to access or use an individual’s Protected Health Information (PHI) in the conduct of research without the express authorization of the individual, you must request a waiver of authorization.

In order to conduct research without the express written consent of a human subject, you must request a waiver of informed consent.

You may also request an alteration in consent or authorization. In other words: you will be obtaining written consent but may require certain elements of the consent be altered and you will need to request an alteration in consent and authorization.

You may request a waiver of documentation of consent. There are required elements that must be met, but a waiver of documentation of consent means that you will obtain consent, but you do not use an informed consent document.

|  |  |
| --- | --- |
| Indicate the nature of this request | waiver of authorization (complete I and III)  alteration or waiver of consent (complete II.A, II.B & III)  waiver of documentation of consent (complete II.A, II.C & III) |
| Does this research present no more than Minimal Risk of harm to subjects | Yes; Explain:  No; **STOP:** This study is not eligible for an Alteration or Waiver of Authorization or Consent or a Waiver of Documentation of Consent |

## I. Authorization

Fill this out if you seek to obtain a waiver of authorization to use and disclosures protected health information.

|  |  |  |
| --- | --- | --- |
| A. Record/Specimen Use Check the boxes of the items that will be used | | |
| Indicate your study’s source(s) of health information | physician/clinic records  interviews/questionnaires  mental health records  billing records | lab, pathology and/or radiology results  biological samples obtained from the subjects  hospital/medical records (in- and out-patient)  data previously collected for research purposes  other; specify: |
| B. Protected Health Information | | |
| Describe the PHI being used or disclosed in your study | Patient/subject name  Address street location  Address town or city  Address state  Address zip code  Elements of dates (except year) related to an individual. (ie. DOB, admission/discharge dates, date of death)  Telephone number  Fax number  Electronic mail (email) address  Social security number  Medical record numbers  Health plan beneficiary numbers  Account numbers  Certificate/license numbers  Vehicle identification numbers and serial numbers including license plates  Medical device identifiers and serial numbers  Web URLs  Internet protocol (IP) address  Biometric identifiers (finger and voice prints)  Full face photographic images  Any unique identifying number, characteristic or code (a rare disease can be considered a unique id)  Link to identifier (code) | |
| C. Request for Waiver of Authorization | | |
| If any box in section I.B above is checked, list every investigator, research staff member or other staff member who will have access to this data |  | |
| Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy |  | |
| Describe investigator’s plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time |  | |
| Explain why it is not possible to seek subjects’ authorization for use or disclosure of the PHI |  | |
| Explain why it is not possible to conduct this research without use or disclosure of the PHI |  | |

## II. Informed Consent

Complete II.A and II.B if you are seeking an alteration or complete waiver of your research subject’s right to informed consent.

Complete II.A and II.C if you are seeking a waiver of documentation of informed consent.

|  |  |
| --- | --- |
| A. Overview | |
| Briefly explain the consent process for your study |  |
| B. Alteration or Waiver of Informed Consent | |
| Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject |  |
| Explain why the waiver/alteration will not adversely affect the rights and welfare of the subjects |  |
| Explain why it is impracticable to conduct this research if informed consent is required |  |
| Explain, if appropriate, how the subjects will be provided with additional pertinent information after participation.  If not appropriate, explain why |  |
| C. Waiver of Documentation of Informed Consent For this subsection, complete either Subsection 1 or 2 Subsection 1 | |
| (a) The only record linking the subject to the research will be the consent document | Yes; explain:      \* note you MUST have completed Section I.B (above)  No; **not eligible for waiver under this section** |
| (b) Would the principal risk would be potential harm resulting from a breach in confidentiality | Yes; explain:  No |
| (c) Will subjects be provided with a written statement regarding the research\* | Yes; Attach document for IRB Review and Approval  No explain: |
| \*to proceed with a waiver meeting the above criteria, each subject must be asked whether they wish documentation linking them to your study. You must include this in your description of the consent process in II.A (above) and in your protocol. | |
| Subsection 2 | |
| (a) Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject |  |
| (b) The research involves no procedures for which written consent is normally required outside the research context | Yes; explain:  No**; not eligible for waiver under this section** |
| (c) Will subjects be provided with a written statement regarding the research\* | Yes; Attach document for IRB Review and Approval  No explain: |
| \*to proceed with a waiver meeting the above criteria, each subject must be asked whether they wish documentation linking them to your study. You must include this in your description of the consent process in II.A (above) and in your protocol. | |

## III. Signatures

### Principal Investigator’s Signature

|  |  |
| --- | --- |
| Date |  |
| Print Name |  |
| Signature | I assure the IRB that the protected health information which I have detailed in this Waiver of Authorization and/or Consent application will not be reused (i.e.: used other than as described in this application) or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by the NYU SoM IRB.  I also assure the NYU SoM IRB that the information that I provide in this application is accurate and complete, and that the PHI that I request is the minimum amount of identifiable health information necessary for my research project. |