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**Supplement Form F**

**Request for Waiver or Alteration of HIPAA Authorization**

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| **PI Name:** | **Date:** Click here to enter a date. |
| Protocol Title: | WMed IRB #:  *(for IRB Office only)* |

The IRB may waive or alter the requirement to obtain written authorization from research subjects for the use or disclosure of their Protected Health Information (PHI) when the investigator justifies, and the IRB agrees, that specific criteria have been met.

**Note:** Authorization must be obtained for the use or disclosure of psychotherapy notes. 45 C.F.R. §164.508(a)(2)

1. **Indicate which of the following you are requesting (check all that apply):**

**Full Waiver.** Authorization will not be sought from any subjects

**Partial Waiver.** Authorization will not be sought from some subjects (e.g., historical cohort) or for some activities (e.g., screening or recruitment)

**Alteration.** Authorization will be sought but one or more required elements will be eliminated or altered (e.g., requirement for signature)

* 1. If the request is for a Partial Waiver, explain what you are requesting and why:

* 1. If the request is for an Alteration, explain which elements you are requesting to eliminate or alter and why.(a list of required elements is provided at the end of this form for your reference):

1. **Provide justification for how each of the following criteria for a waiver or alteration are satisfied:**
   1. 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:
      1. An adequate plan to protect the identifiers from improper use and disclosure. Please explain:

* + 1. 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. Please explain:

* + 1. 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 project, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA. Please explain:

* 1. The research could not practicably be conducted without the waiver or alteration. Please explain:

* 1. The research could not practicably be conducted without access to and use of the protected health information. Please explain:

**HIPAA Authorization Required Elements & Statements**

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| **Core Elements** 45 C.F.R. §164.508(c)(1) | |
|  | A description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner). |
|  | The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure. |
|  | The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure. |
|  | A description of each purpose of the requested use or disclosure. |
|  | Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or repository). |
|  | Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual. |
| **Required Statements** 45 C.F.R. § 164.508(c)(2) | |
|  | The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices. |
|  | Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization. |
|  | The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information. |