

Index of Yale University HIPAA Policies and Procedures Relating to Research

1. Statement of Policy on Use and Disclosure of Protected Health Information for Research Purposes

This is the overarching policy document that will govern the use and disclosure of protected health information for research purposes.

2. Procedure on Determining Whether “Human Subject Research” Activity Involves Use/Disclosure of “Protected Health Information”

This document, which is essentially a checklist, is meant for use by investigators as an aid for deciding at the outset whether a particular research activity will involve protected health information and therefore be subject to HIPAA.

3. Procedure Regarding Research Authorization

This document is meant for use by investigators who seek to use protected health information for research pursuant to a signed research authorization form. The procedure provides instructions and an authorization template.

4. Procedure on Request for Waiver of HIPAA Authorization

This document is meant for use by investigators who seek to use protected health information for research pursuant to a waiver of HIPAA’s requirement for a signed authorization form. The procedure provides instructions and a form for submission to the Institutional Review Board.

5. Procedure for Requesting Access to Protected Health Information for Research Purposes

This document is meant for use by investigators requesting access to protected health information for research purposes. The procedure provides instructions and a form to be completed and given to the individual who controls access to the information sought. The form delineates the various conditions that may permit access to the information (e.g., authorization or review preparatory to research), and the investigator need only indicate which condition applies, make the appropriate assurances, and sign the form.

6. Procedure on Providing Access to Protected Health Information for Research Purposes

This document is meant for use by those individuals who control access to protected health information, such as a medical records office staff member. The document outlines steps for responding to a request for

access and provides a checklist to guide the appropriate response to the request.

7. Procedure for Review of Request for Waiver of HIPAA Authorization

This document is meant for use by the IRB in reviewing and evaluating an investigator's request for waiver of the HIPAA requirement for a signed authorization form for use of protected health information for research purposes.

8. Procedure on Approval of Waiver of HIPAA Authorization

This document is meant for use by the IRB in its review of investigator requests for waiver of the HIPAA requirement for a signed authorization form for use of protected health information for research purposes.

9. Data Use Agreement

This document is a draft form of data use agreement. A data use agreement will be required when an investigator wishes to disclose a limited data set to another investigator. Under the HIPAA regulations, data use agreements must be signed by the covered entity that holds the information (e.g., Yale University) and by the requester of the information; the agreement cannot be signed only by a Yale investigator who holds the information.