# HIPAA in Research
# Policy and Procedure

**Table of Contents**



I. Policy: The IRB acts for the HSC and its affiliated institutions as a Privacy Board for research related issues that fall under the purview of the IRB under applicable federal, state and local law, regulation and policy:

A. IRB determinations include enforcement of protections of individual privacy and maintenance of confidentiality of identifiable information in accordance with applicable federal, state and local law, regulation and policy (e.g., HSC and affiliated institutional policies).

1. During initial review of research, continuation review and requests for modification of previously approved research, the IRB evaluates the proposed arrangements for protecting the privacy interests of research participants during and after their involvement in the research (See Initial Review of Research Policy and Procedure, Continuation Review Policy and Procedure and Modification and Amendments Policy and Procedure).

2. The IRB's determinations do not direct institutions or individuals (i.e., covered entities) to release PHI (institutions are allowed under federal and state law to accept determinations of any Privacy Board or IRB acting as a Privacy Board in these matters).

3. The IRB does not maintain oversight over the contents of HIPAA Authorizations which are created separately from research consent forms.

B. The IRB or designated reviewer (qualified voting members of the IRB and designated by the chair) reviews and authorizes requests to use protected health information **preparatory to research** in accordance with applicable federal, state and local law, regulation and policy.

1. Preparatory to research requests may only be approved where the activities planned are in accordance with the definition of "activities preparatory to research" as defined by the institution maintaining the PHI (e.g., VA does not allow researchers to contact subjects under the preparatory to research provisions as they do not consider this activity to be an activity preparatory to research whether or not they are a member of the covered entity).

2. Identification and Contact: Local policy limits the degree to which the IRB or its designated reviewers may authorize preparatory to research activities to use private identifiable information under the preparatory to research provisions both in circumstances where the researcher is an employee of the institution/covered entity and in circumstances where the researcher is not an employee of the institution/covered entity which would constitute disclosure without valid authorization or Waiver. Circumstances under which a researcher requesting access to individually identifiable information for the purpose of identifying and recruiting subjects may be allowed is further described in Identification and Recruitment of Participants Policy and Procedure.

C. The IRB reviews and approves requests for waivers or alterations of Authorization in connection with a **use or disclosure of PHI** related to research activities in accordance with applicable federal, state and local law, regulation and policy. The IRB will not approve alterations of Authorization for studies involving the South Texas Veterans Health Care System.

D. The Office of the IRB reviews and approves **requests to de-identify PHI without using the "safe harbor" method** in accordance with applicable federal, state and local law, regulation and policy. The IRB review includes having a qualified statistician determine, using generally accepted statistical and scientific principles and methods, that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the anticipated recipient to identify the subject of the information. The qualified statistician must document the methods and results of the analysis that justify such a determination. .

E. The Office of the IRB reviews and approves **use of limited data sets** in accordance with applicable federal, state and local law, regulation and policy. Before disclosing a limited data set to a researcher, a covered entity must enter into a data use agreement with the researcher, identifying the researcher as the recipient of the limited data set, establishing how the data may be used and disclosed by the recipient, and providing assurances that the data will be protected, among other requirements.

II. Overview

A. This procedure starts with a request to alter or waive authorization to use or disclose PHI.

B. This procedure ends when the IRB authorizes activities preparatory to research or approves or disapproves a request to alter or waive authorization.

C. Summary of responsibilities

1. Investigators are responsible for consulting with the appropriate covered entity to identify circumstances where additional authorization is required. The investigator may contact the OIRB to confirm whether preparatory to research activity or HIPAA waiver/alteration are applicable.

2. The Office of the IRB staff are responsible for providing guidance (in addition to that provided by the covered entity) to investigators to identify circumstances where preparatory to research procedure or HIPAA Waiver are or are not applicable and processing requests for preparatory to research procedure or HIPAA Waiver or alteration through expedited or full IRB review. For approval of requests to de-identify PHI without using the "safe harbor" method or use of a limited data set, the OIRB staff provides guidance.

3. IRB Chair, IRB Director, Associate Director or designee is responsible for approving requests for HIPAA Waiver, authorizing preparatory to research procedure, requests to de-identify PHI without using the "safe harbor" method or use of a limited data set when expedited approval is applicable.

4. The IRB is responsible for approving requests for HIPAA Waiver or alteration, requests to de-identify PHI without using the "safe harbor" method or use of a limited data set when expedited approval is not applicable.

III. Procedure

A. The OIRB receives the request for authorization of preparatory to research procedures, HIPAA Waiver or alteration, requests to de-identify PHI without using the "safe harbor" method or use of a limited data set.

B. The OIRB staff route to the appropriate review (expedited or full IRB)

C. IRB Chair, IRB Director, Associate Director or designee reviews and has the authority to determine whether expedited approval is applicable and to approve, disapprove or require changes in to

secure approval for, requests for HIPAA Waiver or alteration when expedited approval is applicable.

D. After review, outcome is reported in accordance with the Reporting Policy and Procedure.

IV. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)