

PEPPERDINE UNIVERSITY

E-Protocol Document Checklist and GPS IRB Guide – Faculty/Staff

Please use this checklist as a guide for the submission of your Exempt, Expedited, or Full Review IRB Applications through the e-protocol system. The following documents are required to be submitted by all Principal Investigators who are requesting IRB approval.

1. Human Subjects Training:

Human Subjects Training is required for all faculty, staff, and students involving exempt, expedited or full review research at Pepperdine University. Please go to www.citiprogram.org to complete the Human Subjects Training course.

A specialized CITI Human Subjects Training course is required for the following groups:

- A. Graduate & Professional Schools - Faculty/Staff Human Subjects Training
- B. Graduate & Professional Schools - IRB Members and Reviewers Human Subjects Training

2. Instruments:

- A. Surveys
- B. Interview Questions
- C. Focus Group Questions
- D. Content/Document Analysis Analytical Frameworks
- E. Observational Rubrics
- F. Miscellaneous Documents

3. Consent/Assent Forms

- A. Informed Consent
- B. Informed Consent without signature of subject (only approved in limited circumstances)
- C. Information Sheet (General)
- D. Information Sheet for In-Person Surveys
- E. Information Sheet for Online Surveys
- F. Information Sheet for Verbal Consent
- G. Parent/Legal Guardian Consent Form

- H. Youth Assent Form (Ages 14-17)
 - I. Child Assent Form (Ages 7-13)
 - J. Verbal Consent Form - (to be used primarily with Non-English speaking populations)
 - K. Short Form Consent for Non-English Speakers to Participate in Research (only applicable for this population)
 - L. California Investigator Bill of Rights (Medical Studies)
 - M. Medical Consent Form
4. Sensitive/Protected Populations Forms
- A. Accessing Capacity to Consent Form (see definition later in document)
 - B. Confidentiality Form
 - C. FERPA Form (K-12/Higher Education Studies)
 - D. Parental Notification Form (Minors)
 - E. Informed Consent for Studies Exceeding Minimal Risk (Full Review Only)
 - F. Debriefing Information Sheet (Deception Studies, but other studies as applicable)
 - G. Debriefing Consent Form (Deception Studies, but other studies as applicable)
5. Recruitment Documents
- A. Advertisement Template (GPS IRB)
 - B. Emails
 - C. Sample Written Recruitment Script Template (GPS IRB)
 - D. Social Media Postings/Announcements
 - E. Verbal Scripts
6. Site Approval Letters
- A. Parent Notification Template
 - B. School Site Permission when working with K-12 schools
 - C. Template Site Approval
7. Cooperative Engagement Agreements (if applicable)
- A. Cooperative Authorization Agreements Between Two or More Institutions
 - B. Unaffiliated Outside Investigator Agreement
 - C. Researcher Consultant Non-Engagement Agreement

8. Data Storage Forms (if applicable)
 - A. Data Protection Plan
 - B. Data Release to Third Parties

9. HIPAA (if applicable)
 - A. Acknowledgement of Receipt of Notice of Privacy Practices
 - B. Business Associate Agreement
 - C. HIPAA Authorization Consent
 - D. Notice of Privacy Policies (Pepperdine University)

10. Grant Application/Grant Award for Funded Studies (if applicable)

11. Any Miscellaneous Documents Not Included Above Relevant to Your Study

Review Categories:

Human subject as defined by United States Department of Health and Human Services (HHS):

A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual or with his or her identifiable private information or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

- **Intervention:** Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subjects' environment that are performed for research purposes.
- **Interaction:** Includes communication or interpersonal contact with a subject or his or her private identifiable information.
- **Private information:** Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (such as a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

Research (as defined by HHS): A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Non-Human Subject Research:

If your research does not involve the participation of human subjects **and** you are not using/collecting any data that has been obtained from individual participants, your research is **not** subject to IRB review and approval. However, you are required to submit a non-human subject's notification form in the IRB office.

Exempt Review:

Exempt reviews are conducted by at least one experienced member of the IRB. In order to qualify for review via exempt procedures, the research must not be greater than minimal risk and must fall into at least one of the exempt categories defined by federal regulations.

Minimal risk is defined by the federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Summary of Exempt Categories:

Category # 1 - Education research

Category # 2 - Surveys, interviews, educational tests, public observations (that do not involve children)

Category # 3 - Studies of public officials

Category # 4 - Analysis of previously-collected, existing, anonymous data

Category # 5 - Public benefit or service program

Category # 6 - Consumer acceptance, taste, and food quality studies

Expedited Review:

Expedited reviews are conducted by at two GPS IRB faculty reviewers. In order to qualify for review via expedited procedures, the research must not be greater than minimal risk and fall into at least one of the expedited categories defined by the federal regulations.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.

Summary of Expedited Categories:

Category # 1 - Clinical studies of drugs and medical devices only when certain conditions are met.

Category # 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts.

Category # 3 - Prospective collection of biological specimens for research purposes by noninvasive means

Category # 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Category # 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes

Category # 6 - Collection of data from voice, video, digital, or image recordings made for research purposes

Category # 7 - Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Category # 8 - Certain continuing reviews

The Code of Federal Regulations (CFR) defines minimal risk as meaning 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.

Full Review:

Research that is greater than minimal risk and/or does not qualify for exempt or expedited review, as defined by the categories, will be reviewed at the Full Board IRB meeting. The GPS IRB meets monthly with the exception of August.

The IRB cannot approve a protocol unless:

- Risks to subjects are minimized;
- Risks to subjects are reasonable in relation to anticipated benefits;
- Selection of subjects is equitable;
- Informed consent is adequate and appropriately documented;
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
- Appropriate safeguards have been included to protect vulnerable subjects.

Continuing Review:

When an expedited or full board protocol is approved, the approval is active for no longer than one year. In order to continue your study, you need to submit a Continuation Request before the date your protocol expires.

Consent Forms:

Information Sheet/Online Information Sheet: For research that qualifies for **exempt** status, this information sheet template may be used for basic research procedures such as surveys, interviews or focus groups. Additional information may need to be added based on individual study details. Template language may be modified as needed; similar language may be used for in-person and email. If you are consenting potential participants/subjects online then use the online information sheet.

Please note that this template does not contain the required elements of consent that are necessary for Expedited or Full Review research studies.

Informed Consent: A structured, written description in lay terms of relevant research project information. The written consent document is not consent itself; it is the record of what has been communicated to a prospective subject. It is the document, based on a template provided by the IRB and approved by the IRB, to ensure that all regulatory elements are present and communicated to a

potential subject. When signed by the potential subject, the consent document is a record of the receipt of research-related information by the subject. It also serves as reference material for the subject as the research project progresses. It is not legally binding, and the subject may choose to withdraw consent at any time. You are required to use an informed consent when you are audiotaping and/or videotaping a conversation.

For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. These terms are defined as:

- **Voluntary** – the decision to either consent or not to consent to treatment must be made by the person themselves, and must not be influenced by pressure from medical staff, friends or family.
- **Informed** – the person must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments and what will happen if treatment does not go ahead.
- **Capacity** – the person must be capable of giving consent, which means they understand the information given to them, and they can use it to make an informed decision.

Medical Consent Form: Incorporates and satisfies the elements required of a HIPAA.

Informed Consent without Signature: The informed consent without signature contains the same elements of consent as an informed consent, however, the Principal Investigator is requesting that the GPS IRB waive the requirement of written consent. As such, the consent document is the only record linking the subject and research and the principal risk is potential harm resulting from a potential breach of confidentiality. Additionally, the research presents no more than risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Oral (Verbal) Consent: A spoken presentation of the elements of informed consent to the prospective subject or their legally authorized representative. The presentation may be based on information contained within an oral consent script or the written consent document. Oral consent is often associated with waiving the documentation of consent. Oral consent is usually recorded in the research project files. This form is also used in situations where the participant is uncomfortable with a form and/or unable to use it.

Parent Consent/Legal Guardian Consent: If you are including minors in your study, this form is required to be signed by their parents/legal guardians.

Youth Assent Form: Consent form for minors ages 14-17 which is required to be signed if this population is participating in your study. A parental/legal guardian consent form is also required.

Child Assent Form: Consent form for minors ages 7-13 which is required to be signed if this population is participating in your study. A parental/legal guardian consent form is also required.

Short Form Consent for Non-English Speakers to Participate in Research: A short form consent and oral translation of the English consent is required if an individual approached for consent is not fluent in English, a written translated version of the full consent is not available, and this was unanticipated.

California Medical Investigators Bill of Rights Form: California law, under Health & Safety Code Section 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent.

GPS IRB Forms:

Cooperative Research Project Form: Research projects that involve more than one institution as defined by federal regulations.

Data Release Form: This form is similar to the Post-Debrief Consent Form; it is used when a participant has been recorded or photographed without their knowledge.

Data Safety Monitoring Plan (DSMP): A DSMP is a quality-assurance plan for a research study. A data and safety monitoring plan (DSMP) is meant to ensure that each clinical investigation has a system for appropriate oversight and monitoring of the conduct of the clinical investigation. The purpose of a DSMP is to ensure the safety of the participants, the validity of the data and the integrity of the study, and the appropriate termination of studies for which significant benefits or risk has been uncovered or when it appears that the investigation cannot be concluded successfully. A DSMP is commensurate with the risks involved with the research study. The DSMP may include a data and safety monitoring board (DSMB).

Materials Release Form: The data you collect from your participants may be useful in other spheres, such as an educational tool and/or library archive. Using data in this manner is beyond the scope of the study and you should seek additional permission to use the participant's data in this way. This form allows a participant to declare how they would like their materials to be used by the researcher if the researcher wants to use the materials in situations beyond the study.

Parent Notification Form: Typically used for studies in an educational setting (particularly where the study is exempt but parent notification is still required), this template is a guide for creating a notification letter to send home to parents.

Post-Debrief Consent Form: This form is used in a deception study after the deception is revealed to the participant. The participant is given an opportunity to decide if they still want to participate after the true purpose of the study is revealed. This form may also be used for other studies as well.

Recruitment Forms: Recruitment materials are part of the consent process and it is important that participants are accurately informed about the study throughout the process. The GPS IRB provides a template recruitment flyer for your convenience.

Sample Debriefing Form: A debriefing form is a summary of the study given to a participant in a deception study and/or a study that includes students from a participant pool. The purpose is to educate participants about the study and to provide them with resources, particularly if the study is upsetting. This form may also be used for other studies as well.

Site Approval Forms: preferably a letter on the organization's letterhead and/or an email from an authorization representative stating that you have been given approval to do research at the site and/or contact the company's employees.

Common IRB Terms and Definitions:

Children/Minors: "Are persons who have not attained the legal age for consent to treatments or procedures involved in research, under applicable law of the jurisdiction in which the research will be conducted" (45 CFR 46.402(a)). The legal age for consent is eighteen. In order to participate in the research it is a requirement that there be assent from the child/minor and parent or guardian permission. In studies that exceed minimal risk, it is a requirement that both parents/guardians provide permission if applicable.

Cooperative research project: Research projects that involve more than one institution as defined by federal regulations.

Co-Principal Investigator (Co-PI): The Co-PI collaborates with the principal investigator who has overall responsibility for study conduct. Conditions of eligibility for the role of Co-PI are the same as for a PI.

Dissertation Proposal: The first three chapters of a dissertation. The dissertation proposal should be uploaded as one document.

Documentation: The act or an instance of furnishing or authenticating with documents. Documentation of informed consent includes use of a written consent form, approved by the IRB and signed and dated by the subject or the subject's legally authorized representative.

Grant Applications/Grant Award Agreement/Stipulations: All of the relevant documents submitted to and received from the funding agency including the documents submitted to the Pepperdine Research and Sponsored Program Office.

Greater than Minimal Risk: “The research involves more than minimal risk to subjects.”

Institutional Engagement: In general, institutions are considered engaged in an HHS-conducted or-supported non-exempt human subject’s research project (and, therefore, would need to hold or obtain OHRP-approved FWAs and certify IRB review and approval to HHS) when the involvement of their employees or agents in that project includes any of the following:

- (a) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
- (b) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.¹

Instruments: For example instruments include data collection tools including, but not limited to: survey, interview and/or focus group questions, etc.

Investigator: refers to an individual performing various tasks related to the conduct of human subjects research activities, **such as obtaining informed consent from subjects, interacting with subjects**, and communicating with the IRB.

Minimal Risk: means 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.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing. If Subpart C does not apply, the IRB may use an equivalent definition of prisoners. [45 CFR 46.303(c)]

Re-consenting: Process of notifying research subjects of changes in the research, including documentation of the subject's continued informed consent through signature on a revised written consent form.

Ward: A child who is placed in the legal custody of the state or other agency, institution or entity, consistent with applicable federal, state or local law.

¹ <http://www.hhs.gov/ohrp/policy/engage08.html>

Withdrawals: Subjects who signed the consent form, but later withdrew from the study, either before or after receiving a study drug, device or intervention.

HIPAA Key Terms and Definitions

Business Associate Agreement: A person or entity who, on behalf of a covered entity, performs or assists in performance of a function or activity involving the use or disclosure of individually identifiable health information, or any other function or activity regulated by the HIPAA Administrative Simplification Rules, including the Privacy Rule. Business Associates are also persons or entities performing legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services for a covered entity where performing those services involves disclosure of individually identifiable health information by the covered entity or another business associate of the covered entity to that person or entity. A member of a covered entity's work force is not one of its business associates. A covered entity maybe a business associate of another covered entity. (45 C.F.R. § 160.103).

Designated Covered Components (or Covered Components): A component or combination of components designated by the University, which is a Hybrid Entity. Pepperdine is a Hybrid Entity because only a select few offices are subject to HIPAA privacy regulations.

Direct Treatment Relationship: A treatment relationship between an individual and a healthcare provider that is not an indirect treatment relationship. 45 C.F.R. § 164.501.

Disclosure: The release, transfer, access to, or divulging of information in any other manner outside the entity holding the information. 45 C.F.R. § 160.103.

Health Information: Any information whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present for future payment for the provision of health care to an individual. (45 C.F.R. § 160.103.)

HIPAA Authorization Consent: A customized document or form that gives permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third party specified by the investigator other than for treatment, payment or health care operations.

Human Subject Identifier: Any word, number, symbol, or combination of words, numbers or symbols that can be used by a third party to uniquely identify an individual, such as name, Social Security number, address or patient registration number that is provided for use in a research protocol.

Individually Identifiable Health Information: Any information collected from an individual (including demographics) that is created or received by a health care provider, health plan, employer, and or health care clearinghouse that relates to the past, present or future physical or mental health or condition of an individual, or the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual and identifies the individual and or to which there is reasonable basis to believe that the information can be used to identify the individual.

Notice of Privacy Policies: Provides individuals with University's policies, safeguards, and practices. When Pepperdine University uses or discloses an individual's PHI, the university is bound by the terms of this Notice of Privacy Practices, or the revised Notice of Privacy Practices, if applicable

Private information: Information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information that has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public, such as a medical record. Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

Protected Health Information (or PHI): Individually identifiable information transmitted or maintained in electronic media (ePHI), or transmitted or maintained in any form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g, records described at 20 U.S.C. § 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer. (45 C.F.R. § § 164.501, 160.103.)

Psychotherapy Notes: (HIPAA): Notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical records. Psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. (45 C.F.R § 164.501)

HIPAA Privacy Rule

The HIPAA Privacy Rule establishes the conditions under which protected health information may be

used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501. A covered entity may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below. **Pepperdine University is considered a covered entity.**

The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research. Currently, most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the Food and Drug Administration’s (FDA) human subject protection regulations (21 CFR Parts 50 and 56), which have some provisions that are similar to, but separate from, the Privacy Rule’s provisions for research. These human subject protection regulations, which apply to most Federally-funded and to some privately funded research, include protections to help ensure the privacy of subjects and the confidentiality of information. The Privacy Rule builds upon these existing Federal protections. More importantly, the Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.

How the Rule Works

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. Research Use/Disclosure Without Authorization. To use or disclose protected health information without authorization by the research participant, a covered entity must obtain one of the following:

- **Documented Institutional Review Board (IRB) or Privacy Board Approval.** Documentation that an alteration or waiver of research participants’ authorization for use/disclosure of information about them for research purposes has been approved by an IRB or a Privacy Board. See 45 CFR 164.512(i)(1)(i). This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information, and the research could not practicably be conducted if research participants’ authorization were required. A covered entity may use or disclose protected health information for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board, provided it has obtained documentation of all of the following:
 - Identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;

- A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria in the Rule;
- A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board;
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

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:
 - an adequate plan to protect the identifiers from improper use and disclosure;
 - 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
 - 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 this subpart;
 2. The research could not practicably be conducted without the waiver or alteration; and
 3. The research could not practicably be conducted without access to and use of the protected health information.
- **Preparatory to Research.** Representations from the researcher, either in writing or orally, that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any protected health information from the covered entity, and representation that protected health information for which access is sought is necessary for the research purpose. See 45 CFR 164.512(i)(1)(ii). This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.
 - **Research on Protected Health Information of Decedents.** Representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on the protected health information of decedents, that the protected health information being sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is being sought. See 45 CFR 164.512(i)(1)(iii).

- **Limited Data Sets with a Data Use Agreement.** A data use agreement entered into by both the covered entity and the researcher, pursuant to which the covered entity may disclose a limited data set to the researcher for research, public health, or health care operations. See 45 CFR 164.514(e). A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The data use agreement must:
 - Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;
 - Limit who can use or receive the data; and
 - Require the recipient to agree to the following:
 - Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
 - Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
 - Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
 - Not to identify the information or contact the individual.

- **Research Use/Disclosure With Individual Authorization.** The Privacy Rule also permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself. Today, for example, a research participant’s authorization will typically be sought for most clinical trials and some records research. In this case, documentation of IRB or Privacy Board approval of a waiver of authorization is not required for the use or disclosure of protected health information. To use or disclose protected health information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the requirements of 45 CFR 164.508. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes. However, several special provisions apply to research authorizations:
 - Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the “end of the research study”.
 - An authorization for the use or disclosure of protected health information for a research study may be combined with a consent to participate in the research, or with any other legal permission related to the research study.
 - An authorization for the use or disclosure of protected health information for a research study may be combined with an authorization for a different research activity, provided that, if research-related treatment is conditioned on the provision of one of the authorizations,

such as in the context of a clinical trial, then the compound authorization must clearly differentiate between the conditioned and unconditioned components and provide the individual with an opportunity to opt in to the unconditioned research activity.

- An authorization may be obtained from an individual for uses and disclosures of protected health information for future research purposes, so long as the authorization adequately describes the future research such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for the future research purposes.
- **Accounting for Research Disclosures.** In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. See 45 CFR 164.528. This accounting must include disclosures of protected health information that occurred during the six years prior to the individual's request for an accounting, or since the applicable compliance date (whichever is sooner), and must include specified information regarding each disclosure. A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose. See 45 CFR 164.528(b)(3). Among the types of disclosures that are exempt from this accounting requirement are:
 - Research disclosures made pursuant to an individual's authorization;
 - Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).

In addition, for disclosures of protected health information for research purposes without the individual's authorization pursuant to 45 CFR 164.512(i), and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by covered entities. Under this simplified accounting provision, covered entities may provide individuals with a list of all protocols for which the patient's protected health information may have been disclosed under 45 CFR 164.512(i), as well as the researcher's name and contact information. Other requirements related to this simplified accounting provision are found in 45 CFR 164.528(b)(4).

Transition Provisions. Under the Privacy Rule, a covered entity may use and disclose protected health information that was created or received for research, either before or after the applicable compliance date, if the covered entity obtained any one of the following prior to the compliance date

An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

- The informed consent of the individual to participate in the research;
- A waiver of authorization approved by either an IRB or a privacy board (in accordance with 45 CFR 164.512(i)(1)(i)); or
- A waiver of informed consent by an IRB in accordance with the Common Rule or an exception under FDA's human subject protection regulations at 21 CFR 50.24. However, if a waiver of

informed consent was obtained prior to the compliance date, but informed consent is subsequently sought after the compliance date, the covered entity must obtain the individual's authorization as required at 45 CFR 164.508. For example, if there was a temporary waiver of informed consent for emergency research under the FDA's human subject protection regulations, and informed consent was later sought after the compliance date, individual authorization would be required before the covered entity could use or disclose protected health information for the research after the waiver of informed consent was no longer valid. The Privacy Rule allows covered entities to rely on such express legal permission, informed consent, or waiver of authorization of informed consent, which they create or receive before the applicable compliance date, to use and disclose protected health information for specific research studies, as well as for future unspecified research that may be included in such permission.