

COLUMBIA UNIVERSITY MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD (IRB)

PROCEDURES TO COMPLY WITH PRIVACY LAWS THAT AFFECT USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Procedures

1. Research, HIPAA and the IRB
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Procedure #1

TITLE: Research, HIPAA, and the IRB

Researchers, including investigators affiliated with Columbia University as well as Sponsors and other Third Party Investigators, seek three kinds of access to data for research:

- (1) Data for evaluating a research hypothesis;
- (2) Data that can be re-analyzed to develop new ideas or ways of looking at a problem; and
- (3) Data to meet government requirements regarding the integrity of research.

Under HIPAA, the use or disclosure of Protected Health Information (PHI) for research purposes requires a signed Research Authorization Form from the research subject unless an exception under HIPAA applies.

Review of research-related HIPAA forms is the responsibility of the Privacy Officer (for those eligible for expedited review) or a Privacy Board, per HIPAA. At Columbia University, the Institutional Review Board (IRB) serves as the Privacy Board, and many research projects will require review for both IRB and HIPAA issues. However, HIPAA also applies to certain human research-related activities that are not covered by the federal regulations for the protection of human subjects (i.e., DHHS 45 CFR 46 Subpart A aka the “Common Rule”, and FDA 21 CFR 56), e.g., research on decedents or studies determined to be exempt from IRB review.

The Privacy Rule applies to the following types of research activities when they involve PHI:

- Research using or creating PHI about living individuals
- Activities preparatory to research
- Research on decedents
- Recruitment
- Research using a limited data set

Research using only de-identified data (data that contains none of the 18 HIPAA identifiers) does not generally present privacy concerns and so is not covered by the HIPAA Privacy Rule; however, review of the protocol by the IRB may be required in limited situations, i.e., when the researcher is collaborating with individuals who have access to identifiers. For those situations, consultation with IRB staff to determine whether a protocol should be submitted is advised. Submission of a Form G (Investigators Certification for Research with De-Identified Data attesting to the fact that the 18 HIPAA identifiers will not be used) to the IRB for review and approval is required.

PROCEDURE: Requirements for Research Use of Protected Health Information (PHI)

1. Provision of data for research

- Investigators who propose to conduct research involving patients of Columbia University, engage in prospective collection of data from patients of Columbia University, create PHI for research subjects in protocols conducted by Columbia University researchers who are not

patients, or analyze medical records maintained by Columbia University regarding its patients, shall indicate to the IRB whether they propose to obtain authorization from each subject.

- Where a researcher proposes to analyze medical records maintained by Columbia University, the IRB shall, wherever possible, encourage use of a data use agreement for a Limited Data Set.
- All authorizations, waivers and alterations of authorization shall be reviewed as part of the IRB review process.
- Except where a Limited Data Set is sufficient for the research analysis, the Privacy Rule states that an investigator may not use or obtain PHI for research purposes unless:

(a) Each participant (or the participant’s legal representative) provides a signed, written authorization to use and disclose the participant’s protected health information for the research purpose; *or* (b) The IRB provides documentation of a waiver of authorization to use and disclose participants’ protected health information for the research purpose. This requirement is independent of and in addition to any informed consent to participate in research that may be required by the Common Rule or other applicable human subject protection laws and regulations, or waiver of informed consent granted by the IRB; however, the two should be compatible.

2. Process to submit a request for approval to use patient information as required by HIPAA utilizing one of the proposed forms:

- The appropriate form(s) must be attached to the IRB Protocol when it is submitted for review and approval by the IRB. The forms are available in RASCAL and the content of the form is automatically populated based on the information included in the protocol. The table below identifies the forms that may be required, depending on the protocol

Nature of Research or Protocol Component	Applicable Form	Procedure
Clinical Research Authorization (sponsored and non-sponsored)	Form A	Procedure#3
Application for a Waiver of Authorization	Form B	Procedure#4
Request for Recruitment Waiver of Authorization	Form C	Procedure#5
Investigator’s Certification for Review Preparatory to Research	Form D	Procedure#6
Investigator Certification for Research with Decedent Information	Form E	Procedure#7
Data Use Agreement for Disclosure of Limited Data Set	Form F	Procedure#8
Investigator Certification for Research with De-Identified Data	Form G	Procedure#9

- The form that is attached to the IRB protocol will be reviewed by the Privacy Officer.
- If the form is denied (i.e., not approved), the reviewer will return the form to the PI electronically and send a note to the Principal Investigator advising him/her of the decision and the reason for the denial (e.g. inadequate information, alteration of the form etc.)
- If the form is approved, the RASCAL system will date and time stamp an approval date on the Form and the PI is notified by an electronic message from RASCAL.
- The protocol approval documentation will indicate which forms attached to the protocol have been approved.

APPLICABLE LAW: 45 C.F.R. §§ 164.508, -.512(i)

Procedure #2

TITLE: Creation and Use of Institutional Research Databases and Repositories

This Procedure sets forth the requirements investigators must satisfy to create a research database or repository.

PROCEDURE:

An investigator who seeks to populate a research database or repository with protected health information received (from clinical care records or prior research) or created as part of a research study or protocol will:

- (1) Obtain written authorization of the individual (Procedure #3) to whom the information refers and which specifically permits the inclusion of the protected health information in a research database or repository;
 - (2) Obtain IRB waiver of authorization in accordance with Procedure #4, which specifically permits the inclusion of the protected health information in a research database or repository; *or*
 - (3) Enter into a data use agreement with Columbia University, which permits the investigator to use a Limited Data Set of participants' protected health information for research purposes, including for the development of databases or repositories.
- The proposed uses of a database or repository described in an authorization or waiver of authorization need not be overly specific, provided that the other requirements for authorization or waiver are satisfied.
 - Investigators and the IRB shall refer to established research policies and procedures for guidance on the creation and population of research databases and repositories of protected health information at Columbia University and for guidance on the subsequent use of the information in such databases and repositories.
 - **The use of information in a research database or repository for subsequent research purposes.** In accordance with current institutional policies, when required to do so, investigators will submit requests to the IRB for access to data in research databases and repositories.
 - The IRB shall review investigators' requests to access research databases and repositories in accordance with guidance issued by the Department and Health and Human Services entitled, "Issues to Consider in the Research Use of Stored Data or Tissue", available at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm>), and applicable federal regulations, state law, and University policy.

Procedure #3

TITLE: Authorization to Use and Disclose Protected Health Information for Research – Form A

PROCEDURE: This procedure includes the criteria to determine when an authorization is needed, the specific content requirements for a valid authorization form and the process to submit an authorization (Form A) for approval.

1. Criteria to determine when an Authorization is needed

An investigator who seeks to conduct research, whether interventional research or records research involving protected health information at Columbia University, shall obtain signed, written authorization to use and disclose study participants' protected health information for the research purpose, unless the investigator obtains IRB approval for Waiver of Authorization or the Use meets other criteria as identified in one of the other IRB HIPAA procedures.

This requirement is not overridden by a decision of the IRB to waive the requirement of informed consent to participate in the research. However, if informed consent is waived the Authorization form will have to be evaluated to determine if the Authorization can be utilized as a stand alone form.

2. Content Requirement for a valid Authorization

The following guidance is to be considered when reviewing research protocols for which authorization is sought.

- **Authorization Must Be In Writing:** Unlike the Common Rule, which permits the IRB to waive the requirement for written documentation of informed consent if certain conditions are met, the Privacy Rule provides for no exception to written documentation of authorization. Authorization to use and/or disclose protected health information for research purposes must be in writing.
- **Combination with Other Documents:** The authorization may be combined with the informed consent to participate in the research (or any other type of written permission for the *same* protocol) to form one document, or it may stand alone as a separate document. If the informed consent (or other written permission) and authorization are combined, it will be important to ensure that each of the elements required by the Privacy Rule is present.
- The research authorization may not be combined with any other document, including authorization to use and disclose the protected health information created or obtained during the research for another study or authorization to place the information in a database or repository for future analysis that is not part of the original protocol (even if informed consent is obtained for both).
- An authorization must include, at a minimum:
 - a specific description of the protected health information to be used or disclosed;
 - the name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
 - the name or other specific identification of the person(s), or class of persons, to whom Columbia University may make the requested disclosure;

- a description of the purpose of the requested use or disclosure, *which must be research study-specific*;
 - an expiration date or an expiration event (e.g., “end of the research study”) related to the individual or the purpose of the use or disclosure, *or* a statement that the authorization does not expire;
 - a statement of the individual’s right to revoke the authorization in writing, a description of how to revoke, and the exceptions to the right of revocation (which may include a statement explaining that revocation may result in termination of study participation and does not affect the use and disclosure of existing information as needed to preserve research integrity);
 - a statement describing the ability or inability of Columbia University and the investigator to condition treatment, payment, enrollment or eligibility for benefits on the authorization (which may include a statement explaining that *research-related* treatment may be conditioned on obtaining the authorization where research involves clinical intervention);
 - a statement that information disclosed pursuant to the authorization may be subject to further disclosure by the recipient and may no longer be protected by the Privacy Rule; and
 - The signature of the individual or personal representative (and, if personal representative, the authority to act for the individual) and date of signature. A personal representative includes the parent of a minor or someone with legal authority to act on behalf of the subject (an incompetent adult)
- In addition to the above statements, the following criteria must be met:
 - The authorization must be study or protocol-specific. The IRB will not approve a blanket authorization. However, the study-specific limitation applies only to Columbia University and *its* use and disclosure of protected health information for research purposes, not to the Investigator’s (or sponsor’s, if any) use of the data obtained on the basis of the authorization.
 - The authorization may include additional guarantees of confidentiality of participants’ information by the investigator and other authorized recipients of the information.
 - The authorization must be written in “plain language.” The IRB will strive to achieve the same level of understandability and reading comprehension that is required of an informed consent form to participate in research. Where appropriate, the IRB will require translations of the authorization to be made available to prospective study participants.
 - The research protocol must provide that the research participant will be given a copy of the signed authorization.
 - Permissible uses and disclosures are limited to those described in the Research Authorization form. If a researcher needs to disclose PHI of a person or organization not listed on the Research Authorization Form, the researcher should obtain an additional authorization / waiver.

APPLICABLE LAW: 45 C.F.R. § 164.508

Issued: April 21, 2008

Procedure #4

TITLE: Waiver of Authorization to Use and Disclose Protected Health Information - Form B

PROCEDURE:

An investigator who seeks to conduct research involving patients of Columbia University or medical records maintained by Columbia University without obtaining signed, written authorization must obtain documentation of a waiver from the IRB.

A decision to waive the authorization requirement will be made independently of a decision to waive the Common Rule requirement of informed consent to participate in research. However, the two decisions should be compatible.

This policy sets forth the process the IRB will follow when reviewing waiver requests, the criteria for approval of waiver, and the IRB's obligations with respect to documentation of waiver.

The IRB will review and approve or disapprove requests for waiver of the Privacy Rule authorization requirement, in whole or in part, in accord with the following standards.

An investigator will be asked to document why a Limited Data Set of PHI is not appropriate for the research purposes (thereby obviating the need for a waiver of authorization).

1. Process for Review

The IRB will follow its policies established under the Common Rule for deciding whether review of a request for waiver or alteration of authorization may proceed under either full Board or expedited review procedures.

2. Criteria for Waiver of Authorization

The IRB may approve a waiver of the authorization requirement, in whole or in part, only if it determines that:

- (1) the proposed use or disclosure of protected health information involves no more than *minimal risk* to participants' privacy, based on the presence of *at least* the following elements—
 - a) in the IRB's view of the research, the investigator, and the protected health information, an adequate plan to protect identifiers from improper use and disclosure;
 - b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (unless there is a health or research justification for retaining the identifiers, or if retention is otherwise required by law); *and*
 - c) adequate written assurances that the protected health information will not be reused or disclosed to any third party except as required by law, for oversight of the research, or for other research for which the use or disclosure would be permitted by the Privacy Rule; *and*
- (2) the proposed research could not practicably be conducted without the waiver or alteration; *and*

(3) The proposed research could not practicably be conducted without access to and use of the protected health information.

- There is no recognized standard for “minimal risk” to privacy. The IRB will take into account at least the three elements listed when determining whether this standard has been met and may consider other elements as well (e.g., whether safeguards proposed to be used by the investigator are appropriate to the sensitivity of the protected health information).
- With respect to retention of identifiers, the IRB will consider the need for continued analysis of the data, subsequent government review of the research, and potential for investigation into possible research misconduct when assessing the investigator’s plan for destruction of identifiers.
- The protected health information made available under a waiver of authorization for research must be the minimum necessary for the research. Although this requirement does not warrant the IRB second guessing which data fields are necessary and appropriate for the research hypothesis, it does bear on a determination of which, if any, of the direct or indirect patient identifiers included in the definition of protected health information may be necessary to the research. In determining that the proposed research could not practicably be conducted without access to and use of the protected health information, the IRB will limit the scope of the protected health information the investigator may obtain and use to the minimum amount necessary for the research purpose. The Privacy Rule permits Columbia University to reasonably rely on the fact of the IRB’s approval of waiver, in conjunction with the Principal Investigator’s description of the data needed, in satisfaction of the Privacy Rule requirement that Columbia University disclose only the minimum amount of protected health information necessary to accomplish the purpose of the disclosure.
- Applicable state health information privacy laws may require the IRB to determine that additional criteria have been satisfied before approving a request for alteration to or waiver of authorization. The IRB will ensure that its decision to waive authorization, in whole or in part is consistent with the requirements of applicable state law. For access to records relating to DNA analysis, HIV status, or treatment in a substance abuse program, the IRB will consult the Office of the General Counsel if additional guidance is needed.
- The IRB shall limit the scope of each waiver of authorization to a specific study. However, the study-specific limitation applies only to Columbia University and *its* use and disclosure of protected health information for research purposes, not to the Investigator’s (or sponsor’s, if any) use of the data obtained pursuant to the waiver. The Investigator (and sponsor, if any) may obtain permission through the informed consent process to use participants’ information for other, unspecified research purposes.

Documentation of Waiver

- Where the IRB determines that the criteria for waiver have been met, the IRB will document its decision in writing and provide a copy of the same to the investigator. The documentation will, at a minimum:
 - identify the IRB and the date on which waiver of authorization was approved;
 - state that the IRB has determined that the waiver satisfies the criteria set forth above;
 - describe the nature and scope of the waiver;

- briefly describe the protected health information for which use or disclosure has been determined to be necessary;
 - state whether the waiver request was reviewed and approved under full Board or expedited review procedures as set forth by the Common Rule; *and*
 - Be signed by the IRB chairperson, other IRB member designated by the chairperson, or IRB staff member in accordance with IRB policy regarding signatories.
- Columbia University must retain a copy of the waiver document for a minimum of six (6) years from the signature date or when the study participants' protected health information was last used or disclosed pursuant to the waiver, whichever is later.

Acceptance of Third Party Waivers

Where review of a protocol for a multi-site research trial for purposes of the Common Rule will be conducted by an Institutional Review Board associated with each institution where data will be collected, the IRB permits a waiver of authorization to be granted by that IRB or by a separate IRB. If Columbia University has accepted a waiver of authorization issued by another IRB, the Institutional Review Board will obtain a copy of such waiver for purposes of its files for any protocol for which it is responsible under the Common Rule.

APPLICABLE LAW: 45 C.F.R. § 164.512(i) (2)

Procedure #5

TITLE: Requests for Recruitment Waiver– Form C

PROCEDURE: This Procedure covers the requirements for contacting Columbia University patients who have been identified as prospective study participants.

In general the researcher is prohibited from directly contacting potential research subjects.

The Privacy Rule imposes limitations on the use and disclosure of protected health information for the purpose of identifying and contacting prospective research participants. Similar limitations are imposed when a prospective researcher or Sponsor seeks to examine existing Columbia University data for purposes of protocol development or evaluation of the suitability of Columbia University as a site for future research.

HIPAA also applies to recruitment and research activities conducted via medical records and medical registry reviews. Investigators must obtain either a Research Authorization from the subject or a Waiver of HIPAA Authorization approved by an IRB prior to commencing research recruitment activities from these sources. A [Waiver of HIPAA Authorization](#) for recruitment purposes only is referred to as a partial waiver. Researchers are required to obtain subjects' Research Authorizations after recruiting and enrolling subjects via a partial waiver and prior to creating or using PHI during research procedures.

A treating provider does, however, have the option to:

- Discuss with his/her own patients the option of enrolling in a study.
 - Obtain written authorization from the patient for referral into a research study.
 - Provide research information to the patient so that the patient can initiate contact with the researcher.
 - Provide information to a researcher when the researcher has obtained an approved Waiver of Research Authorization from an IRB for recruitment purposes.
- Without patient authorization or IRB waiver of authorization, the only persons who may use protected health information maintained by or on behalf of Columbia University to contact a current or former patient about a research opportunity are:
 - (1) Members of Columbia University's workforce (as defined by HIPAA) with a legitimate and permitted purpose with the necessary approvals.
 - (2) Health care providers who have or have had a treatment relationship with the patient.
 - The IRB may approve a research protocol that relies on such persons to contact prospective study participants.
 - The IRB may grant a partial waiver of patient authorization that permits Columbia University to disclose patients' protected health information to a Third Party Investigator for the limited purpose

of contacting patients about a research opportunity. A decision by the IRB to grant a partial waiver of authorization will be made in accord with this policy.

- If the IRB grants a partial waiver for purposes of allowing a third party researcher to contact prospective participants, the information necessary to make a record of the disclosure must be collected in order to provide each patient with an accounting of disclosures.
- The IRB will follow the procedures with respect to identification of prospective research participants, evaluation of Columbia University as a trial site, or protocol development.
- The IRB shall follow HIPAA established policies and procedures with respect to contacting prospective research participants.

APPLICABLE LAW: 45 C.F.R. §§ 164.502(1) (i), -512(i) (2).

APPLICABLE LAW: 45 C.F.R. § 164.512(i)(1)(ii); 45 C.F.R. § 164.512(i)(2); 45 C.F.R. § 164.502(1)(i); 45 C.F.R. § 164.528

Procedure #6

TITLE: Reviews Preparatory to Research – Form D

PROCEDURE: This covers the requirements for identifying patients of Columbia University who may be prospective study participants, as well as evaluation of Columbia University's patient data for purposes of protocol development or site selection for a clinical trial.

If a proposal states that a member of Columbia University's workforce or a healthcare provider who has or has had a treatment relationship with the patient will review protected health information maintained by or on behalf of Columbia University, the IRB may approve such review if the workforce member or provider is governed by the following written restrictions:

- (a) access to the protected health information is solely for the purpose of identifying potential research participants, developing a research protocol, or clinical trial site evaluation;
 - (b) the requested information is necessary for this purpose; *and*
 - (c) No protected health information will be copied or removed from the premises of Columbia University during the course of or following the review.
- The proposal must state if any other person (e.g., an investigator who is not affiliated with Columbia University) will review protected health information maintained by or on behalf of Columbia and provide a representation to the IRB that the individual will protect the information provided.
 - As an alternative to obtaining the above representation from a third party researcher, or where the conditions of the representation cannot be met, the IRB may grant a waiver of patient authorization for the disclosure of protected health information to the third party researcher for the limited purpose(s) of identifying prospective study participants for the identified protocol development, and/or clinical trial site evaluation.
 - Where a researcher who is neither a member of Columbia University's Organized Healthcare Arrangement (OHCA) or its workforce conducts the review, each record reviewed must be annotated with the information necessary to provide for an accounting of disclosures.
 - Authorization of the patient is not required

APPLICABLE LAW: 45 C.F.R. § 164.512(i)(2)

APPLICABLE LAW: 45 C.F.R. § 164.512(i)(1)(ii), (i)(2)

Procedure #7

TITLE: Research with Decedents' Information – Form E

PROCEDURE: Although research involving deceased persons is not subject to IRB review under the Common Rule, decedents' protected health information is subject to the Privacy Rule.

An investigator who seeks to conduct research using decedents' protected health information maintained by or on behalf of Columbia University must:

- (1) Obtain from the decedents' legal representatives signed, written authorization to use and disclose the protected health information for the research purpose;
- (2) obtain documentation of IRB waiver of authorization to use and disclose the protected health information for the research purpose;
- (3) enter into a data use agreement with Columbia University which permits the investigator to conduct the research using a Limited Data Set of the decedents' protected health information; *or*
- (4) Make certain written representations to Columbia University regarding the need for the decedents' information including the submission of a Form E for review and approval by the IRB.

Where an investigator elects not to use a data use agreement or obtain authorization or waiver of authorization, the IRB will review the investigator's proposed written representation to ensure that it satisfies the requirements of this Policy.

Content of Representation

- The investigator must represent in writing that:
 1. access to the requested information about the deceased persons is sought solely for the purpose of research on that information; *and*
 2. The requested information is necessary for the research purpose.
- In approving a representation, the IRB will limit the scope of decedents' protected health information that the investigator may obtain to the minimum amount necessary for the research purpose. The Privacy Rule permits Columbia University to reasonably rely on the certification in satisfaction of the Rule's requirement that Columbia University disclose only the minimum amount of protected health information necessary to accomplish the purpose of the disclosure.
- At its option, the IRB (or Columbia University) may elect to require the researcher to provide evidence that the proposed data subjects are deceased. For example, a list of subjects for whom data is sought may have been culled from county records.

APPLICABLE LAW: 45 C.F.R. § 164.512(i)(1)(iii)

Procedure #8

TITLE: Use or Disclosure of Limited Data Set Pursuant to Data Use Agreement – Form F

PROCEDURES: The IRB will review proposed data use agreements and Limited Data sets in accord. When an investigator proposes to conduct research analyzing medical records of Columbia University the IRB will consider whether use of a Limited Data Set may be sufficient for the research purpose. Even where informed consent will be waived under the Common Rule, a data use agreement is preferable to a waiver of authorization for purposes of the Privacy Rule, as it is more protective of patient privacy and does not require an accounting of disclosures by Columbia University . An investigator who proposes to conduct data research shall be asked to document why a Limited Data Set of protected health information is not appropriate for the research purpose. with the following standards.

Content Requirements

- The data use agreement must, at a minimum:
 - (1) Establish the permitted uses and disclosures of the Limited Data Set by the investigator, which may be only for the purposes of the investigator's research, public health activities, and Columbia University's health care operations;
 - (2) Provide that the investigator will:
 - a) not use or further disclose the Limited Data Set other than as permitted by the data use agreement or as otherwise required by law;
 - b) use appropriate safeguards to prevent any use or disclosure of the information other than as provided for by the data use agreement;
 - c) report to Columbia University any use or disclosure of the information not provided for by the agreement of which the investigator becomes aware;
 - d) ensure that any agents, including subcontractors, to whom it provides the Limited Data Set agree to the same restrictions and conditions that apply to the investigator with respect to such information; *and*
 - e) Not identify or contact the research participants.

There is no required form of data use agreement, but the agreement must at a minimum address each of the elements set forth above. The IRB may require that the data use agreement include additional restrictions on the investigator's ability to use and disclose the Limited Data Set or impose additional obligations on the investigator with respect to such information if the IRB determines that such restrictions or obligations are warranted given the sensitivity of the information and/or the nature of the research.

Parties to the Agreement

- Where the investigator is a member of Columbia University workforce, the data use agreement is between the workforce member and Columbia University and may take the form of an employee confidentiality agreement which includes the data use agreement provisions.

- The IRB will forward investigator-signed data use agreements to the appropriate person authorized to sign the agreements on behalf of Columbia University (the Privacy Officer).

The Limited Data Set

- The data made available under a data use agreement must be the minimum necessary for the purposes. The IRB shall evaluate the identifiers sought by the investigator for the research purpose, including each of the fields listed in the definition of protected health information, to ensure that the minimum necessary standard has been met. The Limited Data Set of information may *not* under any circumstances include any of the following identifiers of a participant or of a participant's relatives, household members, or employer(s):
 - names;
 - street address information other than city, state, and zip code;
 - telephone and fax numbers;
 - e-mail, internet, and web addresses;
 - Social Security numbers;
 - medical record and prescription numbers;
 - health plan beneficiary numbers;
 - account numbers;
 - certificate/license numbers;
 - vehicle identifiers and serial numbers;
 - device identifiers and serial numbers;
 - biometric identifiers; and
 - full face photographic and comparable images

A limited data set may include one or more of the following:

1. Towns
2. Cities
3. States
4. Zip Code and their equivalent geocodes. (Note that a zip code cannot be used if the area composing the zip code has less than 20,000 citizens.)
5. Dates including birth and death
6. Other unique identifying numbers, characteristics, or codes that are not expressly excluded. (Medical record numbers and pathology numbers are excluded.)
7. Relevant medical information

A Limited Data Set may be used only for purposes of research, public health, or health care operations. It may be used only if the covered entity providing the data and the recipient of the data first enter into a [Data Use Agreement](#). The investigator, the holder of the PHI, and their respective institutions, must

sign Data Use Agreements, either for access to a Limited Data Set or for the release of a Limited Data Set. The agreements must, among other things, establish the permitted uses and disclosures of the information included in the Limited Data Set and must provide that the recipient of the Limited Data Set will not identify the information or use it to contact individuals. As with research conducted pursuant to an authorization, disclosure(s) of PHI that are part of a Limited Data Set need not be tracked for purposes of providing an accounting to an individual.

- The IRB will not approve a proposed data use agreement pursuant to which the investigator seeks to obtain more information than is necessary for the research purpose.
- The term “device identifier” is not defined by the Privacy Rule or the Food and Drug Administration. Where information about a medical device will be included in a Limited Data Set, the IRB shall consider whether there is a reasonable basis to believe that the information about the device, when used in accord with the data use agreement, could be used to identify the individual.
- An investigator may propose that Columbia University will disclose study participants’ protected health information to a third party to create the Limited Data Set to be used for the research. The IRB will approve such a protocol only on the condition that the third party provides a copy of a valid business associate agreement with Columbia University for such purpose.

APPLICABLE LAW: 45 C.F.R. § 164.514(e)

Procedure #9

TITLE: Investigator Certification for Research with De-Identified Data – Form G

De-identified data are data that contain none of the 18 HIPAA identifiers. If all of the 18 identifiers are removed, the information is no longer (1) Individually identifiable, (2) PHI, and (3) subject to HIPAA's requirements

- A de-identified data set may be coded with a unique identifier that cannot be traced back to the individual for the purpose of being re-identified by the provider at a later date.
- De-identified data may include gender, age, race, or relevant information regarding disease or tissue source and can later be re-identified, by the original holder of the data, if necessary, by means of a unique, non identifiable, code for purposes of carrying out research.
- It is important to remember that re-identification will subject the information to HIPAA's requirements. A researcher must resubmit the protocol to the IRB for approval when re-identification of the data is desired.
- A data set may also be considered de-identified if an expert in statistical and scientific methods determines and documents that the methods used to de-identify or code the data present a very small risk that the information can be used alone or in combination with other reasonably available information to identify an individual.
- "Anonymous" data are not necessarily considered de-identified under HIPAA. Anonymity under the federal Common Rule requires that individuals cannot be readily ascertained by the investigator and cannot be associated with the data. According to the Common Rule standard, anonymous data may retain dates of treatment. Under HIPAA's more stringent requirements, however, such data would be considered identifiable data.

The use of de-identified data requires the submission of an Investigator Certification for Research with De-Identified Data – Form G.

The form should be completed and attached to the Protocol in RASCAL.