Section 3.20
Confidentiality of Collected Specimens or Data

Policy
Research involving specimens or data that can be linked, directly or indirectly by a code, to personal information concerning the source of the material constitutes research that is subject to federal regulations and IRB approval. Specifically, the federal regulations regarding the criteria for IRB approval of research include, “When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.” Researchers and research staff should understand and follow their department, unit, UCSD, the University of California, the VA San Diego Healthcare System (VASDHS), Rady Children’s Hospital – San Diego (RCHSD), the State of California and Federal privacy laws (HIPAA) policies and procedures, as appropriate, to prevent the disclosure, to other than authorized individuals, subjects’ personal and confidential information. Additional information regarding privacy and confidentiality of research records can be found in the UCSD SOPP, Section 3.6, Privacy and Confidentiality of Research Records.

At a minimum, the following guidelines and standards should be followed regarding confidentiality of collected specimens or data:

1. Only the “minimum necessary” participant identifiers/sensitive information shall be collected. The minimum necessary standard is derived from confidentiality codes and practices in common use today. It is based on sound current practice that patient identifiers/sensitive information not be used or disclosed when it is not necessary to satisfy a particular purpose or carry out a function.

2. Participant identifiers/sensitive information shall be removed/destroyed as soon they are no longer needed and in accordance with local guidance on records retention. Researchers should have procedures in place to periodically review collected participant identifiers/sensitive information to ensure it is still required to satisfy a particular purpose or carry out a function.

3. Physical access to areas or computers that contain identifiers/sensitive information shall be restricted to authorized personnel.

4. Electronic access to files on computers that contain identifiers/sensitive information shall be restricted to authorized research personnel.

5. Participant identifiers/sensitive information transmitted over public networks must be encrypted.

6. If possible, a subject code should be used to identify subjects on data files rather than direct participant identifiers. A data file is document, either paper or electronic, that contains information collected as a result of research procedures. The document linking participants and subject code shall be kept separate either physically or electronically from the data file.

7. If participant identifiers/sensitive information must be retained in the data file because of specific needs of the research study, the investigator should provide appropriate justification for...
such retention. If the data are electronic, the information should be encrypted during storage and decrypted only when needed for the conduct of the study. Justification for retention may include circumstances where retaining identifiers are necessary for research procedures and subject well being.

8. Participant identifiers/sensitive information should not be stored on portable devices including laptops, USB drives, CD/DVD, smart phones, etc. If it is necessary to use portable devices for the initial collection of identifiers/sensitive information, appropriate protection measures such as encryption must be in place before collecting such information and the information must be transferred to a secure system, such as a system that satisfies UCSD Network Security Minimum Standards, as soon as possible.

9. Participant identifiers/sensitive information and contact information may not be distributed outside of UCSD, or its partner institutions, without the specific informed consent of subject, and the approval of the IRB and VASDHS entities, as appropriate. An approved Data Use Agreement and/or Authorization to transport and utilize VA sensitive information outside protected environments may also be required. Circumstances where such distribution may be allowed include name-based reporting for HIV testing done as part of research or clinical care as codified in the California Code of Regulations for Health Care Providers and Laboratories.

Participant identifiers include the 18 HIPAA “PHI” (protected health information) identifiers and “PII” as defined by California Law SB-1386. The identifiers include names, all elements of dates (except year) for dates directly related to an individual, telephone numbers, fax numbers, e-mail addresses, Social Security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers and any other unique identifying number, characteristic or code. Sensitive information includes data in any format that requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration or destruction. The UCSD IRBs consider participant initials to be a participant identifier. Collected information is considered “de-identified” when the above mentioned identifiers have been removed.

Encryption is a process by which information is scrambled so that is it unreadable except to someone who has the “key” to decrypt it. For additional information about encryption and other procedures to address confidentiality associated with participant identifiers/sensitive information, please see the UCSD HIPAA Privacy/Security Newsletter and/or the ORO document, Research Information Protection Frequently Asked Questions.

A security breach is when unencrypted PHI, or PII or sensitive information is reasonably believed to have been acquired by an unauthorized person. A suspected security breach means that this information may have been lost or stolen, accessed in an unauthorized fashion or infected by a virus or worm but it is not yet known whether the information has been compromised to meet the level of a security breach.

In the event of a real or suspected breach of security, the appropriate entities should be notified including the UCSDHS Privacy Officer; the UCSD Medical Center Information Security Officer; security@ucsd.edu; the RCHSD Security Officer; the VA Police, the VA Information Security Officer and/or VA Privacy Officer, as appropriate, and the UCSD HRPP.
Review Procedures

The IRB will consider the application for full-IRB review or an expedited review process providing that the project meets the criteria for an expedited review. In order to facilitate review of the project, the investigator will set forth the following in the Application for IRB Review:

1. An full description of what provisions will be used to maintain confidentiality of participant and study data/specimens. This description should include the following, as appropriate:
   a) How the participant and study data/specimens will be protected/secured.
   b) Who will have access collected information.
   c) Who will control access to the information and how will it be controlled.
   d) Procedures of “deidentifying” participant and study data/specimens.
   e) Procedures associated with removal/destruction of identifiers.
2. Information as to whether it is reasonably foreseeable that the study will collect information that Federal, State, and/or local laws/regulations require reporting to other officials (e.g., child or elder abuse; positive results from lab tests) or ethically requires actions (e.g., suicidal ideation). If such reporting will be done, a description of the reporting procedures/requirements should be provided.

For VA studies, the following elements should also be addressed:

1. VA Sensitive Information (VASI) includes data, in any format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration or destruction, including but not limited to individually identifiable medical or health data. Properly de-identified data records are not considered to be VASI.
2. The particular VASI that will be used in this study.
3. What the VASI used in this study will be used for.
4. VASI will be used by approved study personnel.
5. In the event of a real or suspected breach of security, the VA Police, the VA Information Security Officer, and the VA Privacy Officer will be notified.
6. VASI will be accessed, stored, and destroyed according to a data management plan that will promote security and privacy. The investigator should address the relevant aspects of these issues in an appropriate manner in the consent document.

Note that OHRP guidelines also include the following: “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.”

Informed consent from the subject is generally required for research involving human biological material. In addition to the required and optional elements of informed consent, the informed consent form should contain the following elements regarding confidentiality, if applicable:

1. An full description of what provisions will be used to maintain confidentiality of participant and study data/specimens in lay terms. This description, in lay terms, should include the following, as appropriate:
   a) Study procedures associated with the collection of participant/study data/specimens including when the collection will be done, what will be collected, and how confidentiality associated with the information/specimens will be protected/secured.
   b) Who will have access collected information/specimens and why such access is required.
c) Who will control access to the information/specimens and how will it be controlled.

d) Whether participant and study data/specimens will be deidentified or collected anonymously.

e) Risks associated with possible inadvertent release/access of collected participant/study information outside the research setting.

2. Information as to whether it is reasonably foreseeable that the study will collect information that Federal, State, and/or local laws/regulations require reporting to other officials (e.g., child or elder abuse; positive results from lab tests) or ethically requires actions (e.g., suicidal ideation). If such reporting will be done, a description of the reporting procedures/requirements should be provided.

In the case of research involving existent identified or coded samples, it may not be feasible to obtain such consent. If in the original consent document subjects anticipated and agreed to further participation in this way, then additional consent is unnecessary. However, documents may not exist or, when they exist, they are do not address the possibility of such research. In such cases, unlinking, or new consent may be necessary to conduct the research, unless a waiver of informed consent is possible.

The IRB may waive the requirement for informed consent if the requirements appropriate. The determination of minimal risk must be made, as described above. In determining whether a waiver of consent would adversely affect the rights and welfare of subjects, the IRB will consider whether:

1. The waiver would violate any state or federal statute or customary practice regarding an entitlement to privacy or confidentiality;
2. The study will examine traits commonly considered to have political, cultural, or economic significance to the study subjects; and
3. The study's results might adversely affect the welfare of the subject's community (if applicable).

If the study poses more than minimal risk and consent cannot practicably be obtained, the removal of identifiers may be required.

**Applicable Regulations**

21 CFR 50  
21 CFR 56.109  
38 CFR 16.102  
38 CFR 16.103  
38 CFR 16.110  
38 CFR 16.111  
45 CFR 46.110  
45 CFR 46.111  
OHRP Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure  
UCSD Health Sciences—Standards of Business Conduct  
UCSD HIPAA Privacy/Security Newsletter, Issue: October 2007  

[UCSD Network Security: Minimum Standards](#)  
[UCSD HRPP IRB SOPP, Section 3.6, Privacy and Confidentiality of Research Records](#)  
[University of California Business and Finance Bulletin](#)  
[California Law SB-1386](#)  
[California Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 1](#)  
[VHA Handbook 1200.05](#)  
[VHA Handbook 1605.2](#)  
[ORO Document, Research Information Protection Frequently Asked Questions](#)