

**Guidance and Procedures Number: 52**

**Title: Reporting of Diseases and Conditions Identified in the Course of Research**

**Date of Last Revision: July 5, 2007**

## **I. Introduction**

In the interests of monitoring and protecting the public health, California law requires that health care providers and other specified persons report cases of certain diseases and conditions, both communicable and non-communicable, to a designated agency, such as the local health department. Definitions of who must report vary by condition and may include individuals who are not health care providers. A mandated reporter's obligation to report exists even if the identification occurs in the course of research, and health care providers and facilities may be subject to criminal and/or civil liability for failure to report when required by law to do so.

Federal regulations and state laws governing confidentiality of medical information allow disclosure for mandatory reporting purposes.<sup>1</sup> However, only the minimum information necessary to comply with reporting requirements should be disclosed.

This document provides a general summary of types of reporting requirements and also outlines considerations and exceptions that are specific to the research context. As the IRB only has jurisdiction over the protection of human research subjects, questions about procedures for reporting or whether someone is obligated by law to report should be addressed to an appropriate administrative office (e.g., Medical Center Risk Management, the Office of Legal Affairs).

## **II. Types of Reporting Requirements**

### *Diseases and Conditions Reportable to the Local Health Department*

California law designates certain diseases and conditions as reportable to a local health department. For research taking place at UCLA, such cases would be reported to the Los Angeles County Department of Health, although some reports may also need to be sent to a local health department in another jurisdiction (such as where a patient resides).

Health care providers and laboratories that suspect or identify cases of specified communicable diseases are required to report those cases to the local health department, which publishes a list of reportable diseases as identified in the California Code of Regulations.<sup>2</sup> The list also sets out the urgency with which cases should be reported as well as the methods by which this should be done. Local health departments in turn report cases to the California Department of Health Services (DHS). DHS will further report cases of certain nationally-notifiable diseases to the federal Centers for Disease Control and Prevention. Furthermore, outbreaks of any disease

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<sup>1</sup> 45 Code of Federal Regulations § 164.512(a-b); California Civil Code § 56.10(b)(9)

<sup>2</sup> Title 17 California Code of Regulations § 2500

and occurrences of any unusual disease must be reported, whether or not the disease is listed as reportable in the California Code of Regulations.<sup>3</sup>

State law also requires the reporting of disorders characterized by lapses of consciousness, as defined in the California Code of Regulations.<sup>4</sup> The law further allows physicians and surgeons to report a disorder even if it may not fall within the regulatory definitions of such disorders so long as the physician or surgeon “reasonably and in good faith believes that the reporting of the patient will serve the public interest.”<sup>5</sup> The local health department in turn reports cases to the California Department of Motor Vehicles.

State law also requires reporting by any physician or surgeon who knows, or has reasonable cause to believe, that a patient is suffering from pesticide poisoning or any disease or condition caused by a pesticide.<sup>6</sup> The local health department in turn reports cases to the county agriculture commissioner, and may also report to designated state government officials as necessary.

#### *Diseases and Conditions Reportable to Another Entity Designated by Law or Regulation*

The California Code of Regulations sets out reporting requirements for several diseases and conditions in newborns, including neural tube defects, chromosomal disorders, preventable heritable disorders, deafness and Rhesus Hemolytic Disease.<sup>7</sup> Such diseases are typically reportable by health care facilities to the California DHS.

The California Cancer Registry (CCR) is the statewide population-based cancer surveillance system. The CCR collects information about all cancers diagnosed in California (except basal and squamous cell carcinoma of the skin and carcinoma *in situ* of the cervix). Reporting to the CCR is required by law.<sup>8</sup>

The California Parkinson’s Disease Registry (CPDR) is undergoing pilot testing in designated geographic areas. There is no current reporting requirement for UCLA, but upon establishment of the statewide registry, reporting to the CPDR will be required by law.<sup>9</sup>

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<sup>3</sup> Title 17 California Code of Regulations § 2500

<sup>4</sup> California Health & Safety Code § 103900; Title 17 California Code of Regulations § 2800 *et seq*

<sup>5</sup> California Health & Safety Code § 103900(a)

<sup>6</sup> California Health & Safety Code § 105200

<sup>7</sup> Title 17 California Code of Regulations § 6500 *et seq*

<sup>8</sup> California Health & Safety Code § 103885(d)(2)

<sup>9</sup> California Health & Safety Code § 103865(d)(2)

### **III. IRB Responsibilities**

The IRB is required to determine whether research risks to subjects are minimized, informed consent is appropriate and privacy and confidentiality protections are adequate. Therefore, if the IRB believes that a reportable condition may be detected, diagnosed or treated in the course of a research project, it may ask the Principal Investigator to analyze the possibility of such an occurrence and his or her legal obligations to report. The IRB may also require that informed consent document(s) warn subjects about how the investigator's duty to report to appropriate authorities affects confidentiality.

In the event that new or modified requirements present issues of human subjects protection, the IRB may provide guidance through correspondence issued to a Principal Investigator(s) conducting research affected by the requirement or may ask OPRS to issue detailed guidance to the entire UCLA research community.

### **IV. Investigator Responsibilities**

Any study investigator or staff with an obligation to report under laws or regulations regarding reportable diseases or conditions should report according to applicable institutional policies (e.g., UCLA Medical Center Policy HS 9010, UCLA Medical Center Infection Control Manual) and in consultation with relevant University offices (e.g., Medical Center Risk Management).<sup>10</sup> Exceptions to reporting requirements that may apply in the research context are described in Section V below.

For those research studies in which there is a reasonable expectation that a reportable condition may be detected, diagnosed or treated (e.g., a study in which a test for tuberculosis will be conducted to screen out subjects to whom an investigational drug should not be given), an investigator should describe the information below in the application to the IRB. The following should also be described, using lay language, in any consent document for study subjects unless exceptions to the reporting requirements apply to the research.

1. The reportable disease(s) or condition(s) that may be detected or diagnosed.
2. The test(s) or procedure(s) by which a reportable disease or condition is likely to be detected or diagnosed.
3. The availability of pre- and post-test counseling or referrals, including a description of the financial responsibility for such counseling or referrals.
4. The obligations of investigators, study staff members, and/or clinical laboratories to report a diagnosis or positive test, including the information that will be reported (such as name, Social Security number and contact information), to whom information will be reported and the confidentiality of reported information. The investigator should discuss any exceptions to the reporting requirements that apply to the research.
5. Any risks or consequences associated with the tests or procedures used to detect or diagnose the disease or condition, such as anxiety while awaiting results.

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<sup>10</sup> The legal and regulatory definitions of who must report vary depending on the disease or condition or the type of disease or condition that must be reported, and may include individuals who are not health care providers.

6. Any consequences of detection or diagnosis (e.g., partner notification, loss of driving privileges) and physical, psychological, social and economic risks associated with detection or diagnosis, including potential breach of confidentiality.

Investigators are reminded that laws and regulations vary from location to location. Therefore, investigators conducting research outside of California should familiarize themselves with the applicable local reporting requirements. Investigators planning to conduct research outside of the United States should be particularly sensitive to the social context for study subjects and to whom diseases or conditions are reported (for example if reporting to law enforcement agencies is required).

## **V. Exceptions To Reporting Requirements**

When planning the research, investigators should keep in mind any potential reporting obligations. The laws and regulations set out criteria for when diseases or conditions must be reported and by whom, and such criteria may limit the need for investigators to report.

In general, study investigators and staff who are also the health care providers for study subjects would report according to their statutory obligations as health care providers.

Study investigators or staff who are not otherwise the health care providers for subjects may not have statutory obligations to report. Please note that even if study investigators or staff are not mandated reporters, a clinical laboratory or another healthcare provider engaged to conduct testing for the research project might still be required to report. Depending on the laws or regulations for a particular disease or condition, cases in which reporting may not be required include:

1. The study investigators or staff are not mandated reporters, because:
  - a. The investigators or staff do not fall within the statutory criteria for who must report (e.g., if reporting is limited to physicians and surgeons).
  - b. The investigators or staff would refer a subject suspected of having a reportable disease or condition to another physician for diagnosis and/or treatment and the other physician would be obligated to report. For example, the reporting requirements for cancer do not apply to “those cases directly referred to a treatment facility for diagnosis or treatment of that instance of cancer.”<sup>11</sup> However, it is important to note that a suspicion of a disease may be enough to trigger certain reporting requirements even if the subject is referred elsewhere for diagnosis or treatment.
2. Other statutes may provide additional confidentiality protections for subject information and therefore preclude study investigators or staff from reporting diseases or conditions.

For example, the California AIDS Research Confidentiality Act provides for the confidentiality of the records of HIV- or AIDS-related research.<sup>12</sup> The Act does not

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<sup>11</sup> California Health & Safety Code §103885(d)(2)

<sup>12</sup> California Health & Safety Code § 121075 *et seq*

include a provision allowing the disclosure of identifiable information from such a research record for the purposes of reporting, unless the subject provides his or her informed consent to share such research records. Additionally, to the extent that an investigator desires to maintain the confidential nature of the research records, he or she must appropriately notify third parties (such as laboratories, lab directors or other healthcare providers) that the records are protected as confidential under the Act. Investigators seeking to rely upon the Act, also should obtain a Certificate of Confidentiality.

3. The disease or condition identified does not fall within the statutory definition of the disease or condition.
4. The disease or condition has already been diagnosed or the patient is already undergoing treatment, and the disease or condition has already been reported. In some cases, however, continued testing may be reportable. For example, viral load testing for human immunodeficiency virus (HIV) is reportable.<sup>13</sup>
5. The subject population does not fall within the statutory criteria. For example, disorders characterized by a lapse of consciousness are only reportable if the patient is at least 14 years of age.
6. The research is covered by a Certificate of Confidentiality, which provides protection against compulsory disclosure, such as a subpoena, of identifiable research information. The National Institutes of Health (NIH) may grant a Certificate of Confidentiality for studies collecting information that, if disclosed, could have adverse consequences for subjects and damage their financial standing, employability, insurability or reputation.

A Certificate, however, does not exempt a researcher from performing ethical research and from responsibility for the public good. Moreover, the NIH has advised that the protections afforded by a Certificate of Confidentiality do not automatically preclude an investigator who is a mandated reporter under state law from reporting communicable diseases. When applying to the NIH for a Certificate, an investigator must specifically request that the certificate include an exemption from state communicable disease reporting requirements. In order to balance individual protections with the broader goal of protecting the public health, the NIH considers such requests on a case-by-case basis according to requirements outlined in an August 9, 1991 memorandum from the then-Assistant Secretary for Health (available at [http://grants.nih.gov/grants/policy/coc/cd\\_policy.htm](http://grants.nih.gov/grants/policy/coc/cd_policy.htm)).

Unless the NIH grants a Certificate of Confidentiality with a specific exemption from communicable disease reporting requirements, the IRBs expect investigators to act in an ethical manner by informing subjects in the consent form that the protections offered by the Certificate do not extend to communicable disease reporting and that the investigator will report communicable diseases and other reportable conditions according to State law.

## **Laws and Regulations:**

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<sup>13</sup> Title 17 California Code of Regulations § 2641.30

Communicable Disease Prevention and Control Act, California Health & Safety Code, § 120100 et seq.

45 CFR 164.512(a-b)

California Civil Code § 56.10(b)(9)

17 California Code of Regulations 2500

17 California Code of Regulations 2641.30

17 California Code of Regulations 2800 *et seq*

17 California Code of Regulations 6500 *et seq*

California Health & Safety Code 103900

California Health & Safety Code 103900(a)

California Health & Safety Code 105200

California Health & Safety Code 103865(d)(2)

California Health & Safety Code 103885(d)(2)

California Health & Safety Code 121075 *et seq*

#### **References:**

Memorandum from James O. Mason, M.D., Dr.P.H. *Certificates of Confidentiality -- Disease Reporting*. August 9, 1991. [http://grants.nih.gov/grants/policy/coc/cd\\_policy.htm](http://grants.nih.gov/grants/policy/coc/cd_policy.htm)

FDA, *IRB Information Sheets: Screening Tests Prior to Study Enrollment*, September 1998. <http://www.fda.gov/oc/ohrt/irbs/toc4.html#screening>