

# Human Research Protection Program Policies & Procedures



Research Integrity Office  
Mail code L106-RI  
Portland, Oregon 97239-3098  
Phone: 5 03-494-7887  
Fax: 503-494-5081

## Adhering to State Laws & Regulations

Version 1.0  
Date Effective: 10/11/2011

### Background

The Code of Federal Regulations requires that Institutional Review Boards review proposed research with regard to applicable law 45 CFR 46.107(a). Abiding by Federal laws, regulations and guidelines however, is not enough. State laws must also be adhered to and each state has its own statutes, regulations and case law that may impose stricter or additional requirements on research than those imposed by federal regulations.

### Scope

There are no broad statutes that address human subject research in the State of Oregon. The following are statutes, regulations and case law that have implications for research conducted in the State of Oregon.

#### I. Policy

- A. The State of Oregon has codified law that intersects with the federal regulations governing the protection of human subjects. Investigators working with human subjects need to be aware of these State laws, depending on the nature of the investigator's proposed research and comply as applicable to the research being conducted.
- B. The law or statute that is most restrictive or best protects participants takes precedence.

#### II. State and Local Guidelines and Regulations

- A. Laws Concerning Children or Minors
  - 1. Age of Majority (ORS 109.510, 109.520, 419B.550-558)
    - i. The age of majority is 18 years in the State of Oregon.
    - ii. All persons shall be deemed to have arrived at the age of majority upon their being married according to law or legally emancipated.
  - 2. Relation of Adopted Child to Adoptive Parents (ORS 109.050)
    - i. Same relation in every respect pertaining to the relation of birth parent and child.

- ii. Treated as if the adopted child was the natural child of such parents.
- 3. Medical or Dental Treatment (ORS 109.640)
  - i. A minor 15 years of age or older may give consent to hospital care, medical or surgical diagnosis or treatment.
  - ii. A hospital or any physician, nurse practitioner or dentist may advise the parent or legal guardian of any minor of the care, diagnosis or treatment or the need for any treatment, without the consent of the patient with regard to ORS 109.640 above.
- 4. Treatment for Sexually Transmitted Infections (ORS 109.610)
  - i. A minor who may have come in contact with any venereal disease may give consent to the furnishing of hospital, medical or surgical care related to the diagnosis or treatment of such disease, if the disease or condition is one that is required by law or regulation to be reported to the local or state health officer or board.
- 5. Diagnosis or Treatment for Mental or Emotional Disorder or Chemical Dependency (ORS 109.675)
  - i. A minor 14 years of age or older may obtain, without parental knowledge or consent, outpatient diagnosis or treatment of a mental or emotional disorder or a chemical dependency, excluding methadone maintenance. However, the parents of the minor must be involved by the end of treatment unless the parents refuse or unless there are clear clinical indications to the contrary.
  - ii. The healthcare provider above may advise the parent or legal guardian of any minor described in ORS 109.675 of the diagnosis or treatment if clinically appropriate and in the best interests of the minor's treatment (ORS 109.680).
- 6. Educational/School Records (ORS 336.187)
  - i. A public school or school district shall disclose personally identifiable information from an education record of a student in connection with a health or safety emergency if knowledge of the information is necessary to protect the health and safety of the student or other individuals.
- 7. Wards of the Court
  - i. If a judge finds that the child has been abused or neglected, or the child's behavior is beyond the parents' control, the child may be left in the parents' home under the supervision of CAF, removed to protective foster care, or become a ward of the court.
  - ii. If a child becomes a ward of the court, this means that the parents have lost the right to discipline the child or control the child's education. Those responsibilities then go to the people with whom the child is placed.

## **B. Reporting Abuse**

### **1. Mandatory Reporting**

- i. Oregon state law mandates that workers in certain professions make reports if they have reasonable cause to suspect abuse or neglect. These people are called mandatory reporters and they are a crucial link in the system to protect Oregon's most vulnerable citizens.
- ii. Mandatory reporters include medical personnel: physicians, psychiatrists, surgeons, residents, interns, dentists, dental hygienists, medical examiners, pathologists, osteopaths, coroners, Christian Science practitioners, chiropractors, podiatrists, registered and licensed practical nurses, emergency medical technicians, substance abuse treatment personnel, hospital administrators and other personnel involved in the examination, care or treatment of patients.

### **2. Abuse & Neglect of Children (ORS 419B)**

- i. By law, mandatory reporters must report suspected abuse or neglect of a child regardless of whether or not the knowledge of the abuse was gained in the reporter's official capacity. In other words, the mandatory reporting of abuse or neglect of children is a 24-hour obligation.
- ii. A person making a report of child abuse shall make an oral report to a local Child Welfare Office of the Department of Human Services, to the division's designee, or to a law enforcement agency within the county where the person making the report is at the time of the contact.

### **3. Abuse & Neglect of the Elderly and Vulnerable Adults (ORS 124)**

- i. Mandatory reporters, while acting in an official capacity, who come in contact with an elderly or developmentally disabled adult they suspect have been abused or neglected, must report to DHS or law enforcement.

## **C. Public Records Disclosure – Mental Health Records (ORS 192.496)**

1. Records less than 75 years old which contain information about the physical or mental health or psychiatric care or treatment of a living individual, if the public disclosure would constitute an unreasonable invasion of privacy, are exempt from disclosure.

## **D. Disease Reporting (ORS 431–434, ORS 437 & OAR 333-018-000)**

1. Each Health Care Provider knowing of or attending a case or suspected case of any of the diseases, infections or conditions listed in OAR 333-018-0015 shall report such cases as specified.
2. Where no Health Care Provider is in attendance, any individual knowing of such a case shall report in a similar manner.

## **E. HIV Testing (ORS 433.045-075 & OAR 333-018-0030)**

### **1. Informed Consent**

- i. Generally, informed consent must be obtained from an individual before performing an HIV test.
- ii. Pregnant women are to be tested for HIV and permission for the blood test must be obtained (ORS 433.017).

### **2. Testing Without Consent**

- i. There are several situations in which a person can be tested without his or her consent.
    - ii. A court order is usually necessary.
  - 3. Special Consent Issues (OAR 413-040-0420)
    - i. A minor under 15 may consent to an HIV test, including a minor in the custody of the Oregon Department of Human Services or the Oregon Youth Authority.
    - ii. Under the direction of a physician an infant may be HIV tested if the mother was known to have engaged in high risk behavior.
    - iii. DHS may arrange for HIV testing of a minor in its custody if the minor has been the victim of sexual abuse and the child is too young to give informed consent.
    - iv. A health care representative who has the authority to consent to medical care under ORS 127.505 to 127.660 or OAR 309-041-1500 to 309-041-1610 may consent to an HIV test on behalf of the disabled person, but only if medically necessary for care or treatment.
- F. Inmates Rights (ORS 421.085 & OAR 291-035-0005 through 291-035-0015 & 291-124-0080)
  - 1. Experimentation on inmates is prohibited.
  - 2. For more information see policy: *Biomedical or Behavioral Research Conducted with Prisoners*.
- G. Genetic Privacy Rights (ORS 192.531 through 192-549 & OAR 333-025-0100 through 333-025-0165)
  - 1. Beginning July 1, 2006, health care providers who are “covered entities” must notify their patients that any specimens or health information collected will be available for anonymous or coded genetic research unless the person “opts out” by completing an opt-out form notifying the health care provider that she/he does not want her/his specimen or information available for coded or anonymous genetic research.
  - 2. If an individual does not “opt out,” her/his specimen or information can only be used for anonymous or coded genetic research if the OHSU IRB approves the research study.
  - 3. For more information see: *The Genetic Research Page*  
<http://www.ohsu.edu/xd/research/about/integrity/irb/genetic.cfm#qualify>
- H. Oregon Policy for Protected Health Information (ORS 192.518 through 192.529)
  - 1. It is the policy of the State of Oregon that an individual has the right to have protected health information of the individual safeguarded from unlawful use or disclosure and the right to access and review protected health information of the individual.
  - 2. Authorization by an individual or the individual’s personal representative is required for a health care provider or state health plan to use or disclose protected health information of the individual.
  - 3. For more information see: *ORIO Policy for Collection and Use of Human Biologic Material in Research*.

### **III. Authority**

Association for the Accreditation of Human Research Protection Programs, Inc (AAHRPP) Tip Sheet. <http://aahrpp.org/Documents/D000145.PDF>. AAHRPP Related Accreditation Elements: I.3.F

Oregon Revised Statutes (ORS) 433.017 Test of blood of pregnant woman required; patient consent; rules.

ORS 433.045 through 433.075 HIV and Hepatitis Testing

Oregon State Bar Association <http://www.osbar.org>

Oregon Department of Human Services <http://www.oregon.gov/DHS>

Oregon Administrative Rules (OAR) 333-018-0000 through OAR 333-018-0035 Department of Human Services, Public Health: Disease Reporting

ORS 124.050 through ORS 124.075 Reporting of Abuse of Elderly Persons  
Oregon Department of Human Services: Fact Sheet for Researchers and Institutional Review Boards Legislative Changes in Oregon's Genetic Privacy Law. [www.oregongenetics.org](http://www.oregongenetics.org)

ORS 336.187 When School authorized to disclose information about student; immunity of recipient.

Chapter 9: The Oregon and Washington Experiments  
[http://hss.energy.gov/healthsafety/ohre/roadmap/achre/chap9\\_2.html](http://hss.energy.gov/healthsafety/ohre/roadmap/achre/chap9_2.html)

ORS 109.050 Relation of adopted child to adoptive parents.

ORS 109.510-ORS 109.690 Age of Majority

ORS 419B.550 through ORS 419B.558 Juvenile Code: Dependency

ORS 192.496 medical records; sealed records; records of individual in custody or under supervision; student records.

ORS 192.515 through ORS 192.459 Records of Individual with Disability or Mental Illness

ORS 421.085 Experimentation on inmates prohibited; inmate's right to judicial restraint of violation; action for damages.

Oregon Administrative Rules: Department of Corrections Research Proposals 291-035-0005 through 291-035-015

Oregon Administrative Rules: Department of Corrections Health Services 291-124-0080  
Oregon Revised Statute 421.085 Experimentation on inmates prohibited; inmate's rights to judicial restraint of violation; action for damages.

Department of Human Services, *HIV Rules & Statutes: A Guide for Oregon HIV Service Providers and Advocates* (Updated September 2010)