

Chapter 7:

Investigational

Therapies and

Research Oversight

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Biography

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David Forster has a Juris Doctor degree from the University of Washington School of Law and a Masters degree in medical ethics under Albert Jonsen from the University of Washington Department of Medical History and Ethics. David has broad experience with both academic and independent IRBs. From 1994 until 1996, he was a member of the University of Washington behavioral IRB and also served as a legal intern at the Fred Hutchinson Cancer Research Center investigating subject property rights in tissues as well as ethical issues concerning DNA data banks. After graduation in 1996, David joined WIRB and is currently the Office of Compliance Vice President.

David has extensive background regarding the issues faced by independent IRBs. For example, he has experience with integrating independent IRBs with institutional IRBs, including large academic medical centers and small hospitals. David also has been involved in international IRB capacity building and training. He provides intensive training regarding regulations and ethics for the WIRB International Fellows Program and serves as one of the primary faculty. He has also provided training for IRB members, investigators, and regulators in Costa Rica, Mexico, Venezuela, Brazil, Thailand, and China.

David serves as auxiliary faculty at the University of Washington Department of Medical History and Ethics and was a Co-PI on a three-year NIH grant for teaching research ethics.

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Chapter 7 Investigational Therapies and Research Oversight
(prepared from reference materials available as of April 2, 2007)

Chapter Outline

7.1 Chapter Summary 7-2
7.2 History 7-2
7.3 Federal Regulatory System 7-4
 7.3.1 The HHS Regulations/The Common Rule
 7.3.1.1 Oversight by the Office of Human Research Protections (OHRP)
 7.3.1.2 The HHS Assurance System
 7.3.2 The U.S. Food and Drug Administration (FDA) Regulations
 7.3.3 Emergency and Treatment Use with Investigational Products
 7.3.3.1 Emergency Use
 7.3.3.2 Treatment Use
 7.3.3.3 Off-Label Use
7.4 Washington State Law..... 7-8
7.5 Legal Liability in the Conduct of Research 7-8
**7.6 Accreditation of Human Subject Protection Systems and Institutional Review Board (IRB)
Professional Certification..... 7-9**

Volume 2: Regulation of Healthcare Practitioners and Entities

7.1 Chapter Summary

The protection of human subjects in research draws regular attention from federal oversight agencies, Congress, the media, and plaintiffs' attorneys. Such attention creates increasing responsibilities and concerns for research investigators, institutional review boards, health care institutions, and legal counsel. The purpose of the following material is to provide legal counsel responsible for the oversight of research activities with a historical, regulatory, and legal overview of the human subject protection system, and to highlight a common issue of concern, access to investigational products for patients. The human subject protection system incorporates many best practices, and while it is complex, this chapter will provide a starting point for legal counsel.

7.2 History

From the time of Hippocrates in ancient Greece, for as long as there has been a recognized medical profession, physicians have been involved in research. And, for as long as there has been research, there have been cases of research abuse.¹ Traditionally, the protection of human subjects and research ethics was the responsibility of the physician, with no external oversight or subject participation through informed consent. This began to change approximately 50 years ago, partly in response to the Nazi physician atrocities during World War II. In the war crimes trials at Nuremberg after World War II, one trial was dedicated to prosecuting Nazi physicians for crimes against humanity based on the extensive research abuses of Holocaust prisoners. Often the intentional endpoint of these studies was the death of the subject. During the trial, two American physicians drafted the Nuremberg Code (1949), one of the first documents to present a code of research ethics.

Problems with research and drug development continued to elicit concern during the post-war era. In the late 1950s and early 1960s in Europe, a new drug, Thalidomide, caused many cases of a birth defect called phocomelia.² There were very few such cases in the United States because the United States Food and Drug Administration (FDA) had not yet granted approval of the drug. Due in large part to the Thalidomide experience, new FDA regulations concerning drug oversight were implemented in 1962 through the Kefauver-Harris Act. The regulations contained a requirement for informed consent, but it was vaguely stated and often ignored with little consequence.³

Several cases of research abuse and a number of troubling research practices led to Congress passing the 1974 National Research Act. Most prominent among these cases was the U.S. Public Health Service's (PHS) Syphilis Experiment (the "Tuskegee Study"). From 1932 to 1973, the federal government observed poor, uneducated black men in rural Alabama with untreated, late-stage syphilis. In some cases, government researchers would continue to observe the syphilitic men until they died of their condition, even when effective treatment was available.⁴ Another case of research abuse was the Jewish Chronic Disease Hospital Study in 1963, in which the research physicians injected live cancer cells into patients who did not have cancer in order to determine whether the injected cells would cause cancer. This study was troubling because the patients had given limited or no consent to participate in the study.⁵ In the Willowbrook State School Study, hepatitis was given to mentally disabled, institutionalized

¹ See JAY KATZ, *EXPERIMENTATION WITH HUMAN BEINGS* 284-92 (New York: Russell Sage Foundation 1972); see generally SUSAN LEDERER, *SUBJECTED TO SCIENCE: HUMAN EXPERIMENTATION IN AMERICA BEFORE THE SECOND WORLD WAR* (Johns Hopkins University Press 1997) (1995).

² See KATZ, *supra* note, at 184, 919-21; RUTH R. FADEN, ET AL., *A HISTORY AND THEORY OF INFORMED CONSENT* 203 (Oxford University Press 1986); Advisory Committee on Human Radiation Experiments, *Final Report of the Advisory Committee on Human Radiation Experiments* 97, 98-99 (1995); CYNTHIA MAGUIRE DUNN & GARY L. CHADWICK, *PROTECTING STUDY VOLUNTEERS IN RESEARCH* 19-20 (Sara Gambrill ed., Thomas Centerwatch, 3rd Ed. 2004).

³ See William J. Curran, *The Approach of Two Federal Agencies*, in *EXPERIMENTATION WITH HUMAN SUBJECTS* 402, 412-19 (Paul A. Freund ed., George Braziller 1970).

⁴ See JAMES H. JONES, *BAD BLOOD* 7-9 (Free Press 1993) (1981).

⁵ See *Hyman v. Jewish Chronic Disease Hosp.*, 251 N.Y.S.2d 818, 820 (N.Y. App. Div. 1964), *order reversed by* 206 N.E.2d 338, (N.Y. 1965); KATZ, *supra* note, at 54-9.

Chapter 7 Investigational Therapies and Research Oversight

(prepared from reference materials available as of April 2, 2007)

children.⁶ Finally, in the San Antonio Contraceptive Study, impoverished Mexican-American women were placed on a placebo instead of active birth control without their knowledge for at least half of their participation in the study.⁷

In addition to specific studies, general research practices were also subject to controversy. For example, most Phase I and Phase II drug testing was done in prisons, often under less than optimal conditions for voluntary participation.⁸ There was also great debate regarding research using fetal tissue, particularly from aborted fetuses.

Not all cases of research abuse were medical in nature. For example, the Stanley Milgram *Obedience to Authority* studies were behavioral research studies. While the research ostensibly was designed to determine if electrical shock would increase memory, the real purpose of the study was to see how much pain and injury a “good citizen” would administer to another human if told to do so by an authority figure. Many of the subjects suffered emotional distress because they believed they had inflicted pain and harm on other subjects by administering electrical shock.

In response to these cases involving research abuse, several documents were implemented which established standards for research ethics. As mentioned above, the first was the Nuremberg Code, released in 1949 as part of the Nazi doctors’ trial. Although important to the intellectual development of research ethics, the Nuremberg Code had little effect on the conduct of research at the time of its release. Physicians in the rest of the world felt that the Nazis were barbarians, and, therefore, the code was irrelevant to their presumably civilized research.

In 1964, The World Medical Association (WMA) released the Declaration of Helsinki with the goal of providing a more relevant and universally accepted and applied statement of research ethics. The WMA felt that the Nuremberg Code reflected research done in a wartime setting on prisoners, and as such was not applicable to research in more traditional medical environments. The Declaration of Helsinki therefore specifically addresses research conducted by physicians using patients. This document was revised in 1975, 1983, 1989, 1996, and 2000, with subsequent footnotes in 2002 and 2004.

While the rest of the world largely considers the Declaration of Helsinki as the touchstone for medical research ethics, the Belmont Report, published in 1979, is the most important document for identifying research principles in the United States. This report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and provides the ethical framework for the current FDA and Health and Human Services (HHS) regulations on human subject protection. It identifies *Respect for Persons*, *Beneficence*, and *Justice* as the three ethical principles applicable to the review of research. The Belmont Report, together with several reports previously issued by the Commission, served as the basis for an extensive overhaul of the existing FDA and HHS (then Health, Education, and Welfare (HEW)) regulations in 1981.

From 1981 until 1996, the human subject protection issues were considered largely resolved. Investigators performed research and Institutional Review Boards provided ethics review with little or no outside attention from parties such as the media and Congress. In 1996, however, the General Accounting Office released a report entitled “Scientific Research: Continued Vigilance Critical to Protecting Human Subjects,” which sparked a renewal of interest by the media and Congress.⁹ Attention increased when the HHS Office of the Inspector General (OIG) released a 1998 report entitled “Institutional Review Boards: A Time for Reform,” claiming that “IRBs review too much, too quickly, with too little expertise.”¹⁰ Consequently, Congress put pressure on the FDA and the (then-

⁶ See KATZ, *supra* note, at 1007-10.

⁷ See *Id.* at 791-92; Robert M. Veatch, ‘*Experimental Pregnancy*’, HASTINGS CENTER REP., June 1971, at 2-3.

⁸ See ALLEN M. HORNBLUM, ACRES OF SKIN 75-115 (Routledge, 1998).

⁹ U.S. GEN. ACCOUNTING OFFICE, SCIENTIFIC RESEARCH: CONTINUED VIGILANCE CRITICAL TO PROTECTING HUMAN SUBJECTS, GAO/HEHS-96-72, (Mar. 1996) available at <http://www.gao.gov/archive/1996/he96072.pdf>.

¹⁰ DEP’T OF HEALTH & HUMAN RESOURCES, OFFICE OF INSPECTOR GEN., INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM, OEI-01-97-00193, (June 1998), available at <http://www.oig.hhs.gov/oei/reports/oei-01-97-00193.pdf>.

Volume 1: Patient Care Information, Treatment, and Rights

named) Office for Protection from Research Risk (OPRR) to address this issue. The agencies, in response, “shut down” research at several prominent academic institutions based on IRB compliance issues. These institutions included Rush Presbyterian in Chicago, Duke University, the University of Colorado, Virginia Commonwealth University, and Johns Hopkins University. This increased attention was also prompted by well-publicized deaths of several research subjects and an increase in litigation involving negligence in research.¹¹

While institutions have provided increased funding to human subject protection systems, and IRB accreditation and IRB professional certification programs have been implemented, there continues to be Congressional and media concern regarding the protection of human subjects in research.

7.3 Federal Regulatory System

The federal human subject protection system is administered by two sets of regulations: the Health and Human Services (HHS) regulations (45 CFR Part 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 and 56).

7.3.1 The Health and Human Services (HHS) Regulations/The Common Rule

The HHS regulations are composed of four subparts:

- Subpart A—Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)
- Subpart B—Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization
- Subpart C—Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research

Subpart A of the DHHS regulations constitutes the “Common Rule” for the protection of human subjects (56 FR 28003 (1991)) and has been adopted by 17 agencies. The Common Rule is also codified as a federal regulation at:

7 CFR Part 1c	Department of Agriculture
10 CFR Part 745	Department of Energy
14 CFR Part 1230	National Aeronautics and Space Administration
15 CFR Part 27	Department of Commerce
16 CFR Part 1028	Consumer Product Safety Commission
22 CFR Part 225	International Development Cooperation Agency, Agency for International Development
24 CFR Part 60	Department of Housing and Urban Development
28 CFR Part 46	Department of Justice
32 CFR Part 219	Department of Defense
34 CFR Part 97	Department of Education
38 CFR Part 16	Department of Veterans Affairs
40 CFR Part 26	Environmental Protection Agency
45 CFR Part 690	National Science Foundation

¹¹ CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 496-99 (LexisNexis 2005).

Chapter 7 Investigational Therapies and Research Oversight

(prepared from reference materials available as of April 2, 2007)

49 CFR Part 11

Department of Transportation

The agencies that have codified the human subject protection regulations have generally adopted Subpart A, but not Subparts B through D. In addition, a few of the agencies, such as the Department of Education, made modifications to Subpart A, the Common Rule. It is therefore prudent to check the applicable version of the Common Rule, if research is being conducted or funded by one of these other agencies.

7.3.1.1 Oversight by the Office for Human Research Protections (OHRP)

For those agencies that are part of the Department of Health and Human Services, compliance with the HHS regulations and the Common Rule is enforced by the Office for Human Research Protections (OHRP), located in the office of the Secretary of HHS. OHRP was formerly known as the Office for Protection from Research Risks (OPRR), and was located in the National Institutes of Health (NIH). OHRP moved to the office of the Secretary in June 2000. Much of the guidance from OHRP still lists OPRR in the title or elsewhere. In addition to having jurisdiction over all research funded through HHS, OHRP has jurisdiction over research not funded by HHS when such research is conducted at institutions that have agreed, through an “assurance,” to apply the standards of 45 CFR Part 46 to all research.

7.3.1.2 The HHS Assurance System

The OHRP assurance system is based on 45 CFR 46.103, and requires that any institution receiving HHS funding to conduct research must provide a formal assurance to OHRP that it will establish a human subject protection system. The term “institution” encompasses any legal entity that receives HHS funding. The assurance system was completely revised in 2000, with emphasis on the use of a Federalwide Assurance (FWA) as the predominant type of assurance.¹² An institution must have an assurance on record with OHRP if it is receiving federal funds to conduct human subjects research, or if it is otherwise engaged in the conduct of such research.¹³ A template FWA form is available online at the OHRP website.

When an institution enters into an FWA, it must decide whether the FWA applies only to HHS funded research, or whether it will apply to all research conducted at the institution. The institution must also appoint an Institutional Official (IO) who is responsible to OHRP for compliance with the terms of the FWA. In addition, the institution must list all IRBs that it intends to rely upon for the review of research on its FWA. Any IRB listed on the FWA must be registered with OHRP.¹⁴ OHRP provides a public listing of all institutions holding a current FWA, and a separate listing of all IRBs registered with OHRP.

OHRP has an excellent website that provides access to the HHS regulations, as well as guidance and information on the assurance system (<http://www.hhs.gov/ohrp>). A particularly useful page provides access to compliance letters and a compilation of common compliance findings (<http://www.hhs.gov/ohrp/compliance>).

7.3.2 The US Food and Drug Administration (FDA) Regulations

The FDA regulations on human subject protection are located at 21 CFR Parts 50 and 56. Part 50 addresses informed consent, and also includes subpart D, “Additional Safeguards for Children In Clinical Investigations.” This subpart is nearly identical to HHS 45 CFR 46 subpart D, “Additional Protections for Children Involved as Subjects in Research.” 21 CFR Part 56 addresses Institutional Review Boards. Even though the FDA is part of HHS, the FDA oversees compliance with its human subject protection regulations, in large part because of the

¹² See Office for Human Research Protections, *Assurances*, http://www.hhs.gov/ohrp/assurances/assurances_index.html (last visited July 31, 2008).

¹³ See Office for Human Research Protections, *Frequently Asked Questions, Question 4*, <http://www.hhs.gov/ohrp/FWAfaq.html#q4> (providing guidance on the definition of “engaged in research”).

¹⁴ See the Office for Human Research Protections website for guidance on registering an IRB at <http://www.hhs.gov/ohrp/assurances/index.html>.

Volume 1: Patient Care Information, Treatment, and Rights

differences between the FDA regulations and the HHS/Common Rule regulations. The FDA has jurisdiction over research involving products (primarily drugs, biologics, and devices) that it must approve prior to marketing. Normally, this research is privately funded by companies seeking to patent innovative products, but FDA regulated research can be federally funded as well. In combination, Parts 50 and 56 are largely equivalent to the Common Rule; approximately 60% of the language in the HHS and FDA regulations is identical. However, there are significant differences between the two sets of regulations, and any IRB or institution involved in the conduct of research under the jurisdiction of the two agencies (FDA and HHS) should be familiar with the differences between the two sets of regulations. Compliance with one set of the regulations does not guarantee compliance with the other. For example, the FDA regulations do not include the requirement for an assurance between the agency and the institution conducting the research.

The FDA has an abundance of important content on its website, but unfortunately, it is often difficult to perform searches and locate information. As a starting point for finding information related to IRBs and human subject protection, the most relevant page is located at <http://www.fda.gov/oc/gcp/default.htm>. This page addresses issues concerning "Good Clinical Practice," and provides links to the relevant FDA regulations on this topic, guidance, enforcement information, and contacts for reporting non-compliance.

There are several additional FDA regulations that affect the conduct of research at an institution. These include: 21 CFR Part 54, "Financial Disclosure by Clinical Investigators;" Part 312, "Investigational New Drug Application;" Part 812, "Investigational Device Exemptions;" and Part 814, "Premarket Approval of Medical Devices."

7.3.3 Emergency and Treatment Use with Investigational Products ("Compassionate Use")

One of the most difficult situations for health care counsel occurs when a physician requests help obtaining immediate access to an investigational product for the treatment of a patient. This is often referred to as "compassionate use." However, while it is a common term of art, there are no regulations that reference this term. Access to investigational products under FDA regulations falls under either "emergency use" or "treatment use."

7.3.3.1 Emergency Use

There are several FDA regulations that address emergency use. First, 21 CFR 56.102(d) states: "Emergency use means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval." Second, 21 CFR 56.104(c) provides for the following exemption from IRB requirements: "Emergency use of a test article, provided that such emergency is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review." Finally, if the subject is unable to consent, 21 CFR 50.23 provides for an exception from general requirements for informed consent.

(a) The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

(1) The human subject is confronted by a life-threatening situation necessitating the use of the test article. [FDA has provided guidance on the definition of "life-threatening."¹⁵]

¹⁵ "Life-threatening" under 21 CFR 56.102(d), includes the scope of both life-threatening and severely debilitating. U.S. Food & Drug Admin., *Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators 1998 Update*, <http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency>.

"Life-threatening" means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes,

Chapter 7 Investigational Therapies and Research Oversight

(prepared from reference materials available as of April 2, 2007)

(2) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.

(3) Time is not sufficient to obtain consent from the subject's legal representative.

(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

(b) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (a) of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

(c) The documentation required in paragraph (a) or (b) of this section shall be submitted to the IRB within 5 working days after the use of the test article.

When deciding whether emergency use is appropriate, a careful review of the above-referenced criteria is important in order to ensure that each of the conditions is met. The emergency use regulation generally is used in a situation where the investigational product is available at the site. However, sometimes it is feasible to have the product shipped to the site by the sponsor or another site. Whenever contemplating emergency use, the FDA should be contacted to see if it is possible to obtain an emergency Investigational New Drug (IND) Exemption for drugs and biologics or an emergency Investigational Device Exemption (IDE) for devices. Contact information for these purposes is available online in the FDA Information Sheets at the following website locations:

- <http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency>
- <http://www.fda.gov/oc/ohrt/irbs/devices.html#emergency>

7.3.3.2 Treatment Use

If the conditions for emergency use cannot be established, it is often feasible to obtain the product through a treatment IND for investigational drugs and biologics or a treatment IDE for investigational devices. The treatment IND [21 CFR 312.34 and 312.35] and treatment IDE [21 CFR 812.36] are mechanisms for providing eligible subjects with investigational products for the treatment of serious and life-threatening illnesses, for which there are no satisfactory alternative treatments. Treatment INDs and IDEs may be for individual patients¹⁶ or for large populations. INDs or IDEs may be initiated by the sponsor, by investigators, or by other parties, if the sponsor is willing to provide the product.

7.3.3.3 Off-Label Use

If a product has been approved for any indication, then an investigator may use that product for off-label uses without involving the FDA. The only limitations may be standard of care and malpractice law.

where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible. "Severely debilitating" means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke. *Id.*

¹⁶ See *Physician Request for a Single Patient Investigational New Drug for Compassionate or Emergency Use*, <http://www.fda.gov/cder/cancer/singleIND.htm> (last visited July 31, 2008).

Volume 1: Patient Care Information, Treatment, and Rights

7.4 Washington State Law

Most states have laws related to research and/or food and drugs. Despite these state laws, both the FDA and the Common Rule specifically state that no other regulations, or federal, state, or local laws, supersede the FDA and the Common Rule. In Washington, for example, there are no state laws that go much beyond the requirements set forth in the federal regulations except for some specific laws pertaining to investigational drug storage requirements for hospitals and other special situations. Washington state laws addressing research include:

- RCW Chapter 69.51, “Controlled Substances Therapeutic Research Act”;
- RCW Section 70.54.250, “Cancer registry program — Confidentiality”;
- WAC Section 246-873-100, “Investigational drugs”;
- WAC Chapter 388-04, “Protection of Human Research Subjects,” (policy of the Washington Department of Health for research);
- WAC Section 246-320-245, “Patient rights and organizational ethics,” (part of hospital licensing requirements); and
- WAC Section 284-44-043, “Experimental and investigational prescriptions, treatments, procedures, or services—Definition required—Standard for definition—Written notice of denial required—Appeal process required,” (insurance requirements).

7.5 Legal Liability in the Conduct of Research

There are a number of cases involving clinical research. While these types of cases were traditionally uncommon, there have recently been several high profile lawsuits involving research. Some of the older cases are mostly in the area of physician medical malpractice and only tangentially referenced clinical research. For example, in *Brown v. Hughes*, 94 Colo. 295, 30 P.2d 259 (1934), the Court appeared somewhat hostile to the concept of clinical research, and in *Fortner v. Koch*, 272 Mich. 273, 261 N.W. 762 (1935), the court referred to clinical research as a necessary endeavor. Beginning in the late 1970s, however, there were a growing number of research-specific cases. A summary of some of the key cases is set forth below:

Mink v. University of Chicago (1978) — This case concerned the failure of the investigator, institution, and sponsor to re-contact women who were unknowingly involved in a research study involving diethylstilbestrol (DES).¹⁷

Fante and the Upjohn Company v. Department of Health and Human Service (1980) — In this case, prisoners sued for access to clinical research in response to the new HHS regulations regarding research involving prisoners. In response, the FDA declined to adopt the prisoner regulations currently found at 45 CFR 46, Subpart C, although the regulations were printed with a stayed notice in the FDA regulations for nearly twenty years (see 21 CFR 50, Subpart C).¹⁸

United States v. Stanley (1987) — The U.S. Supreme Court considered the case of an army serviceman who was given LSD by the army without his knowledge or informed consent. The case mostly considered whether the serviceman could sue under the Federal Tort Claims Act.¹⁹

Tracy v. Merrell Dow Pharmaceuticals (1991) — The Ohio Supreme Court found that the learned intermediary doctrine applies even in the context of an investigational drug trial.²⁰

University of Minnesota IRB Case (1994) — This case involved a researcher who sued the University of Minnesota IRB because the Board suspended his research study. The Court held that the IRB acted appropriately when it suspended the study.²¹

¹⁷ *Mink v. University of Chicago*, 460 F. Supp. 713 (1978).

¹⁸ *Fante and the Upjohn Company v. Department of Health and Human Services*, Civil Action No. 80-72778, U.S. District Court, E.D. Mich. (1980).

¹⁹ See *United States v. Stanley*, 483 U.S. 669 (1987).

²⁰ See *Tracy v. Merrell Dow Pharmaceuticals*, 58 Ohio St. 3d 147 (1991).

Chapter 7 Investigational Therapies and Research Oversight

(prepared from reference materials available as of April 2, 2007)

Dahl v. Hem Pharmaceuticals Corp. (1993) — A Ninth Circuit case held that a consent form was a contract based on reliance due to the subject's lengthy participation in the trial. In that case, the plaintiff wanted to continue to receive the study drug even though the sponsor had decided to end the study.²²

In recent years there have been several high profile lawsuits involving research, brought mainly by New Jersey attorney, Alan Milstein. While many of these cases have settled, to date IRBs have not been found to be negligent in the performance of their duties. Institutions and investigators have also generally fared well in court. For example, in *Robertson v. McGee*, an Oklahoma case, the plaintiffs sued the principal investigator, the hospital, the sponsor, members of the IRB, and a bioethicist who served as a consultant to the IRB. The Court dismissed the case because it did not have jurisdiction over the allegations raised in the Complaint. Locally, the Fred Hutchinson Cancer Research Center was largely successful in defending itself in a suit brought by Alan Milstein,²³ and Oregon Health Sciences University settled in another such case.²⁴ The complaints and other documents from these cases are located at Sherman, Silverstein, Kohl, Rose & Podolsky, P.A.'s website, <http://www.sskrplaw.com/gene/index.html>.

7.6 Accreditation of Human Subject Protection Systems and Institutional Review Board (IRB) Professional Certification

Two welcome responses to the recent media and Congressional attention and plaintiffs' lawsuits have been the establishment of a human subject protection system accrediting organization and a certification program for IRB professionals. The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)²⁵ and the Partnership for Human Research Protection, Inc (PHRP) both established human subject protection accreditation.²⁶ However, the latter of these announced that it would cease its activities in November of 2005, leaving only AAHRPP in this role. Accreditation is voluntary at this point, but is gaining popularity. As of January 2006, the two organizations have accredited forty-two organizations.

The Certified IRB Professional (CIP) examination, founded in 2000, provides an objective standard for showing knowledge of human subject protection issues.²⁷ Recertification is required every three years and continuing education can only be used to satisfy this requirement once every six years.

²¹ See Dale E. Hammerschmidt, "There is No Substantive Due Process Right to Conduct Human-Subject Research": *The Saga of the Minnesota Gamma Hydroxybutyrate Study*, 19 IRB ETHICS AND HUMAN RESEARCH 13, (1997).

²² *Dahl v. Hem Pharmaceuticals Corp.*, 7 F.3d 1399 (9th Cir. 1993).

²³ Duff Wilson, *2 More Families File Suit Against, Hutch, 3 Doctors*, SEATTLE TIMES, Nov. 1, 2003, available at <http://community.seattletimes.nwsources.com/archive/?date=20031101&slug=hutch01m0>; see *Wright v. Fred Hutchinson Cancer Research Center*, 2002 WL 32125919, (W.D. Wash. 2002) (No. C01-5217L) (unpublished) (remanding the case to state court); *Wright v. Fred Hutchinson Cancer Research Center* (Superior Ct. of Wash. 2003) (No. 03-2-16586-7).

²⁴ *Beth Wade v. Oregon Health and Science University* (D. Or. 2003) (No. 02-CV-877-KI).

²⁵ Association for the Accreditation of Human Research Protection Programs, <http://www.aahrpp.org/www.aspx> (last visited July 31, 2008).

²⁶ Partnership for Human Research Protection, Inc., <http://www.phrp.org> (indicating the partnership dissolved effective Nov. 15, 2005 but that all previous accreditations awarded are in effect and valid (last visited July 31, 2008).

²⁷ Public Responsibility in Medicine and Research, <http://www.primr.org/certification/certification.html> (last visited July 31, 2008).