

Educational Material—Biomedical IRB Committee (by IRB meeting date)

January 9, 2008

- OHRP. Tips on Informed Consent. Revised 3/16/93.
<http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm> (accessed 1/2/08)
- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 1-2.
<http://www.hhs.gov/ohrp/informconsfaq.html#q1> (accessed 1/2/08)

January 23, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 3-4.
<http://www.hhs.gov/ohrp/informconsfaq.html#q3> (accessed 1/14/08)

February 13, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 5-6.
<http://www.hhs.gov/ohrp/informconsfaq.html#q5> (accessed 2/4/08)
- ECU Social Security Number and PII Policy. <http://www.ecu.edu/cs-itcs/policies/ssnpolicy.cfm> (accessed 2/4/08)

February 27, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 7-8.
<http://www.hhs.gov/ohrp/informconsfaq.html#q7> (access 2/19/08)

March 12, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 9-12.
<http://www.hhs.gov/ohrp/informconsfaq.html#q9> (access 3/3/08)

March 26, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 13-16.
<http://www.hhs.gov/ohrp/informconsfaq.html#q13> (access 3/18/08)

April 9, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 17-21.
<http://www.hhs.gov/ohrp/informconsfaq.html#q17> (accessed 3/31/08)
- OHRP. Guidance for [Repositories, Tissue Storage Activities, Data Banks \(11/97\)](#).
<http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm> (accessed 4/1/08)

April 23, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 22-25.
<http://www.hhs.gov/ohrp/informconsfaq.html#q22> (accessed 4/15/08)

May 14, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 26-30.
<http://www.hhs.gov/ohrp/informconsfaq.html#q26> (accessed 5/6/08)

May 28, 2008

- OHRP. OHRP Informed Consent Frequently Asked Questions: Questions 31-35.
<http://www.hhs.gov/ohrp/informconsfaq.html#q31> (accessed 5/19/08)

June 11, 2008

- OHRP, DHHS. Guidance on Continuing Review, January 15, 2007. <http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm>. Accessed June 2, 2008.

June 25, 2008

- USFDA/USDHHS. Comparison of FDA and HHS Human Subject Protection Regulations. <http://www.fda.gov/oc/gcp/comparison.html>. 2000. Accessed 6/13/08.

July 9, 2008

- OHRP/DHHS. Guidance on Certificates of Confidentiality. <http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm>. February 25, 2003. Accessed June 30, 2008.

July 23, 2008

- OHRP. IRB Guidebook. Special Classes of Subjects: Terminally Ill Patients. http://www.hhs.gov/ohrp/irb/irb_chapter6ii.htm#g8. Accessed 7/15/08.

August 13, 2008

- DHHS. OHRP. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>. Last updated 5/20/08. Accessed 7/31/08.

August 27, 2008

- OHRP: Institutional Review Board: Guide Book: [Risk/Benefit Analysis](http://www.hhs.gov/ohrp/irb/irb_chapter3.htm) http://www.hhs.gov/ohrp/irb/irb_chapter3.htm (accessed 8.19.08)

September 10, 2008

- USDHHS FDA CDRH CBER. Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers. <http://www.fda.gov/cdrh/ode/guidance/1668.pdf>. Document issued on August 5, 2008.

September 24, 2008

- OHRP. IRB Guidebook. Chapter VI: Special Classes of Subjects: Minorities. http://www.hhs.gov/ohrp/irb/irb_chapter6ii.htm#g10.

October 8, 2008

- OHRP. IRB Guidebook: Chapter 3, Basic IRB Review—Risk/Benefit Analysis. http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e1. Accessed September 29, 2008.

October 22, 2008

- Merz, Jon. IRB Forum: When a University Kills Suicide Research. <http://www.insidehighered.com/news/2008/07/07/suicide>. July 7, 2008. Date accessed 10/8/08.

November 12, 2008

- US DHHS FDA. Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Institutional Review Board Inspections. <http://www.fda.gov/oc/ohrt/irbs/reviewboard.pdf>. January 2006.

Last updated 05/18/2012

November 26, 2008

- Bankert E., Amdur R. *Institutional Review Board Management and Function, 2nd Edition*. Informing Subjects About Research Results. Sudbury, MA: Jones and Bartlett; 2006, p232-235.

December 12, 2008

- Review of UMCIRB policies:
 - Fees for IRB Review (Revisions date: 10/29/08)
 - Noncompliance in Human Research Activities (Revisions date: 10/1/08)
 - Defining and Reporting Protocol Deviation (Revisions date: 10/16/08)

January 14, 2009

- Office for Human Research Protections (OHRP). Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued. 11/7/08 (draft): <http://www.hhs.gov/ohrp/requests/200811guidance.html>
- Food and Drug Administration (FDA). Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials. 10/07 (Final) <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0576-gdl.pdf>

January 28, 2009

- OHRP, DHHS. Guidance on Written IRB Procedures. <http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm> January 15, 2007.

February 11, 2009

- Pollack, A, *FDA Approves a Stem Cell Trial*, The New York Times (dated 1.23.09) http://www.nytimes.com/2009/01/23/business/23stem.html?_r=1&hp

February 25, 2009

- DHHS, OHRP. Guidance on Engagement of Institutions in Human Subjects Research. <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>. October 16, 2008.

March 11, 2009

- OHRP. Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure. <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

March 25, 2009

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April 8, 2009

- Congressional Committee on Energy and Commerce. Opening Statements for March 26, 2009 Hearing: Institutional Review Boards that Oversee Experimental Human Testing for Profit. (Complete information: http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1552)

April 22, 2009

- Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS). Guidance on the Genetic Information Nondiscrimination Act:

- Implications for Investigators and Institutional Review Boards.
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- May 13, 2009
- Steinbrook, R., MD, *Controlling Conflict of interest—Proposal from the Institute of Medicine*, New England Journal of Medicine, April 29, 2009
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- May 27, 2009
- Menikoff J. "The Vulnerability of the Very Sick." *Journal of Law, Medicine & Ethics: Vulnerability in Biomedical Research*. Spring 2009.
- June 10, 2009
- OHRP, DHHS. OHRP Guidance on the Involvement of Prisoners in Research. May 23, 2003. <http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm>
- June 24, 2009
- USDHHS FDA CDRH CBER. Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers. Document issued on August 5, 2008.
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM110203.pdf>.
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<http://www.wma.net/e/policy/b3.htm>
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- September 23, 2009
- USDHHS, FDA. Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials. October, 2008.
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf>

November 18, 2009

- OHRP letter regarding site evaluation at ECU (dated 10/9/09)

November 25, 2009

- US DHHS, FDA. Guidance for Industry: Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects. October 2009. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

December 9, 2009

- OHRP, HHS. Guidance on IRB Approval of Research with Conditions http://www.hhs.gov/ohrp/requests/200911guidance_appr.pdf

December 30, 2009

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January 13, 2010

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January 27, 2010

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February 10, 2010

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- UMCIRB Reporting Form: Unanticipated Problems Involving Risks to Participants and Others. <http://www.ecu.edu/irb/docs/Unanticipated%20Problems%20Involving%20Risks%20to%20Participants%20or%20Others%201-22-10.doc>

February 24, 2010

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March 10, 2010

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March 24, 2010

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Last updated 05/18/2012

April 14, 2010

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April 28, 2010

- DeVille, K. "FDA Issues Guidance for Investigators in Clinical Trials." April 2010; Health Care Compliance Association, 8-11.

May 12, 2010

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May 26, 2010

- Harmon, A. (2010, April 23). Where'd You Go With My DNA?. *The New York Times*. <http://www.nytimes.com/2010/04/25/weekinreview/25harmon.html?pagewanted=2>

June 09, 2010

- Human Research Report, Volume 25, No. 4; Title: Continuing Reviews of Research by Institutional Review Boards (Summary) Published by the Deem Corporation, Omaha, NE.

June 23, 2010

- Unguru, Y., Sill, A. M., & Kamani, N.: "The Experiences of Children Enrolled in Pediatric Oncology Research: Implications for Assent", *PEDIATRICS*, April 2010; 125: e876 – e883

July 14, 2010

- US DHHS, Administration for Children & Families. Practical Strategies for Tracking and Locating Youth. http://www.acf.hhs.gov/programs/cb/laws_policies/practical/#. Printed 6/29/10.

July 28, 2010

- FDA Office of Health Affairs: Guidance for Institutional Review Boards and Clinical Investigators: Significant risk and non significant risk medical device studies. Pages 66-70; Printed on 7/20/10.

August 11, 2010

- Ramsey J, Vulcano D. FDA Warning Letters to IRBs: Who is Receiving Them and What Can Be Done to Prevent Them. *Monitor*, June 2010, 15-19.
- Presentation: Recognizing Conflict of Interest—Norma Epley. COI is more than financial COI or performing work on a study. Situations that cause a member to have bias is also a COI—participation in a discussion of the study would be acceptable but then the member would need to recuse for the vote. The IRB member needs to determine if they feel a bias for personal reasons.

August 25, 2010

- Bigby, Barbara G. Using the Belmont Principles to Create and Sustain a Healthy Relationship Between IRBs and Investigators. *Monitor*, August 2009, 41-44

September 8, 2010

- Human Research Report, July, 2010; Volume 25, No. 7; Title: Subjects with Diminished Decision-Making Capacity; Published by the Deem Corporation, Omaha, NE. (Hard copy provided in packets)

September 22, 2010

- Kolata, G. (2010, August 23). What to Tell the Patients After a Trial Goes Awry. *The New York Times*

October 13, 2010

- Office of Human research Protections (OHRP); Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues; dated 9/21/10.

October 27, 2010

- Bankert E., Amdur R. *Institutional Review Board Management and Function, 2nd Edition*. Research Involving Genetic Testing. Sudbury, MA: Jones and Bartlett; 2006, p465-468.

November 10, 2010

- Human Research Report, October, 2010; Volume 25, No.10; Title: Guidance for Institutional Review Boards (IRBs); Published by the Deem Corporation, Omaha, NE. (Hard copy provided in packets)

November 24, 2010

- NCI Cancer Bulletin, May 18, 2010, Volume 7 / Number 10, *Insurance Coverage Expanding for Cancer Clinical Trials*, <http://www.cancer.gov/ncicancerbulletin/051810/page5> (Hard copy provided in packets)

December 8, 2010

- IRB Ethics & Human Research, January/February 2010, pages 16-19; Title: “Motivated by Money? The Impact of Financial Incentive for the Research Team on Study Recruitment”; By Sharon Unger, Lesley Wylie, Shafagh Fallah, Lee Heinrich, and Karel O’Brien (Hard copy provided in packets).

December 29, 2010

- U.S. DHHS, FDA Draft Guidance, October 2010, *Guidance for Industry: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND* (hard copy included)
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf> -

January 12, 2011

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January 26, 2011

- McNeil, Donald G. “U.S. Apologizes for Syphilis Tests in Guatemala.” *The New York Times* October 1, 2010: 1-4
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Last updated 05/18/2012

February 9, 2011

- IRB Ethics & Human Research, January/February 2011, pages 15-17; Title: “Institutional Not-for-Cause Compliance Review Programs”; By Terry M. VandenBosch and Ronald F. Maio.

February 23, 2011

- UMCIRB Standard Operating Procedure 605 – Defining and Reporting Protocol Deviations – Revision 1.1

March 9, 2011

- Journal of Clinical Research Best Practices; August, 2010; Volume 6, No. 8; “Advice from a Biostatistician on an IRB” by David Drachman.
http://firstclinical.com/journal/2010/1008_Biostatistician.pdf

March 23, 2011

- UMCIRB Standard Operating Procedure 402 – Emergency Use of a Test Article – Revision 1

April 13, 2011

- Children’s Oncology Group (COG) Data Safety Monitoring & Data Collection Policy and Procedures
 - Policy 7.5.2 Data and Safety Monitoring Plan for the COG Phase I/II/Pilot Consortium Studies
 - Policy 7.5.3 Data and Safety Monitoring Plan for the COG Phase III Studies

April 27, 2011

- IRB Ethics & Human Research, March/April 2011, pages 14-19; Title: “Protecting Research Subjects: IRBs in a Changing Research Landscape”; By Ann Freeman Cook & Helena Hoas.

May 11, 2011

- Cook, Freeman & Hoas, Helena, “*Protecting Research Subjects: IRBs in a Changing Research Landscape*,” IRB Ethics & Human Research, March-April 2011

May 25, 2011

- FDA, 21CFR56.109 - IRB Review of Research
- FDA, 21CFR50.27 - Documentation of Informed Consent

June 8, 2011

- IRB Ethics & Human Research, May/June 2011, pages 1-5; Title: “Broad Data Sharing in Genetic Research: Views of Institutional Review Board Professionals”; By Amy A. Lemke, Maureen E. Smith, Wendy A. Wolf, Susan Brown Trinidad, and the GRRIP Consortium

June 22, 2011

- Glossary of Genetic Terms; National Human Genome Research Institute, NIH,
<http://www.genome.gov/Glossary/>

July 13, 2011

- ePIRATE IRB Committee Member Training 12:15 – 12:45 – Michelle Eble

Last updated 05/18/2012

July 27, 2011

- ePIRATE IRB Committee Member Training 12:00-1:00 PM- Michelle Eble

August 10, 2011

- The federal government is considering changes to the Common Rule (45CFR46). The U.S. DHHS has published an Advance Notice of Proposed Rulemaking (ANPRM) in the July 26, 2011 issue of the Federal Register. The ANPRM is entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators". You may access the ANPRM at: <http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm>.
- ANPRM Frequently Asked Questions (FAQs) July 2011
<http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>.
- Regulatory Changes in ANPRM: Comparison of Existing Rules with some of the Changes Being Considered.
<http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>.

August 24, 2011

- "Privacy Boards and the HIPAA Privacy Rule" - NIH Publication Number 03-5448 dated 9/2003
http://search2.google.cit.nih.gov/search?site=NIH_Master&client=NIHNEW_frontend&proxystylesheet=NIHNEW_frontend&output=xml_no_dtd&filter=0&getfields=*&q=Privacy+Boards+and+the+HIPAA+Privacy+Rule

September 14, 2011

- OHRP / DHHS - Guidance on Reporting Incidents to OHRP – dated 06/20/2011
<http://www.hhs.gov/ohrp/compliance/reports/incidreport062011.pdf>

September 28, 2011

- Advanced Notice of Proposed Rule Making for Revision to Common Rule -
<http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>

October 12, 2011

- Grady, Christine. "Vulnerability in Research: Individuals with Limited Financial And/or Social Resources." *The Journal of Law, Medicine & Ethics* 37.1 (2009): 19-27. Print

October 26, 2011

- Continuing Review under Expedited Procedures

November 9, 2011

- Feero, W. Gregory, Alan E. Guttmacher, and Kathy L. Hudson. "Genomics, Health Care, and Society." *New England Journal of Medicine* 365.11 (2011): 1033-041. Print

November 23, 2011

- Ohm, Paul. "Is Anonymization a Real Possibility?" *Protecting Human Subjects* (2011): 1, 14-15. *Human Subjects Research Database*. U.S. Department of Energy, 2011. Web. 23 Nov. 2011. <<http://hsrd.orau.gov>>.

December 14, 2011

- Neergaard, Lauran. "Cold Critical Care - Trying to save Trauma Patients via Deep Chill." *The Daily Reflector* [Greenville] 17 Nov. 2011, Look sec.: 6. Print

December 21, 2011

- Malmqvist, Erik. "(Mis)Understanding Exploitation." *IRB Ethics & Human Research* 33 (Mar.-Apr. 2011): 1-5. Print

January 11, 2012

- Bierer, Barbara E. "SACHRP Recommendations Relevant to DHHS Human Subjects Protection Regulations at 45CFR46." Letter to The Honorable Kathleen Sebelius. 13 Oct. 2011. MS

January 25, 2012

- Whicher, Danielle, Currie, Peter, and Taylor, Holly A. "Factors that Influence Institutional Review Board Members' Commitment to Their Role Responsibilities." *IRB Ethics & Human Research* (Sept.-Oct. 2009): 15-19. Print

February 8, 2012

- Bankert, Elizabeth A., Robert J. Amdur, and Robert J. Amdur. "Expedited Institutional Review Board Review." *Institutional Review Board: Management and Function*. 2nd ed. Sudbury, MA: Jones and Bartlett, 2006. 97-100. Print

February 22, 2012

- "Compensation Recommended for Human Subjects Injured in Research Projects." *Human Research Report* 26 (Feb. 2012): 1-2. Print.

March 14, 2012

- IRB Net. *National Research Network: 2011 Benchmark Report*. Rep. 2011. Print

March 28, 2012

- ePIRATE Refresher – S. Sparrow

April 11, 2012

- U. S. DHHS - FDA Guidance – *Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff – Humanitarian Device Exemption (HDE) Regulation: Questions and Answers* – dated 07/08/2010

April 25, 2012

- OHRP Guidance – *Guidance on IRB Approval of Research with Conditions* – dated 11/10/2010

May 9, 2012

- Reviewed of a proposed alternative to the use of the Spanish Short Form for currently approved studies being conducted by Dr. M. Grossi in Peds HemOnc

May 23, 2012

- 45CFR46.111 - Criteria for IRB approval of research, including minimizing risk, ensuring confidentiality, and protecting vulnerable populations - <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111>

***June, 2012: This list will no longer be populated as the minutes in electronic IRB system are always available which include information about the IRB member education provided at the IRB meetings.