Annotated Compendium of NIH Resources on Informed Consent

Prepared by the Clinical Research Policy Analysis and Coordination (CRpac) Program
Office of Biotechnology Activities
Office of Science Policy
Office of the Director
National Institutes of Health

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Fully informed consent is critical to the ethical conduct of clinical research. Although the consent document is only one component of the entire consent process, its content is defined in federal regulations and is a critical tool to help potential participants understand the risks and benefits of a research project. Over time, as research has increased in complexity, the informed consent document has become lengthy, complicated and sometimes difficult to understand. Documents are often written at reading levels considerably higher than that of the majority of the U.S. population. Further, there can be a large discrepancy between the information in the informed consent document and a participant's understanding.

Policy Underpinnings

The ethical guidelines related to informed consent are based on the following regulation and guidance:

- **45 CFR Part 46** - Protection of Human Subjects (The Code of Federal Regulations) http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr46_06.html
- **The Belmont Report** http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

An aim of the Clinical Research Policy Analysis and Coordination (CRpac) program is to develop informed consent resources that will be of assistance to investigators, IRBs, and prospective research participants. Toward that end, the CRpac program has compiled a list of informed consent resources available online from the National Institute of Health's Institutes and Centers (ICs). Among the resources are informed consent templates, frequently asked questions, guidance created by specific ICs, and other relevant materials. The topics addressed are diverse, and they include general guidance on the informed consent process, tools for the development of informed consent forms, and materials designed to navigate users through some notable challenges in informed consent, such as working with populations that may present special considerations relative to communication or decision-making capacity.

The resources can be browsed either by **Topic** or by **NIH Institute or Center**. In addition, a **Navigational Aid** is available at the end of the resources to help you browse and locate relevant documents.

RESOURCE BY TOPIC

GENERAL GUIDANCE

- A Guide to Understanding Informed Consent (NCI)
  http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide/allpages
  This guide for potential research participants describes the informed consent process, details the history and regulation of clinical trials, provides a "questions to ask" checklist, and suggests additional resources for gathering more information.

- NHLBI Guidelines for Consent Forms in Multicenter Clinical Studies (NHLBI)
  http://www.nhlbi.nih.gov/funding/policies/consent-forms.htm
  NHLBI guidelines mandate that multicenter studies funded by them develop consent form templates to be used across the study in order to harmonize the study protocols. This document explains the guidelines, as well as the permissible alterations to templates and the review process for consent document approval.

- Guidelines for Writing Informed Consent Documents (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet6.html
  This document provides guidance for NIH clinical researchers and IRBs on the procedures and requirements for informed consent including disclosure of relevant information to potential subjects, subjects' comprehension of that information, and their voluntary agreement to participate in the research. Suggestions are made for writing informed consent documents, including recommendations for formatting and content.

- Simplification of Informed Consent Documents (NCI)
  Includes "Informed Consent Template for Cancer Treatment Trials"
  http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/allpages
  This document presents the results of a working group (the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials) formed by the NCI, OHRP, and FDA in 1998. The group investigated the simplification of informed consent documents in response to concerns raised by research participants and investigators. The recommendations are intended to be useful for investigators who write consent forms and IRBs which review those forms. A template for informed consent documents is also included.

- Informed Consent (NHGRI)
  http://www.genome.gov/10002332
  This comprehensive webpage provides information on informed consent for genetic research. It contains links to informed consent resources including federal policies and legislation, as well as NIH reports.

- Requirements for Informed Consent Development (NIAID)
  http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/Protocol/InformConsent.pdf
  This document details the NIAID requirements for the development of informed consent documents for the Division of Acquired Immunodeficiency Syndrome (DAIDS) funded and/or sponsored human subjects clinical research.

- NIH Intramural Medical Executive Committee, Policy and Communications Bulletin, Medical Administrative Series: Informed Consent (CC) ***
  http://internal.cc.nih.gov/policies/PDF/M77-2.pdf
  This document details the revised policy and procedures of the Clinical Center for obtaining informed consent from individuals who come to the Clinical Center to participate in research. It includes sections on: general background, definitions, the process of informed consent, the written informed consent document, approval of the informed consent document, and the researcher's responsibilities. Specific procedures are outlined relating to oral informed consent, non-English speaking subjects, invasive surgical procedures, additional forms for specific procedures, postmortem examination, emergency procedures, and consent from someone not at the CC. The intended audience includes physicians, dentists, other practitioners, and IRB chairs.

Research on Ethical Issues in Human Studies

- Research on Ethical Issues in Human Studies (OER)
  http://grants.nih.gov/grants/policy/ethics_research.htm
  This webpage provides information about a particular NIH initiative, "Research on Ethical Issues in Human Studies," which has provided funding for research on ethical issues that arise with studies involving human participants since 1995. The funded research is intended to create an understanding of how best to protect human participants in research through the support of empirical findings. Principle investigators, their contact information, topics of study, and institutions are provided for the active and inactive awards.

TOOLS FOR CONSENT DOCUMENT DEVELOPMENT

Informed Consent Checklists

- Clinical Research Guide: How do I develop consent forms and who reviews them? (NHLBI)
  http://www.nhlbi.nih.gov/crg/funding_consent.php
  This short resource provides guidance on how to develop consent forms and provides relevant links.

- Requirements for Informed Consent Development (NIAID)
  http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/Protocol/InformConsent.pdf
  This document details the NIAID requirements for the development of informed consent documents for the Division of Acquired Immunodeficiency Syndrome (DAIDS) funded and/or sponsored human subjects clinical research. In the appendices the document links to an Informed Consent Checklist provided by the Office of Human Research Protections.

Sample Consent Templates

- Simplification of Informed Consent Documents (NCI)
  Includes "Informed Consent Template for Cancer Treatment Trials"
  http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/allpages
  The Comprehensive Working Group on Informed Consent in Cancer Clinical Trials prepared a template for informed consent documents in response to concerns raised by research participants and investigators. The template is a linked word document found on the working group's main page.

- DOE-NHGRI (National Human Genome Research Institute) Model Consent for Use of Tissue Samples for Human Genome Project Cell Lines (NHGRI)
  http://www.science.doe.gov/ober/humsubj/doenhgri.html
  This sample consent form from the Department of Energy (DOE) and NHGRI is offered as an example for investigators who are writing informed consent documents and IRBs. The consent template covers the following topics: what will be done with tissue samples, what they will be used for, and who will use them; benefits of allowing samples to be used to create DNA libraries; policy regarding releasing information about DNA to subjects; privacy protection policies; risks of allowing tissue samples to be used to create a cell line and a DNA library; payment policy; information about the development of commercial products; and options for withdrawing from participation.

- Clinical Investigation Consent Form (NIAMS)
  http://www.niams.nih.gov/Funding/Clinical_Research/invest_form.asp
  This sample patient consent form from NIAMS serves as an example for investigators who are writing informed consent documents and for IRBs. The categories included in this document are: purpose of the trial, number of participants, procedures, sample storage and use, treatment assignment, treatment visits, risks/discomforts, risks associated with standard medicines, risks associated with a specific drug, any other possible risks, benefits, alternatives to participation, right to refuse treatment or withdraw from the study, reasons to be removed from the study, costs or payments, confidentiality, questions, injuries, and joining of your own free will.

- Consent to Participate in a Clinical Research Study (NICHD)
  http://dir2.nichd.nih.gov/nichd/deb/segen/documents/00-CH-0160.1.Linkag.040824.7.23.05.pdf
  This sample parental consent form from NICHD serves as an example for investigators who are writing informed consent documents and for IRBs. The form outlines the voluntary nature of participation in the study, provides a brief background of the research, and describes possible risks and benefits. Pertinent information concerning confidentiality, the policy regarding research-related injuries, payment, the resolution of problems or questions, and the actual consent template is included.

- Model Informed Consent Form (NIDDK)
  http://www.niddk.nih.gov/fund/diabetesspecialfunds/T1DGC_Informed_Consent_Template.pdf
  This comprehensive model informed consent document has been developed and provided by NIDDK. Suggested but optional wording is indicated in brackets and instructions are italicized for easy user accessibility. The document details a study developed to identify genes linked to diabetes and includes a description of: the purpose of the study, consent to produce a cell line, ownership and the right to have genetic material destroyed, risks and discomforts, benefits, alternatives and one's right to withdraw, confidentiality, cost, compensation and treatment, questions, and the participant's statement/consent.

- Model Subject Consent (NIDA)
  http://www.drugabuse.gov/about/organization/Genetics/model_consent.pdf
  This Model Subject Consent from NIDA is a guideline intended to be tailored to individual studies. Topics outlined include: a description of the study, effects on participating individuals, possible risks/discomforts, an explanation of the research funding, compensation, and discontinuing participation. This example form depicts a genetics study, although it is designed to be widely applicable and adaptable.

Writing Tools

- Informed Consent Document Writing Tool (under development) (CC) ***
  http://sherpa.cc.nih.gov
  Consent Authoring Tool (C.A.T.) is an informed consent authoring application created by the Clinical Center at NIH. The purpose is to assist researchers in creating easy-to-read and well structured informed consent documents that take into account health literacy comprehension gaps between medical researchers and research subjects. The application is under development and is currently open to a limited set of users.

- Guidelines for Writing Research Protocols (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet5.html
  These guidelines provide the necessary information for Principal Investigators (PIs) to write a research protocol that meets the standards of an NIH IRB. The required content of a research protocol, in addition to required statements and headings, are listed in detail. Emphasis is placed on minimizing risks, equitable selection of participants, confidentiality, and privacy.

ASSENT

Assent Templates

- A Guide to Understanding Informed Consent (NCI)
  http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide/allpages
  This guide for potential research participants offers an assent form for ages 7-12. It can be found by following the link labeled "What To Expect."

Children's Assent

- Children's Assent to Clinical Trial Participation (NCI)
  http://www.cancer.gov/clinicaltrials/understanding/childrensassent0101/allpages
  This guide is aimed at parents considering enrolling their children in a clinical trial; it discusses the issues surrounding a child's agreement to participate in a clinical trial, including parental involvement in the process, legal responsibilities, and when assent of the child is and is not necessary. Links to further resources on the topic are included.

- Research Involving Children (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet10.html
  The "Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" issued by the NIH in 1998 mandates that all human subjects research that is supported or conducted by the NIH must include children, unless there are scientific and ethical reasons not to include them. Accordingly, this policy is outlined with topics including special considerations for the inclusion of children in research studies, permission and assent to participate, and the types of studies that involve children.

CONSIDERATIONS FOR CONSENT IN UNIQUE POPULATIONS

Hearing Impaired

- Working Group on Communicating Informed Consent to Individuals Who Are Deaf or Hard-of-Hearing, including: "Guidelines on Communicating Informed Consent for Individuals Who are Deaf or Hard-of-Hearing and Scientists" (NIDCD) ***
  http://www.nidcd.nih.gov/news/releases/99/inform/toc.asp
  These guidelines were produced by a Working Group on communicating informed consent to individuals who are deaf or hard of hearing. The issues addressed refer to the special circumstances surrounding research involving the hearing impaired, including the wide range in type and degree of hearing loss, and differences in factors such as etiology, age of onset, communication experience, communication preference, and language use. Specific recommendations regarding these issues are made.

Non-English Speaking Subjects

- NIH Intramural Medical Executive Committee, Policy and Communications Bulletin, Medical Administrative Series: Informed Consent (CC)
  http://internal.cc.nih.gov/policies/PDF/M77-2.pdf
  This document details the revised policy and procedures of the Clinical Center for obtaining informed consent from individuals who come to the Clinical Center to participate in research. Specific procedures are outlined relating to non-English speakers. The intended audience includes physicians, dentists, other practitioners, and IRB chairs.

Oral Consent

- NIH Intramural Medical Executive Committee, Policy and Communications Bulletin, Medical Administrative Series: Informed Consent (CC) ***
  http://internal.cc.nih.gov/policies/PDF/M77-2.pdf
  This document details the revised policy and procedures of the Clinical Center for obtaining informed consent from individuals who come to the Clinical Center to participate in research. Specific procedures are outlined relating to oral consent. The intended audience includes physicians, dentists, other practitioners, and IRB chairs.

Postmortem

- NIH Intramural Medical Executive Committee, Policy and Communications Bulletin, Medical Administrative Series: Informed Consent (CC) ***
  http://internal.cc.nih.gov/policies/PDF/M77-2.pdf
  This document details the revised policy and procedures of the Clinical Center for obtaining informed consent from individuals who come to the Clinical Center to participate in research. Specific procedures are outlined relating to postmortem informed consent. The intended audience includes physicians, dentists, other practitioners, and IRB chairs.

Questionable Capacity to Consent

- Research Involving Individuals with Questionable Capacity to Consent: Points to Consider (OER)
  http://grants.nih.gov/grants/policy/questionablecapacity.htm
  This points to consider document is intended to inform IRBs and clinical investigators planning clinical research involving people with impaired decision making capacity in order to help protect potential research participants. Conflicts of interest, assessment of the capacity to consent, the responsibilities of the IRBs and investigators, and safeguarding measures are detailed.

- Research Involving Cognitively Impaired Subjects: A Review of Some Ethical Considerations (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet7.html
  This review document explains the challenge of responding to a medical and scientific obligation to further knowledge about diseases that cause cognitive impairment while simultaneously recognizing that these diseases present challenges to the consent process due to impaired comprehension and ability to consent. Federal guidelines, NIH guidelines, and the suggestions given in the Belmont Report regarding heightened awareness with cognitively impaired subjects are detailed. Case studies are provided to promote understanding of research risk and impairment and appropriate responses in particular situations.

RESEARCH SITUATIONS REQUIRING SPECIAL CONSIDERATIONS

Blinded, Randomized Studies

- Issues Regarding Blinded, Randomized Studies in the NIH Intramural Research Program (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet13.html
  A 1998 subcommittee of the NIH Human Subjects Research Advisory Committee (HSRAC) compiled this document on studies where the research design prevents subjects from knowing at the outset the experimental treatment or drug they will receive. The document addresses three issues: language use, the appropriateness, if ever, of unblinding a study, and the circumstances under which an IRB would be aware of whether participants received a placebo or active drug. Each issue is discussed and the subcommittee's recommendations are given.

Emergency Situations

- NIH Intramural Medical Executive Committee, Policy and Communications Bulletin, Medical Administrative Series: Informed Consent (CC) ***
  http://internal.cc.nih.gov/policies/PDF/M77-2.pdf
  This document details the revised policy and procedures of the Clinical Center for obtaining informed consent from individuals who come to the Clinical Center to participate in research. Specific procedures are outlined relating to emergency situations. The intended audience includes physicians, dentists, other practitioners, and IRB chairs.

Gene Transfer

- NIH Guidance on Informed Consent for Gene Transfer Research (OD/OBA)
  http://www4.od.nih.gov/oba/rac/ic/
  Intended for a wide audience of investigators, sponsors, IRBs, potential participants, and the public, this document explores the nuances of the informed consent process for gene transfer research. It provides a detailed outline of the considerations for preparing consent documents with NIH guidelines for each topic, a discussion and sample language.

HUMAN SPECIMENS AND DATA

- Guidance for Addressing Tissue Sharing in Informed Consent (NHLBI)
  http://www.nhlbi.nih.gov/funding/policies/tissue.htm
  This NHLBI guidance highlights the importance of including information in the consenting process related to the potential distribution of tissue samples.

- DOE-NHGRI (National Human Genome Research Institute) Model Consent for Use of Tissue Samples for Human Genome Project Cell Lines (NHGRI)
  http://www.science.doe.gov/ober/humsubj/doenhgri.html
  This sample consent form from the Department of Energy (DOE) and NHGRI is offered as an example for investigators who are writing informed consent documents for clinical trials involving human specimens. The consent covers the following topics: what will be done with tissue samples, what they will be used for, and who will use them; benefits of allowing samples to be used to create DNA libraries; policy regarding releasing information about DNA to subjects; privacy protection policies; risks of allowing tissue samples to be used to create a cell line and a DNA library; payment policy; information about the development of commercial products; and options for withdrawing from participation.

- NIH Requirements for the Research Use of Stored Human Specimens and Data (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet14.html
  This informational sheet describes the requirements that must be met before an Intramural Research Program can use stored specimens for research. The discussion is consistent with the National Bioethics Advisory Commission's (NBAC) 1999 report entitled "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance." Definitions of terms, policies, and implementation of the policies are discussed.

IRB PROCEDURES, REVIEW, AND APPROVAL

- Criteria for Institutional Review Board (IRB) Approval of Research Involving Human Subjects (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet3.html
  This informational sheet details the primary objective of IRBs to protect the rights and well-being of human subject participants. This document describes the role of IRBs in the approval and review of research activities and includes a list of federal requirements that IRBs must ensure are met before approving research. A chart is also included with minimal regulatory requirements for IRB review, discussion, and documentation in the meeting minutes.

- Continuing Review of Research Involving Human Subjects (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet9.html
  This information sheet explains the requirements for reviewing human subjects research at regular intervals. General requirements, as well as the documentation IRBs request for review and matters of timing, are explained.

- NIH Institutional Review Board Administrative Procedures (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet12.html
  This webpage describes the composition of NIH Institutional Review Boards, IRB meetings, their procedures for research protocols, and the relationship between IRBs and the federal government. IRB actions are discussed in relation to the federal mandate that they ensure that human subjects research meets the standards set by the Belmont report regarding ethical conduct, federal regulations on human subjects protections (45 CFR 46), state and local laws, and professional standards.

FREQUENTLY ASKED QUESTIONS

- OER Human Subjects Web Site: Frequently Asked Questions From Applicants (OD/OER)
  http://grants.nih.gov/grants/policy/hs/faqs_aps_hsp.htm
  This frequently asked questions webpage provides information relevant to applicants for NIH funding with a focus on human subjects protections. Topics include "passive consent," waivers of documented informed

consent, submission of informed consent documents to NIH, and how to address incidental findings in NIH grant applications. Responses cite and provide links to relevant federal documents and NIH guidelines.

- Answers to Questions Frequently Asked of NIH's Office of Human Subjects Research (OHSR) (OD/OHSR) ***
  http://ohsr.od.nih.gov/info/sheet8.html
  A list of 16 frequently asked questions at the Office of Human Subjects Research, ranging from what the office itself does to inquiries regarding federal policies and regulations on human subjects research and the role of IRBs.

*** *These documents are intended for internal use by the NIH, although they may be accessed by the general public and may prove useful. Guidance from the intramural research program may extend beyond regulatory requirements of 45 CFR 46 or FDA regulations. Adherence to policies outlined by Office of Human Subjects Research (OHSR) and Clinical Center (CC) is required for NIH intramural researchers but may not necessarily be required by institutions external to NIH.*

RESOURCE BY INSTITUTE/CENTER

National Cancer Institute (NCI)

- A Guide to Understanding Informed Consent
  http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide/allpages
  This guide for potential research participants describes the informed consent process, details the history and regulation of clinical trials, provides a "questions to ask" checklist, and suggests additional resources for gathering more information.

- Children's Assent to Clinical Trial Participation
  http://www.cancer.gov/clinicaltrials/understanding/childrensassent0101/allpages
  This guide aimed at parents considering enrolling their children in a clinical trial discusses the issues surrounding a child's agreement to participate in a clinical trial, including parental involvement in the process, legal responsibilities, and when assent of the child is and is not necessary. Links to further resources on the topic are included.

- Simplification of Informed Consent Documents
  Includes "Informed Consent Template for Cancer Treatment Trials"
  http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/allpages
  This document presents the results of a working group (the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials) formed by the NCI, OHRP, and FDA in 1998. The group investigated the simplification of informed consent documents in response to concerns raised by research participants and investigators. The recommendations are intended to be useful for investigators who write consent forms and IRBs which review those forms. A template for informed consent documents is also included.

National Heart, Lung, and Blood Institute (NHLBI)

- NHLBI Guidelines for Consent Forms in Multicenter Clinical Studies
  http://www.nhlbi.nih.gov/funding/policies/consent-forms.htm
  NHLBI guidelines mandate that multicenter studies develop consent form templates to be used across the study in order to harmonize the study protocols. This document explains the guidelines, as well as the permissible alterations to templates and the review process for consent document approval.

- Guidance for Addressing Tissue Sharing in Informed Consent
  http://www.nhlbi.nih.gov/funding/policies/tissue.htm
  This NHLBI guidance highlights the importance of including information in the consenting process related to the potential distribution of tissue samples.

- Clinical Research Guide: How do I develop consent forms and who reviews them?
  http://www.nhlbi.nih.gov/crg/funding_consent.php
  This short resource provides guidance on how to develop consent forms and provides relevant links.

National Human Genome Research Institute (NHGRI)

- Informed Consent
  http://www.genome.gov/10002332
  This comprehensive webpage provides information on informed consent for genetic research. It contains links to informed consent resources including federal policies and legislation, as well as NIH reports.

- DOE-NHGRI (National Human Genome Research Institute) Model Consent for Use of Tissue Samples for Human Genome Project Cell Lines
  http://www.science.doe.gov/ober/humsubj/doenhgri.html
  This sample consent form from the Department of Energy (DOE) and NHGRI is offered as an example for investigators who are writing informed consent documents and IRBs. The consent covers the following topics: what will be done with tissue samples, what they will be used for, and who will use them; benefits of allowing samples to be used to create DNA libraries; policy regarding releasing information about DNA to subjects; privacy protection policies; risks of allowing tissue samples to be used to create a cell line and a DNA library; payment policy; information about the development of commercial products; and options for withdrawing from participation.

National Institute of Allergy and Infectious Diseases (NIAID)

- Requirements for Informed Consent Development
  http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/Protocol/InformConsent.pdf
  This document details the NIAID requirements for the development of informed consent documents for the Division of Acquired Immunodeficiency Syndrome (DAIDS) funded and/or sponsored human subjects clinical research.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

- Clinical Investigation Consent Form
  http://www.niams.nih.gov/Funding/Clinical_Research/invest_form.asp
  This sample patient consent form from NIAMS serves as an example for investigators who are writing informed consent documents and IRBs. The categories included in this document are: purpose of the trial, number of participants, procedures, sample storage and use, treatment assignment, treatment visits, risks/discomforts, risks associated with standard medicines, risks associated with a specific drug, any other possible risks, benefits, alternatives to participation, right to refuse treatment or withdraw from the study, reasons to be removed from the study, costs or payments, confidentiality, questions, injuries, and joining of your own free will.

National Institute of Child Health and Human Development (NICHD)

- Consent to Participate in a Clinical Research Study
  http://dir2.nichd.nih.gov/nichd/deb/segen/documents/00-CH-0160.1.Linkag.040824.7.23.05.pdf
  This sample consent form from NICHD serves as an example for investigators who are writing informed consent documents and IRBs. The form outlines the voluntary nature of participation in the study, provides a brief background of the research, and describes possible risks and benefits. Pertinent information concerning confidentiality, the policy regarding research-related injuries, payment, the resolution of problems or questions, and the actual consent template is included.

National Institute on Drug Abuse (NIDA)

- Model Subject Consent
  http://www.drugabuse.gov/about/organization/Genetics/model_consent.pdf
  This Model Subject Consent from NIDA is a guideline intended to be tailored to individual studies. Topics outlined include: a description of the study, effects on participating individuals, possible risks/discomforts, an explanation of the research funding, compensation, and discontinuing participation. This example form depicts a genetics study, although it is designed to be widely applicable and adaptable.

National Institute of Deafness and Other Communication Disorders (NIDCD)

- Working Group on Communicating Informed Consent to Individuals Who Are Deaf or Hard-of-Hearing, including: "Guidelines on Communicating Informed Consent for Individuals Who are Deaf or Hard-of-Hearing and Scientists"
  http://www.nidcd.nih.gov/news/releases/99/inform/toc.asp
  These guidelines were produced by a Working Group on communicating informed consent to individuals who are deaf or hard of hearing. The issues addressed refer to the special circumstances surrounding research involving the hearing impaired, including the wide range in type and degree of hearing loss, and differences in factors such as etiology, age of onset, communication experience, communication preference, and language use. Specific recommendations regarding these issues are made.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

- Model Informed Consent Form
  http://www.niddk.nih.gov/fund/diabetesspecialfunds/T1DGC_Informed_Consent_Template.pdf
  This comprehensive model informed consent document has been developed and provided by NIDDK. Suggested but optional wording is indicated in brackets and instructions are italicized for easy user accessibility. The document details a study developed to identify genes linked to diabetes and includes a description of: the purpose of the study, consent to produce a cell line, ownership and the right to have genetic material destroyed, risks and discomforts, benefits, alternatives and one's right to withdraw, confidentiality, cost, compensation and treatment, questions, and the participant's statement/consent.

Office of the Director (OD)

Office of Extramural Research (OER)

- OER Human Subjects Web Site: Frequently Asked Questions From Applicants
  http://grants.nih.gov/grants/policy/hs/faqs_aps_hsp.htm
  This frequently asked questions webpage provides information relevant to applicants for NIH funding with a focus on human subjects protections. Topics include "passive consent," waivers of documented informed consent, submission of informed consent documents to NIH, and how to address incidental findings in NIH grant applications. Responses cite and provide links to relevant federal documents and NIH guidelines.

- Research Involving Individuals with Questionable Capacity to Consent: Points to Consider
  http://grants.nih.gov/grants/policy/questionablecapacity.htm
  This points to consider document is intended to inform IRBs and clinical investigators planning clinical research involving people with impaired decision making capacity in order to help protect potential research participants. Conflicts of interest, assessment of the capacity to consent, the responsibilities of the IRBs and investigators, and safeguarding measures are detailed.

- Research on Ethical Issues in Human Studies
  http://grants.nih.gov/grants/policy/ethics_research.htm
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Office of Biotechnology Activities (OBA)

- NIH Guidance on Informed Consent for Gene Transfer Research
  http://www4.od.nih.gov/oba/rac/ic/

Intended for a wide audience of investigators, sponsors, IRBs, potential participants, and the public, this document explores the nuances of the informed consent process for gene transfer research. It provides a detailed outline of the considerations for preparing consent documents with NIH guidelines for each topic, a discussion and sample language.

NIH Intramural Research Program

These documents are intended for internal use by the NIH, although they may be accessed by the general public and may prove useful. Guidance from the intramural research program may extend beyond regulatory requirements of 45 CFR 46 or FDA regulations. Adherence to policies outlined by the Office of Human Subjects Research (OHSR) and the Clinical Center (CC) is required for NIH intramural researchers but may not necessarily be required by institutions external to NIH.

Office of Human Subjects Research (OHSR)

- Criteria for Institutional Review Board (IRB) Approval of Research Involving Human Subjects
  http://ohsr.od.nih.gov/info/sheet3.html
  This informational sheet details the primary objective of IRBs to protect the rights and well-being of human subject participants. This document describes the role of IRBs in the approval and review of research activities and includes a list of federal requirements that IRBs must ensure are met before approving research. A chart is also included with minimal regulatory requirements for IRB review, discussion, and documentation in the meeting minutes.

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  http://ohsr.od.nih.gov/info/sheet5.html
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- Research Involving Cognitively Impaired Subjects: A Review of Some Ethical Considerations
  http://ohsr.od.nih.gov/info/sheet7.html
  This review document explains the challenge of responding to a medical and scientific obligation to further knowledge about diseases that cause cognitive impairment while simultaneously recognizing that these diseases present challenges to the consent process due to impaired comprehension and ability to consent. Federal guidelines, NIH guidelines, and the suggestions given in the Belmont Report regarding heightened awareness with cognitively impaired subjects are detailed. Case studies are provided to promote understanding of research risk and impairment and appropriate responses in particular situations.

- Answers to Questions Frequently Asked of NIH's Office of Human Subjects Research (OHSR)
  http://ohsr.od.nih.gov/info/sheet8.html
  A list of 16 frequently asked questions at the Office of Human Subjects Research, ranging from what the office itself does to inquiries regarding federal policies and regulations on human subjects research and the role of IRBs.

- Continuing Review of Research Involving Human Subjects
  http://ohsr.od.nih.gov/info/sheet9.html

This information sheet explains the requirements for reviewing human subjects research at regular intervals. General requirements, as well as the documentation IRBs request for review and matters of timing, are explained.

- Research Involving Children
  http://ohsr.od.nih.gov/info/sheet10.html
  The "Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" issued by the NIH in 1998 mandates that all human subjects research that is supported or conducted by the NIH must include children, unless there are scientific and ethical reasons not to include them. Accordingly, this policy is outlined with topics including special considerations for the inclusion of children in research studies, permission and assent to participate, and the types of studies that involve children. Studies involving children are broken into four categories within which PIs must classify their studies for NIH intramural IRB approval.

- NIH Institutional Review Board Administrative Procedures
  http://ohsr.od.nih.gov/info/sheet12.html
  This webpage describes the composition of NIH Institutional Review Boards, IRB meetings, their procedures for research protocols, and the relationship between IRBs and the federal government. IRB actions are discussed in relation to the federal mandate that they ensure that human subjects research meets the standards set by the Belmont report regarding ethical conduct, federal regulations on human subjects protections (45 CFR 46), state and local laws, and professional standards.

- Issues Regarding Blinded, Randomized Studies in the NIH Intramural Research Program
  http://ohsr.od.nih.gov/info/sheet13.html
  A 1998 subcommittee of the NIH Human Subjects Research Advisory Committee (HSRAC) compiled this document on studies where the research design prevents subjects from knowing at the outset the experimental treatment or drug they will receive. The document addresses three issues: language use, the appropriateness, if ever, of unblinding a study, and the circumstances under which an IRB would be aware of whether participants received a placebo or active drug. Each issue is discussed and the subcommittee's recommendations are given.

- NIH Requirements for the Research Use of Stored Human Specimens and Data
  http://ohsr.od.nih.gov/info/sheet14.html
  This informational sheet describes the requirements that must be met before an Intramural Research Program can use stored specimens for research. The discussion is consistent with the National Bioethics Advisory Commission's (NBAC) 1999 report entitled "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance." Definitions of terms, policies, and implementation of the policies are discussed.

Clinical Center (CC)

- Informed Consent Document Writing Tool (under development)
  http://sherpa.cc.nih.gov
  Consent Authoring Tool (C.A.T.) is an informed consent authoring application created by the NIH. The purpose is to assist researchers in creating easy-to-read and well structured informed consent documents that take into account health literacy comprehension gaps between medical researchers and research subjects. The application is under development and is currently open to a limited number of users.

- NIH Intramural Medical Executive Committee, Policy and Communications Bulletin, Medical Administrative Series: Informed Consent
  http://internal.cc.nih.gov/policies/PDF/M77-2.pdf
  This document details the revised policy and procedures of the Clinical Center for obtaining informed consent from individuals who come to the Clinical Center to participate in research. It includes sections on: general

background, definitions, the process of informed consent, the written informed consent document, approval of the informed consent document, and the researcher's responsibilities. Specific procedures are outlined relating to oral informed consent, non-English speaking subjects, invasive surgical procedures, additional forms for specific procedures, postmortem examination, emergency procedures, and consent from someone not at the CC. The intended audience includes physicians, dentists, other practitioners, and IRB chairs.

NAVIGATIONAL AID

This navigational aid is intended to help you easily locate resources related to a particular topic or those developed by a specific NIH Institute or Center. Clicking on a topic heading in the far left column will take you to the list of resources on that topic; alternatively, you can use the heading row across the top of the chart to navigate to the resources offered by a specific Institute or Center.

	NCI	NHLBI	NHGRI	NIAID	NIAMS	NICHD	NIDA	NIDCD	NIDDK	OER	OBA	OHSR	CC
General Guidance	●	●	●	●								●	●
Research on Ethical Issues in Human Studies										●			
Tools for Consent Document Development													
IC Checklist		●		●									
Sample Consent Template	●		●		●	●	●		●				
Writing Tools												●	●
Assent													
Assent Template	●												
Children's Assent	●											●	
Considerations for Consent in Unique Populations													
Hearing Impaired								●					
Non-English Speaking Subjects													●
Oral Consent													●
Postmortem													●
Questionable Capacity to Consent										●		●	
Research Situations Requiring Special Considerations													
Blinded, Randomized Studies												●	
Emergency Situations													●
Gene Transfer											●		
Human Specimens and Data		●	●									●	
IRB Procedures, Review, and Approval												●	
FAQs										●		●	

Acronyms: National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Human Genome Research Institute (NHGRI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Child Health and Human Development (NICHD), National Institute on Drug Abuse (NIDA), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Office of Extramural Research (OER), Office of Biotechnology Activities (OBA), Office of Behavioral and Social Sciences Research (OBSSR), Office of Human Subjects Research (OHSR), Clinical Center (CC)