

Tip Sheet for the Informed Consent Template

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The UIC Office for the Protection of Research Subjects (UIC OPRS) has created core [consent templates](#) to assist you in one part of the informed consent process. The core template captures a wide range of points, many of which may not be relevant to your research. Delete any OPTIONAL sections that do not apply to your research.

The sections marked as REQUIRED must be included in all informed consents. If you do not include them, you must request an alteration of informed consent and must provide the rationale for the omission in the appropriate application form. Please note that if you are conducting research involving deception, you must also request an alteration of informed consent.

Match information across all study documents to ensure it is consistent (e.g., Consent document, Clinical Trial Agreement, and Protocol)

If your research is sponsored, please ensure that the payment/cost terms of the informed consent and clinical trial agreement match. For example, if the clinical trial agreement states that the sponsor will pay for the study drug, please ensure that the cost section of the informed consent also states this. Or, if the clinical trial agreement provides that the sponsor does not cover any costs for injury and UIC is not paying for any injury costs, then the informed consent should state this.

If the research is not sponsored, please ensure that the informed consent document accurately states the cost terms and matches the protocol.

PI Responsibilities and Delegation

Remember that on the Initial Application form, the PI must inform the IRB as to whether he or she will personally perform the consent process, including the documentation of informed consent and/or assent, or whether the PI will retain responsibility for overseeing this process but delegate the authority to perform these duties to others. If the PI allows the designees to obtain informed consent, these persons must complete project-specific training on the informed consent process (in addition to the required initial investigator and research HIPAA training) before performing the task. In most cases, the designees must be listed on Appendix P.

PI Essential Documentation

Remember that the PI is responsible for creating his or her own filing system of essential documents, which includes the original signed informed consent form for each subject, as applicable. For additional information and a list of examples of essential documents, please refer to the UIC HSPP policy and procedure [Investigator Essential Documents](#).

Minimal Risk Research

An [optional consent template](#) is available for biomedical research that is minimal risk.

Non-English Speaking Subjects

If subjects are non-English speaking, the consent process and form (if applicable) must be provided in the appropriate language. For additional information for consenting non-English speaking individuals, please refer to the UIC HSPP tip sheet [Involvement of Non-English Speaking Subjects in Research at the University of Illinois at Chicago](#).

VA Research

VA Research requires a specific consent template. There are also certain VA restrictions and additional permission requirements for international research, research with children, prisoners, pregnant women, and research involving in-vitro fertilization, human fetuses, and fetal tissue. For additional information as to these requirements, please refer to the following UIC HSPP policies and procedures [Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB \(UIC IRB #4\)](#) and [International Research](#).

Emergency Use of a Test Article

A specific template consent is required for the emergency use of a test article. For additional information for consent in emergency use of test article situations, please refer to the UIC HSPP policy and procedure [Emergency Use of a Test Article](#).

Research Involving Decisionally Impaired and Cognitively Impaired Subjects

Research involving decisionally or cognitively impaired subjects raises many questions, including how to identify these subjects, how to assess and handle subjects with fluctuating capacity to consent, parameters for research, state law questions, and who is able to provide surrogate consent for the subject. The answers to these questions may affect the required content of your consent form. For more information on research possibly involving this vulnerable population, please refer to the UIC HSPP policy and procedure [Approval Criteria: Decisionally Impaired and Cognitively Impaired Subjects](#).

Research Involving Pregnant Women, Human Fetuses and Neonates, and Fetal Tissue

Research involving these vulnerable populations raises issues, including but not limited to, pregnant minors, parameters for research, additional VA permission requirements and prohibitions, state law questions, and who is able to provide consent. The answers to these questions may affect the required content of your consent form. For more information on research involving this vulnerable population, please refer to the UIC HSPP policy and procedure [Research Involving Pregnant Women, Human Fetuses and Neonates, and Fetal Tissue](#).

Research Involving Prisoners

Research involving prisoners raises complex issues, including but not limited to, how to define a prisoner, Illinois state law restrictions on certain prisoner research, VA limitations, and additional protections required. The answers to these questions may affect the content of your consent form. For more information, please refer to UIC HSPP policy and procedure [Research Involving Prisoners](#).

Research Involving Children

Research involving children may require the use of very specific consent templates. The research also raises concerns, including but not limited to, parental permission, assent, who may consent, whether some children are treated as adults for purposes of research, and certain Illinois state law exceptions and requirements. The answers to these questions may affect the content of your consent form and which consent form you must use. For more information on research involving children, please refer to UIC HSPP policy and procedure [Research Involving Children \(Including Wards of the State\)](#).

Research Involving Wards of the State

Research involving wards of the state raises issues, including but not limited to, additional federal regulatory requirements, potential local foster agency requirements, DCFS requirements, and possible change in the status of the individual able to consent. The answers to these questions may affect the content of your consent form. For more information, please refer to UIC HSPP policy and procedure [Research Involving Children \(Including Wards of the State\)](#).

Research that is or May Become Funded by the Genome-Wide Association Studies (GWAS)

Research that is or may become funded by GWAS has additional consent requirement and concerns. For the GWAS Policy on Sharing Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (which includes information on Informed Consent), please refer to: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>. For more information on research involving GWAS, please refer to: <http://grants.nih.gov/grants/gwas/>.

Investigator has Requested or Obtained a Certificate of Confidentiality from DHHS or Other Federal Agency for the Research

Certificates of Confidentiality allow the PI and the subjects protection against compelled disclosure of identifying information about subjects in various types of human subjects research trials (biomedical and social and behavioral) that are of an identifiable and of a sensitive nature. Information about the certificate must be included in the informed consent. For more information, please refer to UIC HSPP policy and procedure [IRB Approval Criteria: Confidentiality](#) and tip sheet [Certificate of Confidentiality Language for Informed Consent](#).