

## Guidance for Investigators: Informed Consent

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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.

**Evaluation of participants' understanding of the research and of their capacity to provide consent.** An important component of the consent process is the assessment of the participants' understanding of the material presented in the consent and ability to make a reasoned choice concerning their participation. The extent of the assessment should

be guided by the complexity of the study, risks, and potential for subjects to be recruited who may be capable of providing informed consent but due to circumstances have a diminished decision-making ability, e.g., educationally disadvantaged, substance abuse, trauma, immediately before or after an invasive medical procedure, institutionalized, terminally ill. In most circumstances, assessment should involve interviewing the participant following the consent presentation concerning the nature of the research and their participation; consequences of their participation, particularly risks, benefits or impact on their health; and alternatives to participation.

Sample questions that may be posed to the subject to elicit this assessment are listed below. The consent process, including the person obtaining consent and the subject's understanding of the research and ability to provide an informed decision, should be documented, as appropriate, in the medical record, source document or study file. Depending on the study and population, the IRB may require additional safeguards, including a witness, formal assessment of capacity to consent or use of a subject advocate/ombudsperson.

Name at least two potential risks that may occur as a result of participating in the research?

Name at least two things that will be expected of you during the study?

Explain what you will do if you experience distress or discomfort during the study?

Are we offering you your usual medical care, or asking you to be in a research study?

Do you have to take part in this study, or is it OK to say "no"?

What is the purpose of this study?

Tell me the main things that would happen to you in this study. ? Tell me the main risks to you of being in this study.

Will this study mainly help you or others?

If you want to drop out of the study, when can you do this?

Considering the risks and benefits we've discussed, what have you decided about taking part in this study?

### **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](#).

### **National Institute of Justice-Funded Research (Department of Justice).**

Applicants for NIJ funding are required to submit a Privacy Certificate as a condition of approval of a grant application or contract proposal. The Privacy Certificate assures that the applicant understands his responsibilities to protect the confidentiality of research and statistical information and has developed specific procedures to ensure that this information is only used or revealed in accordance with the requirements of 42 USC §3789g and 28 CFR Part 22 (<http://www.nij.gov/nij/funding/humansubjects/privacy-certificate-guidance.htm> ). Under the DOJ confidentiality statute (42 USC 3789g), this makes the identifiable data collected immune from any legal action. Neither the Privacy Certificate nor the informed consent documentation should contain language about Certificates of Confidentiality.

The consent should accurately describe that the identifiable data collected is immune from legal process because the researcher submitted a Privacy Certificate; it was approved by NIJ and is, therefore, covered by DOJ statute. Under the privacy certificate, researchers and research staff do not have to report child (or domestic or elder) abuse unless the subject signs another consent document to allow abuse reporting. A template for the separate consent is available at: <http://www.nij.gov/nij/funding/humansubjects/faqs.htm> .

The consent should also include a statement describing the extent to which confidentiality of records identifying the subject will be maintained (<http://www.nij.gov/nij/funding/humansubjects/informed-consent.htm>). For studies

sponsored by NIH the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified. If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The UIC Social Behavioral Informed Consent template contains language identifying that confidentiality can only be broken if the subjects reports immediate harm to themselves or others and reportable communicable diseases (for example, tuberculosis [TB] or HIV/AIDS).

**Waiver or Alteration of Consent:** Examples of protocol-specific justifications for the 4 waiver criteria.

1. Research involves no more than minimal risk  
Examples:
  - A. *Research involves retrospective review of medical records to ascertain frequency of weight gain with pregalin treatment in elderly women; Data is coded and the file containing the key linking identifiers to data kept in a separate location from data file and both files encrypted.*
  - B. *Research involves medical records review to identify potential subjects during the recruitment aspect of the research; Data is coded and the file containing the key linking identifiers to data kept in a separate location from data file and both files encrypted. Data deleted or de-identified for subjects determined to not meet eligibility criteria or who later decline participation in the consent process once the recruitment aspect of the research is completed. Research has no impact on subjects past clinical care or services received.*
  - C. *Subjects who respond to flyer or when contacted self disclose the minimum necessary information to further assess eligibility criteria in the phone screen and interest in participating in the research.*

2. Alteration or waiver of informed consent would not adversely affect the rights or welfare of subjects

Examples:

- A. *Measures to prevent adversely affecting the rights or welfare of subjects in the retrospective chart review above include privacy notice that patients receive when they register at University of Illinois Hospital & Health Sciences System notifying them that their records may be used without their authorization for research purposes and appropriate procedures in place to protect confidentiality, i.e., primary risk of this research. Also, information learned will not impact the subjects as they experienced this treatment effect in the past. The investigators have access to records as part of their clinical duties.*
- B. *Measures to prevent adversely affecting the rights or welfare of subjects in the records review for research purpose above include privacy notice that patients receive when they register at University of Illinois Hospital & Health Sciences System notifying them that their records may be used without their authorization for research purposes and appropriate procedures in place to protect confidentiality, i.e., primary risk of this aspect of the research. Also, information learned will not impact the subjects as they experienced this treatment effect in the past. The investigators have access to records as part of their clinical duties.*
- C. *The phone script used contains brief overview of the study (purpose, aims, risks). After hearing study overview, subjects who express continued interest are asked to self disclose eligibility information. Subjects may refuse to answer a question or decline continued participation. Unless subjects permit, data collected during the screening process will be de-identified or be destroyed*

3. Research could not practicably be carried out without the waiver or alteration.

Example:

- A. *With the chart review scenario, the research would be impracticable because it would require contacting over 1000 patients who have received this treatment in the past 8 years, contact information may not be current for*

*patients seen in distant past, and many of the elderly subjects may have moved out of area or died. Thus contacting much of the target population would be unduly burdensome.*

- B. *Not feasible to effectively identify potential subjects who may be eligible to participate in the research by other means.*
- C. *Not feasible to written informed consent document or for phone script/information sheet to containing all of the required elements of informed consent.*

4. When appropriate, subjects will be provided with additional pertinent information after participation.

Examples:

- A. *The information expected to be learned from the chart review is not expected to influence the current or future treatment of the subjects. Thus, though the findings may impact treatment of future patients, there will not be any pertinent information for study participants.*
- B. *Subjects determined to meet eligibility criteria will be approached to participate in the research through the approved informed consent process.*
- C. *Subjects determined to meet eligibility/entry criteria will be invited to participate in the research through the approved informed consent process.*