



Informed Consent in Research

Monthly IRB Investigator Meeting
February 21, 2019

Objectives

- Informed Consent Basics
 - Definition
 - Basic Elements
 - Review of the Process
 - Documentation of Informed Consent
 - Waivers
 - e-Consent and Remote Consent
 - Special Situations
 - Informed Consent Review Observations
 - Q&A
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Informed Consent Basics

Definition



What is Informed Consent?

The communication and information exchange between a prospective subject and an investigator.

- Begins with the initial approach of an investigator to the prospective subject, and continues with new information as the clinical investigation progresses until the completion of the research study
- Provides adequate information about the study
- Gives sufficient opportunity for the subject to understand and consider whether or not to participate in the study
- Is documented by the Investigator

Why is It Important?

- Ensures the protection of subjects' rights
- Records information that was discussed with the subject
- Documents the subject's willingness to participate

Who is Involved?

- The principal Investigator (PI) is responsible for obtaining legally effective informed consent of subjects.
 - The PI can delegate the task of obtaining consent to other individuals, who should be
 - ↳ **Qualified** by education, training, and experience
 - ↳ **Knowledgeable** about the clinical investigation
 - ↳ **Supervised** by the PI

Who is Involved? (cont.)

- The person obtaining consent must
 - 👍 Be named in the IRB-approved Personnel list
 - Yes to “obtaining consent”
 - Listed among Engaged personnel
 - 👍 Have completed required training, e.g.,
 - TC0087: HSP (with Minors/FDA-regulated as applicable)
 - TC0019: HIPAA if PHI is involved
 - TC0098: CRC if applicable
 - TC3700: IC training for obtaining IC if ROR and genetic testing
- Regardless of whom is delegated, the PI remains responsible.

Who is Involved? (cont.)

- Under special circumstances, other individuals may need to be present during the informed consent process
 - Children: parent/legal guardian
 - Surrogate: surrogate/proxy and licensed physician
 - Non-English Speaking: interpreter and witness
 - When a Study Partner is required



What is Generally Required?

- Information must be presented in lay terms and in a language that is understandable to the subject
 - Consent documents should be written no greater than an 8th grade reading level
 - Avoid using complicated medical or technical terms
- Should not contain any exculpatory language (verbal or written)
 - Avoid language that waives the subject's legal rights
 - Avoid language that frees the investigator, the sponsor, or the institution from liability of negligence
- Information must include the required regulatory elements.
- A copy of the consent form must be provided

What is Generally Required?

- Information must be provided that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
 - Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
 - Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
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Informed Consent Basics

Basic Elements



What are the 9 Basic Elements?

1. Study description
 - Statement that the study involves research
 - Description and identification of procedures that are experimental
2. Any reasonable foreseeable risks or discomforts to the subject
3. Benefits to the subject or to others which may be reasonably expected
4. Disclosure of alternative procedures/treatments, if any, that may be available and beneficial to the subject
5. Confidentiality of records
6. Compensation and medical treatment of injury
7. Contact information for questions/answers regarding the research and subject's rights and research-related injuries

What are the 9 Basic Elements?

8. Participation is voluntary
 9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens, as applicable:
 - a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
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What are the Additional Elements?

- May be currently unforeseeable risks to the subject (or embryo/fetus)
- Termination of the subject's participation without the subject's consent
- Additional costs from participation in the research
- New findings
- Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- Approximate number of subjects involved



What are the Additional Elements?

- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

And more elements that may be required...

- Requirements of NYS 79-I if Genetic Testing
 - See Genetic Testing Policy
- Incidental Findings language if certain imaging that is beyond SOC
 - See Incidental Findings Policy
- Clinicaltrials.gov language
- Radiation risk language approved by JRSC if ionizing radiation exposure beyond that of SOC

Consent Templates

Templates and sample language were developed to facilitate the development of consent forms that include the basic elements required by federal regulation. These are available on the IRB website:

<https://research.columbia.edu/irb-protocol-resources>

▼ Consent Form Templates

General

- [Consent Form Builder Sample Language](#)
- [Information Sheet: Consent and HIPAA Authorization](#)
- [Incidental Finding Consent Template Language](#)
- [Radiation Risk for Studies Using Ionizing Radiation](#)

Minimal Risk Consent Form Templates

- [Assent Form \(ages 7-11\)](#)
- [Assent Form \(ages 12-17\)](#)
- [Minimal Risk Consent Form Template \(no recording\)](#)
- [Minimal Risk Consent Form Template \(studies involving audio/video recording\)](#)
- [Standard Format for Social/Behavioral Science Consent Documents](#)

For use when the primary focus of a study is whole exome or whole genome sequencing:

- [Consent Form for genetic/genomic studies](#)
- [Cover sheet for consent forms for genetic/genomic studies](#)
- [Assent Form \(ages 7-12\)](#)



Informed Consent:

From Start to Finish



Preparation

The PI or designee should ...

- Ensure the consent form and study documents are IRB-approved.
- Confirm that the most current version of the consent form and study documents are available.
- Print the consent form from Rascal on the day of the consent process.



Initial Approach

To minimize use of private information by anyone other than those individuals who have legitimate access to the patient and his/her PHI, acceptable methods of recruitment include:

- The patient's treating physician introduces the study to the patient.
- A patient's treating physician introduces the study to the patient and provides the patient with written material about the study so that the patient can contact the researcher directly to obtain further information about the study.
- A patient's treating physician introduces the study to the patient and obtains the patient's permission to provide his/her contact information to the researcher directly to provide further information about the study.
- The patient obtains recruitment material and contacts the researcher directly to obtain further information.

Initial Approach (cont.)

The PI or designee should protect subject privacy:

- Recruitment should not take place in an open public area or a crowded waiting room to jeopardize subject privacy.
- Informed Consent should take place in a private room, where subject can ask questions without feeling embarrassment or discomfort.



Obtaining Consent

The PI or designee should ...

- Obtain consent prior to any study procedures and assessments being performed
 - Demonstrate that all elements of informed consent are explained, and that the subject understands all of such elements of informed consent.
 - Give the subject opportunity to consider all information related to research, review and complete their portion of the consent form.
 - Check the consent form for accuracy and completeness, and complete his/her portion of the consent form.
 - Provide the opportunity for questions to be asked, and answered
 - Provide a copy of the completed consent form to the subject, and file the original copy in the subject's research file.
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Obtaining Consent

NYPH Inpatients:

- The physician of record must be informed if a hospital inpatient will be enrolled in a study that involves a medical intervention.
- The time that consent is obtained must be recorded.
- Inclusion of the signed consent form in the medical record/chart is required.



During the Study - Updates

- The PI or designee must inform subject of new study information related to
 - Change in PI
 - New contact information for PI or study staff
 - Change in risks
 - Additional or modified procedures
 - Other factors that may affect the subjects' willingness to continue participation

Documentation

Document specifically how the subject was informed

- Obtain signature on a revised consent form, and provide subject with a copy
- Provide an IRB-approved letter/summary of the new information
- If subject is verbally informed by telephone or in person, record the discussion in subject's research file
- Documentation of the re-consent process should be provided in the research records, and should also include any questions raised by the participant regarding the new information/updates and any other relevant information regarding their continuing participation in the study
- Generally, signature on a revised consent form is required for new safety or risk information, or revision to study requirements, but administrative items may be managed in other ways

End of Treatment / Withdrawal

- End of Treatment – The PI or designee should verify whether or not the subject wishes to continue into the follow up phase of the study, if applicable
- Early withdrawal – If the study has multiple components (study treatment, safety follow up, optional/future research), the PI or designee should confirm whether the subject is withdrawing from the entire study OR only one component of the study (e.g., the subject would like to discontinue receiving the study drug but is willing to be contacted for survival follow up for the next five years)
- Safe Exit – At the time of study termination, the PI or designee should document that the subject was informed of safe exit from the study (e.g., drug washout period, device management, safety follow up visits, safety testing, etc.)

Documentation of Informed Consent



Documentation

The consent process must be documented by

- **Obtaining the signature** of the prospective participant on the IRB-approved informed consent document(s), unless this requirement has been waived by the IRB,

AND

- **Documenting the process** itself in the research records.

Documentation (minimum requirements)

- For minimal risk research
 - Signed IRB-approved ICF
 - For all research that is greater than minimal risk
 - Signed IRB-approved ICF
 - Documentation of consent process (with relevant information)
 - For inpatients
 - Signed IRB-approved ICF
 - Documentation of consent process (with relevant information)
 - Time of the consent in ICF
 - For verbal consent
 - Documentation that consent was obtained in accordance with IRB requirements
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Waiver of Some/All Elements of IC

Waiver of **informed consent (elements or the entire process)** may be allowed if *all* of the following can be satisfied:

- Research involves no more than minimal risk to the subjects;
- Waiver or alteration will not adversely affect the rights and welfare of the subjects;
- Research could not practicably be carried out without the waiver or alteration; and
- Research could not practicably be carried out without using identifiable information/biospecimens, if the research involves using using identifiable private information or identifiable biospecimens
- Whenever appropriate, the subjects/legally authorized representative will be provided with additional pertinent information after participation.



Waiver of Documentation of IC

Waiver of **written documentation of informed consent (i.e., a signature on a consent form)** may be allowed if:

- Only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or
 - Research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context; or
 - If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
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E-Consent and Remote Consent

- E-consent takes many forms
 - May involve face-to-face interaction and signature in an electronic format (e.g., on a tablet) or be entirely electronic and remote (i.e., with the subject in a different location than the researchers)
 - In exempt research, e-consent has few restrictions
 - In non-exempt research, consent requirements must be met, unless a waiver is applicable (either waiver of IC or of documentation)
 - Whether the consent process involves a valid *electronic signature* is an important consideration
 - See IRB guidelines



Special Situations

Consent in Exempt Research

- Not required – “exempt from requirements of regulations”
- Encouraged, when appropriate
- Reasonable to follow consent guidelines of regulations, as they are pertinent and it is logical to do so
- Maintain documentation

Research Involving Children

- For research involving children aged 7 or above, assent, a child's affirmative agreement to participate in research, is usually required.
- Parents/guardian permission must be obtained in a written informed consent document or a separate Parental Permission Form, AND
 - Children aged 7-11:**
 - Assent should be obtained in the presence of a parent/guardian
 - Children aged 11-17:**
 - Documented assent should be obtained. Child can sign his/her own Assent Form or co-sign the Parental Permission Form.
- Informed consent (adult) must be obtained before participation continues when a child turns 18 years old during the course of the study.

For more information: http://www.cumc.columbia.edu/dept/irb/policies/docs/Research_Involving_Children_Policy.pdf
http://cumc.columbia.edu/dept/irb/policies/documents/Informed_Consent_Policy102610Final.pdf
<http://www.cumc.columbia.edu/dept/irb/Templates.html>

Research Involving Adults Lacking Capacity to Consent

- “Surrogate consent”, consent obtained from a representative of an adult subject rather than directly from the subject, may be used when pre-approved by the IRB.
- The IRB will generally consider the use of surrogate consent for research that would:
 - a) provide the prospect of direct benefit to subjects who lack capacity; or
 - b) study disorders, conditions, or factors that affect individuals who lack capacity when the research is minimal risk, with or without the prospect for direct benefit, and the research could not otherwise be conducted on subjects who have capacity.
- A licensed physician must assess the capacity of a subject, and an authorized surrogate must be identified.

For more information: http://cumc.columbia.edu/dept/irb/policies/documents/Informed_Consent_Policy102610Final.pdf.

Obtaining Consent from Non-English Speaking Subjects (I)

A significant number of non-English speaking subjects anticipated

- A certified translation of the English version of the consent document (“long form”) is required after the English version has been approved by the IRB.
- Other study documents (e.g., study questionnaires) that are presented to the subject must be translated into the subjects’ language and approved prior to use.

A significant number of non-English speaking subjects is NOT anticipated but one or more non-English speaking subjects are encountered

- Investigators may rely on oral translation of the approved “long form” (which may serve as the Written Summary) and a “short form.”

A “short form” is one page form that identifies the PI, the title of the research study, and summarizes the elements of informed consent in a language understandable to the non-English speaking subject; this form does not describe any specific research study.

Obtaining Consent from Non-English Speaking Subjects (II)

Consent process using a Short Form

- Parties involved:
 - Individual authorized to obtain consent
 - Witness who is fluent in English and the language of the non-English speaking subject
 - Translator who is fluent in both languages, if the person obtaining consent is not fluent in both languages (Document the name of the translator in research records)
- Short form is signed by non-English speaking subject and witness & Long form is signed by person obtaining consent and witness
- A copy of the “short form” and the “long form” must be given to the subject.

SAMPLE SHORT FORM WRITTEN CONSENT DOCUMENT
FOR SUBJECTS WHO DO NOT SPEAK ENGLISH
***THIS DOCUMENT MUST BE WRITTEN IN A LANGUAGE UNDERSTANDABLE
TO THE SUBJECT***

Consent to Participate in Research

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact name at phone number any time you have questions about the research.

You may contact name at phone number if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

signature of participant date

signature of witness date

11/09/95

參加研究同意書

您被邀請參加一項研究。

在您簽署本同意書之前，研究人員必須告知您有關 (i) 本研究的目的、程序和期限；(ii) 任何實驗性的程序；(iii) 任何合理可預知的風險、不適與利益；(iv) 任何潛在有利的替代性程序或治療；以及 (v) 保密的方法。

必要時，研究人員也將告訴您有關 (i) 受傷時可獲得的任何補償或醫療；(ii) 不可預知的風險的可能性；(iii) 研究人員可能不要您繼續參加的情況；(iv) 您必須負擔的任何費用；(v) 如果您決定不參加研究會如何；(vi) 何時會通知您有關可能影響您參加意願的新發現；以及 (vii) 參加研究的總人數。

如果您同意參加這項研究，您必須收到一份簽名同意書和研究的書面摘要說明。

如果您對這項研究有任何疑問，可隨時撥 電話號碼 聯絡 姓名。

如果您對作為研究對象的權利或受傷該怎麼辦有任何問題，可隨時撥 電話號碼 聯絡 姓名。

您對研究的參與是出於自願，如果您拒絕參加或半途決定退出研究，您不會受到懲罰或喪失福利。

簽署本同意書表示，本研究包括上述資料，已向您口頭說明，並且您自願同意參加。

參加者簽名 日期

證人簽名 日期

在HIPAA授權表中的信息也已經向我解釋，我有機會問問題並得到答案，我同意授權使用我的健康資訊，如HIPAA文件中說明。

**Subject
signs here**

**Witness/
Interpreter
signs here**

**Witness/
Interpreter
writes the
HIPAA
statement
and
signs here**

**Subject
signs here**



**Person
Obtaining
consent
signs here**


**Witness/
Interpreter
signs here**

Signature

Study Participant
Print Name _____ Signature _____ Date _____

Person Obtaining Consent
Print Name _____ Signature _____ Date _____

Medical Center Institutional Review Board: 212-305-5883
Consent Form Number: CF-AAAM1234
Printed On: 07/11/2015 at 12:00 page 5 of 5

 **Columbia University IRB**
IRB Approval Date: 07/11/2015
for use until: 07/10/2016

Other Special Situations

- Individuals who
 - have physical limitations and cannot write
 - are deaf
 - are blind
 - were enrolled through surrogate consent and have regained capacity to consent
 - will be enrolled on the same day as an elective surgical procedure

Consult with the HRPO if in doubt about how to proceed

Informed Consent Observations



Common Issues

- Process is not documented
- Incorrect Process (Person Obtaining Consent is not authorized/delegated, incorrect consent form version/type)
- Incomplete fields or pages (e.g., signature/date section, initials for optional studies or additional questions, missing pages)
- Outdated or unapproved consent form is used
- Consent is obtained after performing research-related procedures
- Re-consent is not obtained
- Process for enrolling non-English speaking subjects is not compliant with regulations or IRB policy (e.g. short form process used inappropriately)

Common Issues (I)

Issues	Prevention
<p>Incorrect Process</p> <ul style="list-style-type: none">• Person obtaining consent is not authorized/ delegated • Outdated or unapproved consent document is used.	<ul style="list-style-type: none">✓ Ensure that study personnel is approved in Rascal, delegated to obtain consent on the Delegation of Authority (DoA) log, and is listed on Form FDA 1572 (if applicable).✓ Print from Rascal prior to the consent visit. Do not use previously saved/printed consent form.
<p>Process is not documented</p>	<ul style="list-style-type: none">✓ Prepare a checklist to complete during the consent visit and/or ensure that the person who obtained consent documents the process.

Common Issues (II)

Issues	Prevention
<p>Incomplete fields or pages</p> <ul style="list-style-type: none">• Incomplete signature/date section• Initials for optional studies or additional questions are unavailable• Missing pages	<p>✓ Confirm that all fields and pages are completed prior to obtaining signature.</p>
<p>Consent is obtained after performing research related procedures.</p>	<p>✓ Ensure that consent is obtained as part of eligibility assessment.</p>
<p>Reconsent is not obtained</p>	<p>✓ Always review modifications to a consent form and consider whether re-consent is required. If it is not clear, consult with IRB and/or sponsor.</p>
<p>Process for enrolling non-English speaking subjects is not compliant with regulations or IRB policy</p>	<p>✓ Review the IRB policy for enrollment of Non-English speaking subjects prior to enrollment.</p> <p>✓ If short form process is used, ensure you review the signature requirements</p>

Reminders

The process of obtaining consent must comply with all applicable state, federal and IRB requirements To ensure that “**CONSENT**” is “**ACQUIRED**” appropriately from a subject, remember the following :

- C**oncise and focused presentation of the key information at the start of the consent process and form.
- O**rganized consent as a whole, with sufficient detail about the research.
- N**ecessary information that a reasonable person would want to have in order to make an informed decision about whether to participate.
- S**igned original consent form in research chart, copy of signed consent form to subject.
- E**xculpatory language forbidden.
- N**ew study information should be shared with subjects.
- T**ime must be given to the subject to make an informed decision, free of coercion/undue influence.

Reminders (continued)

- A**fter consent only can research procedures begin.
- C**urrent and IRB-approved documents must be used to obtain consent.
- Q**ualified and knowledgeable individuals should obtain consent.
- U**nderstandable terms and language must be used during the discussion and in the consent documents.
- I**nscribe and document the discussion in the research chart.
- R**ecruitment only by those who have legitimate access to subject/patient and his/her PHI.
- E**lements of consent must be understood by the subject at the time of the consent discussion and after.
- D**elegated individuals should obtain consent.

Any Questions / Comments?

THANK YOU!

