TIPS FOR CREATING A CONSENT DOCUMENT

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Objectives:

✓ Define informed consent and types of consent
✓ Review of the changes to the new consent templates
✓ Creating the Key Information section of the consent
✓ Using consent in research that meets an exempt category
Informed Consent

- Providing a potential participant with adequate information about the research to allow for an informed decision about the participant’s voluntary participation in a research study.

- A continuous conversation or process during study participation, beyond obtaining the participant’s initial consent at the time of enrollment.
  - May involve providing additional information as the research progresses or as the participant or situation requires

- Participants have the right to withdraw from the research, for any reason at any time, without impacting their standard care
  - Participant withdrawal may be explicit or implied

- Elements of informed consent: 45 CFR 46.116 and 21 CFR 50.21
Informed Consent Process

- The consent document (or form) is not the same as informed consent process
- The consent document is a guide, not a substitute, for the informed consent process
- IRB guidance for conducting the consent process: HRP-090 – SOP Informed Consent Process
- Best practice recommendation: use a Consent Process Checklist to document the study team’s initial consent discussion with each participant
Types of Consent

Consent is obtained:
- Written Consent
  - Wet ink or electronic ("eConsent") signatures
- Alteration of Consent
- Waiver of Documentation of Consent
  - No participant signature
  - "Online" or "Verbal" Consent

Consent is not obtained:
- Waiver of Consent for part or all of study

Detailed consent type definitions here:
https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/consent-hipaa/consent-and-waiver.html
## Types of consent:

<table>
<thead>
<tr>
<th>Example:</th>
<th>Written Consent Obtained</th>
<th>Partial Waiver*</th>
<th>Full Waiver*</th>
<th>Alteration of Consent**</th>
<th>Waiver of Documentation of Consent**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interacting with participants; prospective; signed eConsent</td>
<td>Consent is not obtained for one part of the study.</td>
<td>• Consent not obtained • Participants may not know they are in a research study • Planned emergency research</td>
<td>Consent is obtained but one or more of the required elements of consent are altered or omitted</td>
<td>Elements of consent are used, but participant’s signature is not obtained. Consent is obtained online (recorded with “I Agree” button) or verbally (recorded by person obtaining consent)”</td>
<td></td>
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<tr>
<td>Large chart review before subset survey</td>
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<tr>
<td>Not interacting with participants; chart review</td>
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</tr>
<tr>
<td>Consent elements left out or changed; deception</td>
<td></td>
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<tr>
<td>Internet or phone survey, verbal consent, online consent with no participant signature</td>
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</table>

### What is it?

Informed consent and its documentation (*signatures*) are required for all non-exempt research. If interacting with participants or LARs, then obtain consent.

### How do I get it?

See NU IRB website for required templates

*You may also need a *Waiver of HIPAA Authorization*

**You may also need an *Alteration of HIPAA Authorization*”

Refer to the NU IRB protocol template and address how criteria are met in the protocol
### Types of consent:

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<thead>
<tr>
<th>Partial Waiver</th>
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<th>Alteration of Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3 Options if OHRP regulated non-exempt research:</strong></td>
<td></td>
<td>See 45 CFR 46.116(c)&amp; (d)</td>
</tr>
<tr>
<td>1) Research meets the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Involves no more than <em>minimal risk</em> to the participants;</td>
<td></td>
<td></td>
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<tr>
<td>• Waiver will not adversely affect participants' rights and welfare;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• <em>Research could not practicably be carried out without waiver or alteration of consent</em>;</td>
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</tr>
<tr>
<td>• If using <em>identifiable</em> private information or biospecimens, the research could not practicable be carried out without using these in an identifiable format (only for studies approved after 1/21/2019); <strong>AND</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• <em>Whenever appropriate</em>, participants or LARs will be given additional pertinent info after participation. <strong>OR</strong></td>
<td></td>
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</tr>
<tr>
<td>2) a) Research or demonstration project will be conducted by/ subject to approval of state/local government officials and is designed to study, evaluate, or otherwise examine:</td>
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<tr>
<td>• Public benefit or service programs;</td>
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<tr>
<td>• Procedures for obtaining benefits or services under those programs;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Possible changes in or alternatives to those programs or procedures; <strong>OR</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Possible changes in methods or levels of payment for benefits or services under those programs; <strong>AND</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) <em>Research could not practicably be carried out without the waiver or alteration of consent.</em> <strong>OR</strong></td>
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<td></td>
</tr>
<tr>
<td>3) Planned emergency research waiver of consent: cannot use for pregnant women or prisoners; OHRP follows seven conditions at FDA 21 CFR 50.24</td>
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<td><strong>FDA regulated - NEW:</strong> For minimal risk non-exempt research that meets the following:</td>
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Still under discussion, but in the future the FDA may also require that:

- If using identifiable private information or biospecimens, the research could not practicable be carried out without using these in an identifiable format

**For greater than minimal risk research:**

- If *screening tests or procedures* are being used solely to determine eligibility, then full consent required.
- Waiver of consent is not required for *screening in the medical chart for eligibility criteria or contact info*, but HIPAA regs apply.
- Consent is required if accessing medical record for other research reasons.

- Full waiver of consent is only allowed in limited circumstances for:
  - **Emergency use of a test article** – see regulations 21 CFR 50.23 for details
  - **Planned emergency research** - cannot use for pregnant women or prisoners; See 21 CFR 50.24 for requirements

The FDA does not allow for the elements of consent to be altered or omitted for greater than minimal risk research.

See 21 CFR 50.25 for requirements
Types of consent:

<table>
<thead>
<tr>
<th><strong>Waiver of Documentation of Consent</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is required?</strong></td>
</tr>
<tr>
<td><strong>OHRP</strong> (and not FDA regulated)</td>
</tr>
<tr>
<td><strong>2 Options for OHRP regulated non-exempt research:</strong> See 45 CFR 46.117 (c)</td>
</tr>
<tr>
<td>1) Only record linking participant and the research is consent document <strong>and</strong> the principal risk is potential harm from breach of confidentiality. <strong>and</strong> Participants will be asked if they want documentation linking them to the research, and their wishes govern;</td>
</tr>
<tr>
<td><strong>OR</strong></td>
</tr>
<tr>
<td>2) Research presents no more than minimal risk of harm to participants <strong>and</strong> involves no procedures for which written consent is normally required outside of research context.</td>
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<th>Waiver of Documentation of Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FDA</strong></td>
<td>The FDA-regulated non-exempt research must present:</td>
</tr>
<tr>
<td></td>
<td>• No more than minimal risk of harm to participants <em>and</em></td>
</tr>
<tr>
<td></td>
<td>• Involve no procedures for which written consent is normally required outside of research context.</td>
</tr>
<tr>
<td></td>
<td>See 21 CFR 56.109(c)(1)</td>
</tr>
</tbody>
</table>
Common errors using the consent document template language

- Not using the **required template language**, especially for these sections of the consent document:
  - COI management
  - Research-related injury
  - HIPAA authorization

- Indicating that the "research presents no risk" - typically there is at least the risk of loss of confidentiality

- **Not obtaining a signature when one should be obtained** (use IRB approved document)

- Not using **IRB suggested language** – see website

- Radiation dosimetry – refer to memo

Changes to the consent templates - 11/2023

Updated templates available on the Biomedical & Social Behavioral Consent Templates Page with tracked changes version of Biomedical Consent template. Always download the current version from website.

- Biomedical Consent (HRP-592) - tracked changed online
- Social Behavioral Consent (HRP-582)
- Social Behavioral Consent & HIPAA (HRP-1721)
- Emergency Use (HRP-506)
- Verbal Consent (HRP-1710)
- Parent Consent & Permission with Child Consent (HRP-1711)
- Debriefing Information (HRP-1726)
Changes to consent templates

- Gender-affirming: changed "pregnant women" to "pregnant persons"
- Diversity inclusion: changed "men and women" to "you and your partner"
- IRB FAIR Committee: Fostering Accessibility and Inclusivity in Research
  - [https://irb.northwestern.edu/about/fair/](https://irb.northwestern.edu/about/fair/)
Changes to the Biomedical and Social Behavioral consent templates

New in the "What happens to the information collected for the research?" section:

- P. 9 Added section for when identifiable private information or identifiable specimens will be collected during the research (deidentified data/samples shared without consent)
- P. 8 Added instructions to include for Department of Defense research, that representatives of the DOD are authorized to review research records.

Also, P. 12- Department of Defense section added regarding potential eligibility for health care services through military for research injuries.
Changes to consent templates

- P. 2 – "Why is research being done?" "(5) Indicate the **FDA approval status** of other relevant drugs and devices used in the study."
- P. 3 - "Whom can I talk to?" **Phone number** has changed to (312) 503-1376
- P. 4-5 - Section for when study will or may conduct **whole genome sequencing** *(what it is, whether results are returned)*
- P. 6 – Language added when data and samples will be collected or stored for **future research** *(protect them and risk of breach)*
- P. 10 New "**Will my data or samples be used for future research?**" Section replaces old "Data sharing" section, with more whole genome sequencing language, plus data and specimen language for broad future use and sharing and whether there is a link.
Impact of consent templates changes

- Use the new consent template for **new studies**
- If your **current study's** consent is impacted by the changes that are more substantial and there are participants currently enrolled, please revise the consent when you have a need to submit a modification or at continuing review. For example, if the consent includes:
  - Whole genome sequencing language
  - Future research language
  - Specimen language
  - Dept of Defense language
  - FDA status
Key Information section of the consent

Understand the Common Rule regulatory requirements for the key information section of your informed consent form.

Recommendations for best practices and IRB review of the key information sections.

Results from an Empirical study on KI sections
The 2018 Requirements included a new requirement in § __.116(a)(5)(i):

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative 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.

Applies whether written, electronic or verbal.

Part of several changes intended to improve and clarify consent requirements.
How long should KI be?

- Common rule does not specify—“concise and focused”

- **Length** – What is the optimum length?
  Too long? Too short? Narrative summary versus graphics

- **Readability** – 8th grade reading level, simple language, NCCN Informed Consent Language Database, IRB suggested language

- **Formatting** – bulleted lists, graphics/images

- For some simple studies with limited risks and benefits, an institution may determine that virtually all the information required by §__.116 would also satisfy §__.116(a)(5)(i) (For e.g. research limited to survey procedures or blood draw.)

- Information included at the beginning of a consent form need not be repeated later, although there is no prohibition on repeating information
Key information requirements

- Must be provided at the beginning
- Concise and focused
- Information most likely to assist participants/LARs understand reasons of why/why not to participate
- Organized and presented in a way that facilitates comprehension.

What information should be included in the KI section?

- Common Rule does not specify – “most likely to assist...in understanding the reasons why one might or might not want to participate...”
- Determining key information is fact-specific, but in general, OHRP expects:

<table>
<thead>
<tr>
<th>OHRP Elements</th>
<th>NU Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>The fact that consent is being sought for research and that participation is voluntary</td>
<td>Permission to Take Part in a Human Research Study</td>
</tr>
<tr>
<td></td>
<td>What happens if I do not want to be in this research?</td>
</tr>
<tr>
<td>The purposes of the research, the expected duration of the prospective participant’s participation, and the procedures to be followed in the research.</td>
<td>Why am I being asked to take part in this research study?</td>
</tr>
<tr>
<td></td>
<td>What should I know about a research study?</td>
</tr>
<tr>
<td></td>
<td>Why is this research being done?</td>
</tr>
<tr>
<td></td>
<td>How long will the research last and what will I need to do?</td>
</tr>
<tr>
<td>The reasonably foreseeable risks or discomforts to the prospective participant. Examples include, “you will have to avoid exposure to sunlight for four months,” “all of your hair will fall out,” “you will not be able to drink alcohol for six months,” “you should avoid sexual contact” or “you will have 20 study visits.”</td>
<td>Is there any way being in this study could be bad for me?</td>
</tr>
<tr>
<td>The benefits to the prospective participant or to others that may reasonably be expected from the research.</td>
<td>Will being in this study help me in any way?</td>
</tr>
<tr>
<td>Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective participant.</td>
<td>What happens if I do not want to be in this research?</td>
</tr>
</tbody>
</table>
What about the format and organization of KI?

- Common Rule does not specify – “organized and presented in a way that facilitates comprehension”
- Overall, the Common Rule emphasizes “efforts to foster understanding” as opposed to setting rigid parameters. For example:
  § “The information...shall be in language understandable to the subject or the legally authorized representative” (§__.116(a)(3)).
- § As a whole, consent is not merely a list of isolated facts (§__.116(a)(5)(ii)).
- Recent OHRP presentation on participant-centered consent: https://www.hhs.gov/media/3880/modal
Examples

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have or may have peripheral artery disease (PAD). PAD is a condition in which blockages in the leg arteries prevent blood from getting down to the legs and feet during exercise.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
Few medical treatments are available to improve walking ability in patients with PAD. This research study will help determine the effects of home-based walking exercise combined with light therapy on walking ability in people with blockages in their leg arteries. Early evidence suggests that light therapy may improve blood flow.

How long will the research last and what will I need to do?
We expect that you will be in this research study for approximately five months, including approximately one month of baseline testing and four months of study participation. You will be asked to perform baseline testing and return for follow-up testing. You will be asked to walk with your legs in front of a light device for 10 minutes twice per day for 4 months, meet with a study coach for 4 in-person visits, and walk at home for exercise. More detailed information about the study procedures can be found under the section “What happens if I say ‘yes, I want to be in this research?’”

Is there any way being in this study could be bad for me?
The light device, while registered with the FDA, is not approved by the FDA as a medical device for the way it is being used in this study. Therefore, it is considered an experimental device.
Examples

**Drug B Research Study for Acute Pancreatitis**

*Should I participate in this research?*

**Key Information to help you decide**

**What is research?**

The goal of research is to find better treatments for patients with diseases like yours. This is different from medical care, which is focused on looking after your medical needs and interests. Participation in research is voluntary. You do not have to participate to receive care for your disease.

**Who is this research study recruiting?**

We are recruiting people like you who have been diagnosed with sudden onset inflammation of the pancreas, also called acute pancreatitis, to participate in a research study.

**What’s the current treatment for acute pancreatitis?**

There is no known treatment to block or reduce inflammation in the pancreas. Current treatment for acute pancreatitis is mainly supportive, to reduce symptoms. This includes providing IV fluids to treat the bowel, controlling pain, and monitoring the disease for the development of complications.

**Why are we doing this research study?**

We want to find out if a drug called Drug B can reduce the severity of pancreatic inflammation and related medical complications in patients just diagnosed with acute pancreatitis.

**Why do we think that oral Drug B could be a useful treatment?**

Drug B blocks a key factor of inflammation. Animal studies and a small pilot study in humans showed that Drug B treatment could reduce the severity of inflammation in acute pancreatitis. This could mean less damage to the pancreas, fewer medical complications (such as those that require admission to the intensive care unit), and better treatment outcomes (such as shorter hospital stays).

Drug B has been given to many children with other inflammatory diseases such as arthritic conditions and inflammatory diseases of the blood vessels to reduce the severity of the inflammation. Doctors have many years of experience using this drug and know that many medically serious side effects are rare (please see P of this form for details).

**What would it mean to participate in the research study?**

**How is this research study being done?**

This research study will involve two groups:

- **Drug B group**: will receive the standard treatment for acute pancreatitis and Drug B. The group will receive standard treatment and drug B by mouth four times a day for up to four weeks. You will not know that you will be given this drug. You will receive standard treatment and no drug B.
- **Placebo group**: will receive standard treatment and a placebo pill four times a day for up to four weeks. You will not know that you will be given this drug. You will receive standard treatment and no drug B.

**What is the placebo?**

The placebo is a pill that looks the same as Drug B, but it does not contain any medicine. You will also not know that you are given the placebo.

**What is the difference between the two groups?**

If you receive Drug B, you will receive the drug and the placebo.

If you receive the placebo, you will receive the placebo alone.

**What if I decide to participate?**

If you decide to participate in the study, you will be required to take the study drug or placebo. You will need to take the study drug for at least 12 weeks. You will also be asked to fill out a questionnaire at the end of the study.

**What if I decide not to participate?**

If you decide not to participate in the study, you will be given the standard treatment for acute pancreatitis and no drug B.

**What will I be asked to do?**

You will be asked to answer questions on a form to check for signs of inflammation.

**What could I receive from participating?**

Participating in the research gives you a chance to try out a drug that seems to have few side effects and that might help better treat my disease at no additional financial cost to you.

**What do I do if I choose to not participate?**

You do not have to choose a treatment. You can still receive the standard treatment for acute pancreatitis.

**Who needs to know that I am participating?**

Your doctor will be informed about your participation in the study.

**What if I have any side effects?**

If you receive Drug B, you will be asked to report any side effects you experience. If you receive the placebo, you will not be asked to report any side effects.

**Other considerations**

- This research will pay for the pills used in the study and the blood tests that look for signs of inflammation.
- If you decide to participate, you may be asked at any time if you would be willing to take the study drug or placebo alone.

**Making a Decision About Whether or Not to Participate in the Drug B Pancreatitis Study**

**Other considerations**

- You may qualify to participate in the study if you have not been diagnosed with acute pancreatitis.
- You will be asked to sign a form that states you understand the risks and benefits of participating in the study.

**What is the standard treatment for acute pancreatitis?**

Standard treatment involves the use of medications and supportive care, such as fluid replacement, pain management, and monitoring for the development of complications.

**What are the potential risks of participating in the study?**

There are no known risks associated with participating in this study.

**What are the potential benefits of participating in the study?**

Participating in the research gives you a chance to try out a drug that seems to have few side effects and that might help better treat my disease at no additional financial cost to you.

**How can I learn more about the research study?**

You can learn more about the research study by speaking with your doctor or by reviewing the information provided by the research team.

**How can I learn more about the benefits of participating in the research study?**

Participating in the research gives you a chance to try out a drug that seems to have few side effects and that might help better treat my disease at no additional financial cost to you.

**How can I learn more about the risks of participating in the research study?**

There are no known risks associated with participating in this study.

**What should I do if I have any questions about the research study?**

You should contact your research team or your doctor if you have any questions about the research study.

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Empirical study results of KI sections

- ICF's posted on ClinicalTrials.gov
  - Readability – Many are written at a reading level that lay people with a high school education are likely to struggle with (58% > 8th grade level).
  - Formatting – Lots of room for use of more formatting elements to improve readability (e.g., bulleted lists, graphics/images)
  - Length – What is the optimum length? Is 1.3 pages (mean of sample; n=102). Narrative summary versus graphics.
  - Surprising number of sampled KI sections did not include reasons for and against, which include risks and benefits. Arguably, all KI sections should include some info about main risks and benefits, as applicable
  - More empirical work needed on what information people find most helpful for making thoughtful decisions about research participation
Using consent in research that meets an exempt category

- Researchers sometimes think that if a study is determined to be Exempt, then informed consent is not necessary
  - This is FALSE
  - Informed consent is necessary even when a study seems ‘low risk’
  - The expectation for informed consent for Exempt studies is derived from the Belmont Principle of “Respect for Persons”
Using consent in research that meets an exempt category

- At Northwestern, researchers are encouraged to use the IRB’s consent templates to help ensure participants are fully informed about the study.

- Example: an anonymous, online survey is posted on MTurk:
  - After reading the recruitment post, participants click on a link that takes them to the consent document, hosted on Qualtrics.
  - After reading the consent document, participants must click the “I agree” button before they are able to take the survey.
  - This helps ensure that participants are fully informed about the research study, of their rights, how the data will be used, and who to contact if they have questions or concerns.
Consent Forms and Reliance

- If you are preparing a consent form for a study where Northwestern is not the IRB of Record, expect to use the External IRB or Sponsor’s consent template. HOWEVER, Northwestern local context language must replace template/sponsor language in the following sections (as applicable): disclosures, subject injury, compensation, and HIPAA Authorization. Insufficient language may delay Initial Acknowledgement.

- If Northwestern is the IRB of Record for an external site, expect to use the Northwestern consent template for those sites. HOWEVER, external site local context language may be included in the following sections (as applicable): disclosures, subject injury, compensation, and HIPAA Authorization. Additional language may require additional review.

- Reliance Questions? Check out the Reliance Team’s Office Hours: https://irb.northwestern.edu/reliance/
Things to keep in mind

- Always check the Northwestern University IRB Website for most up to date templates and guidance (https://irb.northwestern.edu/).
- Use the language provided in the IRB’s templates as much as possible and read through the directions carefully. Delete the language that is not applicable and template instructions.
- Avoid including Industry Sponsor language that is overly complicated, redundant, or conflicting with Northwestern template language.
  - The IRB has Suggested Consent Language written in lay terms on our website
- Avoid any exculpatory language like statements using “I understand”.

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References

- Relevant section of the preamble to the 2018 Requirements: https://www.federalregister.gov/d/2017-01058/p-819
- Federal Plain Language Guidelines: https://www.plainlanguage.gov/guidelines/
- OHRP FAQs on the consent-related changes to the Common Rule: https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#informed-consent
Questions?