Northwestern | INSTITUTIONAL REVIEW BOARD

TIPS FOR CREATING A CONSENT DOCUMENT

Rozelle Copeland, PhD, MA, CIP
Lead IRB Analyst
Biomedical Research

Pranjal Patankar, MBBS, MPH, CIP
Lead IRB Analyst
Biomedical Research

Edeth Engel, BS
Lead IRB Analyst
Social and Behavioral Research

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:

Example:	Interacting with participants; prospective; signed eConsent	Large chart review before subset survey	Not interacting with participants; chart review	Consent elements left out or changed; deception	Internet or phone survey, verbal consent, online consent with no participant signature
	Written Consent Obtained	**Partial Waiver***	**Full Waiver***	**Alteration of Consent****	**Waiver of Documentation of Consent****
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.	Consent is not obtained for one part of the study.	• Consent *not* obtained • Participants may not know they are in a research study • Planned emergency research	Consent is obtained but one or more of the required elements of consent are altered or omitted	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)"
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:

	Partial Waiver	Full Waiver	Alteration of Consent
What is required? **OHRP** (and not FDA regulated)	***3 Options if OHRP regulated non-exempt research:*** See 45 CFR 46.116(c)& (d) **1)** Research meets the following: • Involves no more than *minimal risk*** to the participants; • Waiver will not adversely affect participants' rights and welfare; • ***Research* could not practicably be carried out without waiver or alteration of consent;** • If using identifiable 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)*; ***AND*** • *Whenever appropriate*, participants or LARs will be given additional pertinent info after participation. *OR* **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: • Public benefit or service programs; • Procedures for obtaining benefits or services under those programs; • Possible changes in or alternatives to those programs or procedures; ***OR*** • Possible changes in methods or levels of payment for benefits or services under those programs; ***AND*** **b)** *Research* could not practicably be carried out without the waiver or alteration of consent. *OR* **3) Planned emergency research waiver of consent:** cannot use for pregnant women or prisoners; OHRP follows seven conditions at FDA 21 CFR 50.24		

Types of consent:

What is required?

FDA

Partial Waiver	Full Waiver	Alteration of Consent
FDA regulated - NEW: **For minimal risk non-exempt research** that meets the following: • Involves no more than *minimal risk* to the participants; • Waiver will not adversely affect participants' rights and welfare; • Research could not practicably be carried out without waiver or alteration of consent; ***AND*** • *Whenever appropriate*, participants or LARs will be given additional pertinent info after participation. *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:

	Waiver of Documentation of Consent
What is required? **OHRP** (and not FDA regulated)	***2 Options for OHRP regulated non-exempt research:*** See 45 CFR 46.117 (c) **1)** Only record linking participant and the research is consent document **and** the principal risk is potential harm from breach of confidentiality. ***and*** Participants will be asked if they want documentation linking them to the research, and their wishes govern; ***OR*** **2)** Research presents no more than minimal risk of harm to participants ***and*** involves no procedures for which written consent is normally required outside of research context.

Types of consent:

	Waiver of Documentation of Consent
What is required? FDA	**The FDA-regulated non-exempt research must present:** • No more than minimal risk of harm to participants ***and*** • Involve no procedures for which written consent is normally required outside of research context. See 21 CFR 56.109(c)(1)

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

Download current templates here: https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/ **and suggested language here:** Suggested Consent Language: Institutional Review Board (IRB) Office - Northwestern University

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/

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

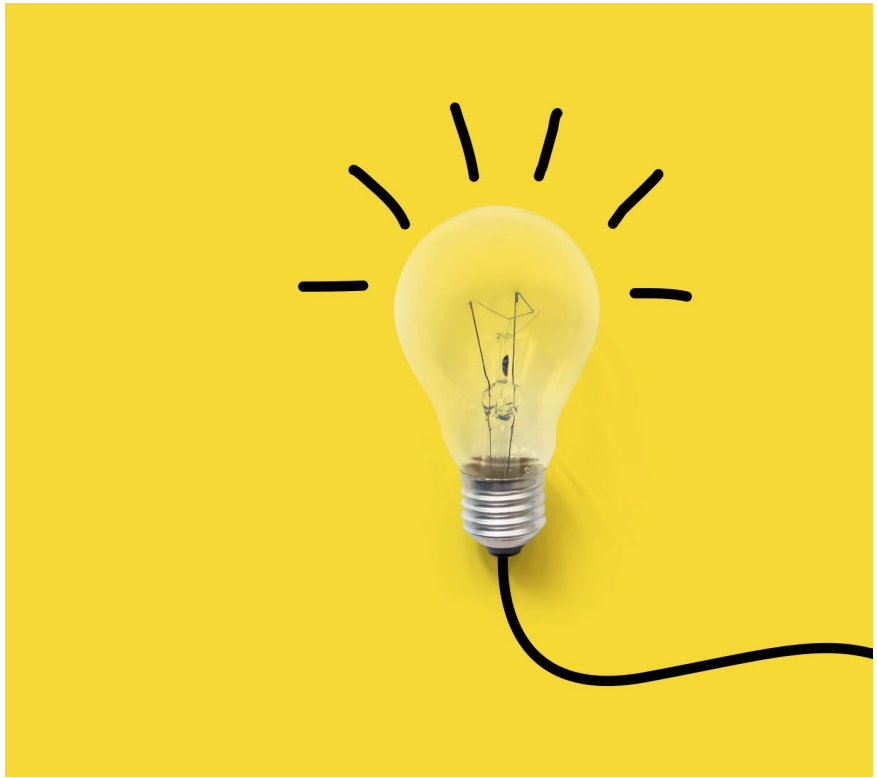
Key Information section of the consent

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

New requirement in the Revised Common Rule



- 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

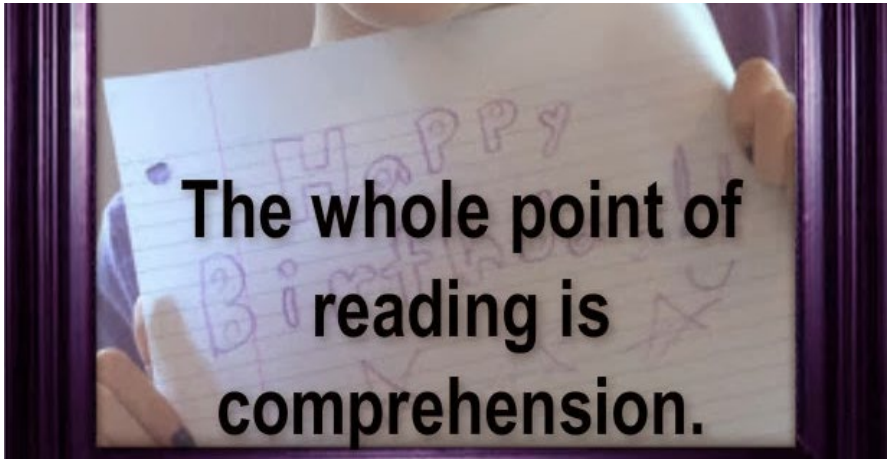
- For some simple studies with limited risks and benefits, an institution may determine that virtually all the information required by §__.116 would also satisfy §__.116(a)(5)(i) (For e.g. *research limited to survey procedures or blood draw*.)

- 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.

- Guidance: https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects#p-819



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:

OHRP Elements	NU Template
The fact that consent is being sought **for research** and that participation is **voluntary**	Permission to Take Part in a Human Research Study What happens if I do not want to be in this research?
The **purposes** of the research, the expected **duration** of the prospective participant's participation, and the **procedures** to be followed in the research.	Why am I being asked to take part in this research study? What should I know about a research study? Why is this research being done? How long will the research last and what will I need to do?
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."	Is there any way being in this study could be bad for me?
The **benefits** to the prospective participant or to others that may reasonably be expected from the research.	Will being in this study help me in any way?
Appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the prospective participant.	What happens if I do not want to be in this research?

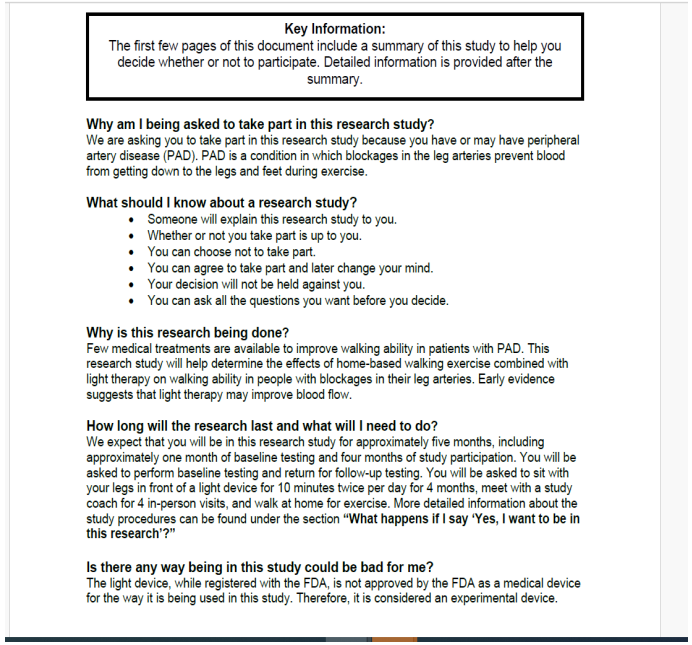
What about the format and organization of KI?

- 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 sit 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.

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.

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IRB #: STU00219103 Approved by NU IRB for use on or after 12/6/2023 through 11/30/2024.

Permission to Take Part in a Human Research Study

Looking directly into the light can damage the eyes, and it is therefore recommended that you protect your eyes by using the sunglasses or goggles provided by the study while using the device. It is possible that there are some adverse effects that are currently unknown. In addition, study testing and exercise may be associated with falling or chest discomfort in people with PAD. If you participate in the optional muscle biopsy portion of the study, risks include local pain and/or discomfort, infection, and bleeding. More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. Taking part in this study may help scientists better understand ways to improve walking ability in people with peripheral artery disease.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Instead of being in this research study, your choices may include discussing alternative treatment with your physician such as medication, supervised treadmill exercise, or lower extremity revascularization (surgery or angioplasty), if you are a candidate for lower extremity revascularization. Medicare and some other medical insurance companies may cover three months of supervised treadmill exercise. If you are interested in any of these alternative treatment options, you may discuss them with your physician.

Examples

Drug B Research Study for Acute Pancreatitis[1]

"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 rest 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 by mouth to treat patients with other inflammatory diseases such as alcoholic hepatitis 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 any medically serious side effects are rare (please see P.X of this form for details).

What would it mean to participate in the research study?

11

How is this research study being done?

This research study randomly assigns participants to one of two study groups:

- Both groups will receive the same standard treatment for acute pancreatitis that they would receive if they were not in the research.
- One group will receive standard treatment and Drug B by mouth four times a day for up to a week.
- The other group will receive standard treatment and a placebo pill four times a day for up to a week. The **placebo** is a fake pill that looks the same as Drug B, and is taken the same way, but doesn't have any medicinal value.

The research uses a double-blind random assignment study design. This means that a random process, like a coin flip, will determine which study group a participant joins. Nobody gets to **choose** which group a participant will be in; not the participants, not the participants' doctors, and not the researchers.

Also, nobody gets to **know** until the study is completed which study group a participant is in; not the participants, not the participants' doctors, and not the researchers.

If you decide to participate, in addition to the standard treatment, you will need to be willing to either receive Drug B or the placebo and you have to accept that during the study you will not know which one you actually get.

Here's a brief comparison between the two study groups:

If you receive Drug B *(50% chance)*	If you receive the placebo *(50% chance)*
You will receive the standard treatment for acute pancreatitis AND you will receive a pill to take by mouth four times a day for up to a week. **You will not know that this pill contains Drug B and that you are in the Drug B group.**	You will receive the standard treatment for acute pancreatitis AND you will receive a pill to take by mouth four times a day for up to a week. **You will not know that this pill is a placebo and that you are in the placebo group.**
Medically serious side effects from taking Drug B are rare. See page X of this form for more details.	A placebo does not contain any drug. It is an inactive compound that does not have any treatment effects or side effects.
You will have blood tests once a day while in the hospital to check for signs of inflammation.	You will have blood tests once a day while in the hospital to check for signs of inflammation.

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If you receive Drug B *(50% chance)*	If you receive the placebo *(50% chance)*
We do not know if Drug B can help treat your disease. If it is effective, you may have less inflammation, less damage to your pancreas, fewer medical complications, and a shorter hospital stay.	You do not stand to receive any potential benefits (and will not experience any side effects) that might result from Drug B because you are not receiving it. The placebo does not add anything to the symptom relief that you will receive from the standard treatment for acute pancreatitis.
If Drug B is not effective in reducing the inflammation of the pancreas, you will only get the symptom relief from the standard treatment for acute pancreatitis. There is a possibility that Drug B could make your condition worse.	If Drug B is not effective or harmful, it would not have mattered that you do not receive it. Your treatment is essentially the same as the current standard of care treatment for people with acute pancreatitis.

- **No promises.** Doctors do not know if oral Drug B is useful for treating acute pancreatitis. If it works, it may reduce the severity of the inflammation, damage to the pancreas, and other medical complications. If it does not work, study participants run a risk of having side effects from Drug B without getting any treatment benefit.
- If you participate in this study, you would help doctors find out whether Drug B is helpful in treating patients with acute pancreatitis.
- If you do not participate in the study, you will still receive the standard of care for acute pancreatitis. Your refusal will not lead to any penalty or loss of benefits to which you are entitled.

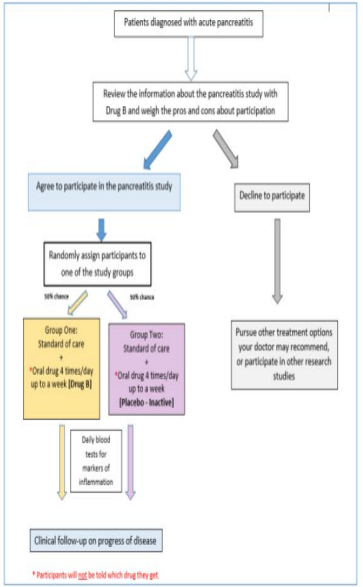
Some Reasons for Why One Might or Might Not Want to Participate in the Study

Why one might want to participate?	Why might one NOT want to participate?
• I want to help researchers find a better treatment for future patients like me. I have little or no preference for receiving or not receiving Drug B. I am willing to accept a 50% chance of receiving Drug B and a 50% chance of not receiving it, and I'm okay not knowing which group I'm in. • Participating in the research gives me a chance of trying out a drug that seems to have few side effects and that might help better treat my disease at no additional financial cost to me.	• I do not want any chance of receiving a drug that has not yet been shown to be effective for treating acute pancreatitis. • I want more than a 50% chance of getting Drug B. I want to talk with my doctor to see if he/she would agree that Drug B is appropriate for me outside of the study.

Other considerations

- This research study 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 withdraw at any time without any penalty or loss of benefits to which you are entitled.

MAKING A DECISION ABOUT WHETHER OR NOT TO PARTICIPATE IN THE DRUG B PANCREATITIS STUDY



NOTE: This explanation provides the key information to help you decide whether to participate. You should review all of the information that follows before making a decision about participation.

Empirical study results of KI sections

- ICF's posted on ClinicalTrials.gov

> J Clin Transl Sci. 2023 Aug 14;7(1):e185. doi: 10.1017/cts.2023.605. eCollection 2023.

Characterization of key information sections in informed consent forms posted on ClinicalTrials.gov

Luke Gelinas [1 2], Walker Morrell [2], Tony Tse [3], Ava Glazier [2 4], Deborah A Zarin [2], Barbara E Bierer [2 5]

- **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 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".

References

- **Educational Videos on Consent:** https://www.hhs.gov/ohrp/education-and-outreach/online-education/videos/informed-consent/index.html
- **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's Key Information examples**: https://www.regulations.gov/document/HHS-OPHS-2020-0003-0007 and https://www.regulations.gov/document/HHS-OPHS-2020-0003-0008
- **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?