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Welcome!

- The session will begin shortly; please take a moment to make sure your microphone is muted.
- The presentation portion of this session will be recorded.
- There will be a Q&A after the presentation.
  - Please hold questions until then so we can discuss them live, OR
  - Type them into the chat for one of my colleagues from the Operations Team to address

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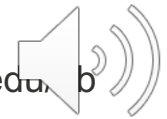
Informed Consent in Research

Regulatory Requirements, Ethical Considerations, & Creating Your Informed Consent Form

Presented by
Kaori Kubo Germano, PhD
Sr. Manager, Clinical Research Education and Communications

Office of Human Research Compliance
Melissa Epstein, PhD, MBE, CIP *Executive Director*

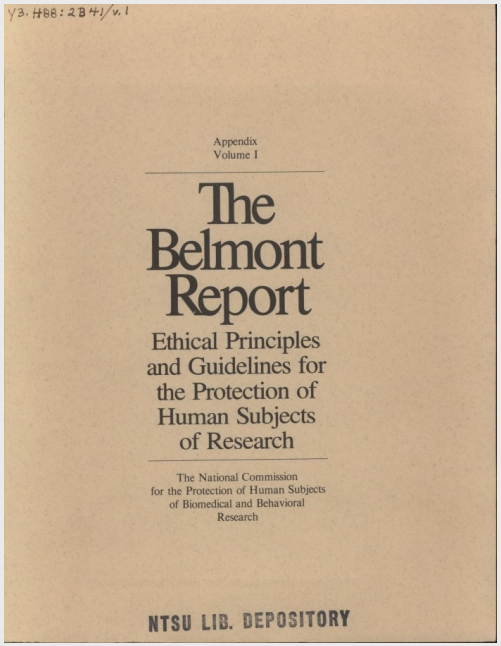
https://research.weill.cornell.edu/...p



Overview

- Why Informed Consent?
- Elements of Informed Consent
- Waivers of Consent
- Creating an Informed Consent Form

Why Informed Consent?



- **Regulatory requirement borne out of Nuremberg Trials, among other events**
- **The Belmont Report's basic principles:**
  - **Justice**
  - **Beneficence**
  - **Respect for Persons**

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Respect for People's Rights and Dignity

We must:

- **Ensure comprehension**
- **Avoid undue influence**
  - Explicit or implied threats = **coercion**
  - Excessive compensation = **undue inducement**
- **Obtain informed consent**

Vulnerable populations must be protected:

- Children/Neonates
- Prisoners
- Persons with limited decision-making ability
- Pregnant Persons/Fetuses
- Students or Direct Reports of a PI

Informed Consent Documentation

45 CFR 46.117(a): Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

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Fundamental Aspects of Informed Consent

01

Disclosure
Researchers must disclose all aspects of the study

02

Comprehension
Individuals must have the mental capacity to understand the information presented to them

03

Voluntariness
Consent must be freely given or truly voluntary

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The Informed Consent Process

Informed
- Having full knowledge and understanding of what participation entails

Consent
- Autonomous decision to voluntarily participate in the research

Process
- A continuous dialogue to ensure ongoing consent to participate

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9 Basic Elements of Informed Consent

1. WHAT IS IT ABOUT?
A statement about, and description of, the study

2. WHAT ARE THE RISKS?
A description of risks or discomforts to the subject

3. WHAT ARE THE BENEFITS?
A description of any benefits to the subjects

4. ARE THERE ALTERNATIVES?
A disclosure of appropriate alternative procedures or courses of treatment

5. WHO WILL KNOW?
A statement describing how confidentiality will be maintained

6. IS THERE COMPENSATION?
For greater-than-minimal risk studies, compensation and/or medical treatment

7. WHO IS THE CONTACT?
Contact information for questions or more information

8. IS IT MANDATORY?
A statement that participation is voluntary

9. WHAT HAPPENS AFTER?
A statement about what will be done with collected information

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1. WHAT IS IT ABOUT?

A statement about, and description of, the study

- **Why is this study being done?**
- **What will you ask your participant to do?**
- **How long will the study last?**
- **How many people will be enrolled?**

Why is this study being done?
You are being asked to join a research study that is being done by [PI name] . *[If this project is funded, identify the funding source.]* We hope to learn [describe the purpose of the project] . You are being asked to join because [insert inclusion/exclusion criteria] .

Who will be in the study? About [*[if multisite:* [*number* people will take part in this study at all sites, and] [number] people will be asked to join the study at Weill Cornell Medicine/New York Presbyterian Hospital.

What will I be asked to do? [Using plain language, provide an accurate description of what the participants will do, what will happen during the project, where procedures will take place, whether any procedures are experimental, time commitment for each procedure, whether there will be randomization, etc. If applicable, include procedures for photographing, audio, or videotaping. State what will be recorded (participant's face/name, will family member or others be identifiable?) Include the setting of the recording, how will recordings be used (e.g. only for tabulation of finite criteria by the research team, for possible use as a teaching tool to graduate or other students who are not members of the research staff).
--If your research involves deception, give as much information as possible without using statements that are part of the experimental deception.
--If your research involves an interview or a survey, be transparent in the types of questions to be asked and inform participants that they can skip any question that makes them uncomfortable and they can stop the interview/survey at any time.
--If your research involves genetic testing, specify why it is necessary to achieve the goals of the study.
--If applicable, provide any information on contraception, barrier use and pregnan testing requirements for the study. Explain what should occur if they or their partne become pregnant while participating in the study.] .

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2. WHAT ARE THE RISKS?

A description of risks or discomforts to the subject

- **Detail any known risk of harm that the participant may experience**
  - Physical, psychological, social, economic, legal, or unknown risks
- **Any/all risks in protocol must be addressed**

What are the risks? [Detail any known risk of harm that the participant may experience from participating in the research including physical, psychological, social, economic, legal, or unknown risks. Any risks listed in the protocol must be addressed in the consent form. Include likelihood (e.g., likely, rare), magnitude/seriousness (e.g., mild, severe) and temporary or permanent, and side effects that may be temporary, irreversible, long-term, or life-threatening.] . There are risks of stress, emotional pain, inconvenience, and possible loss of privacy and confidentiality when joining research study.

[Is this a genetics research study? If yes, add template language for genetics research found in Appendix A.]

[Does the study involve opioid use? If yes, add template language for opioid use found in Appendix A.]

- **Include:**
  - Likelihood
  - Magnitude
  - Permanence
  - Side effects

3. WHAT ARE THE BENEFITS?

A description of any benefits to the subjects

- **Detail any known direct benefits to the participants here**
- **If the COI committee requires it, provide a description here of how this might benefit the researchers or WCM/NYP**

Can being in this study help me? [Detail any known direct benefits that the participant may experience from participating in the research.] . *[If there is no direct benefit to participants:* Being in this study may or may not help you; however, we hope that information learned will help *[describe anticipated generalized societal benefit of the research.]*.

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4. ARE THERE ALTERNATIVES?

A disclosure of appropriate alternative procedures or courses of treatment

- **If there are alternatives to participation, state so here:**
  - Commonly used therapies
  - Disclose standard diagnostic procedures or treatment being withheld
  - Other research studies
  - Are study drugs/intervention/devices available off-label or through standard of care?

Do I have other choices? [Explain other choices participants have if participants have any, including commonly used therapy(ies) or disclose standard diagnostic procedures or treatment being withheld, other research studies, etc. Please specify if any of the study drugs/interventions/devices are available off-label or through standard of care.]

5. WHO WILL KNOW?

A statement describing how confidentiality will be maintained

- **How will information be used and protected?**
- **Where will data be stored?**
- **Who will have access to the data?**
- **How will data be transferred? To whom? Where?**
  - When will data be de-identified?
- **How secure is storage?**
- **When/how will data be destroyed?**

How will the researchers share my information?

[Indicate how information will be shared, with whom, and why OR state that information will not be shared.]

How will my information be used and protected? [Discuss steps that you will take to ensure confidentiality, e.g. where will data be stored, who will have access to the data, how will data be transferred, to whom and where, when will data be de-identified, security of storage, when and how data will be destroyed (including recordings if applicable)] . We will take steps to protect all of yo

Will my information be used in the future?

[Choose one] [For more information regarding the NIH Data Sharing policy, please set up a consult with the Library by contacting Sarah Ben Maamor (sbm4003@med.cornell.edu) or John Ruffing (jruffing@med.cornell.edu)]

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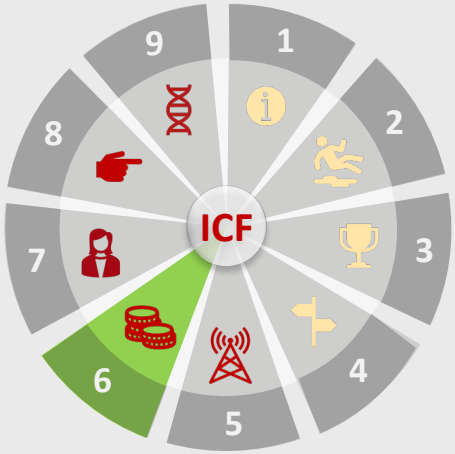

6. IS THERE COMPENSATION?

For greater-than-minimal risk studies, compensation and/or medical treatment

- **A statement that the participant will be paid/they will NOT be paid**
- **What if injury occurs?**

Will I be paid?
[Choose one]
You will not be paid.

OR

You will be paid [amount] by [method] for each visit, for a total of [amount]. You will be paid [indicate when payment will be recieved]. If you do not complete the entire project, you will be paid [amount] for each visit you complete. This payment is considered taxable income. Payments of $600 or more in a calendar year will be reported by WCM to the Internal Revenue Service (IRS). You will be asked to complete a W9 form. At the end of the tax year, Weill Cornell Medicine will use this information to provide you with Federal Form 1099-MISC. If you do not complete the W9 form, you may join this study, but you will not get any payments. *[If applicable, include any alternatives to the payment schedule or information regarding reimbursements.]*

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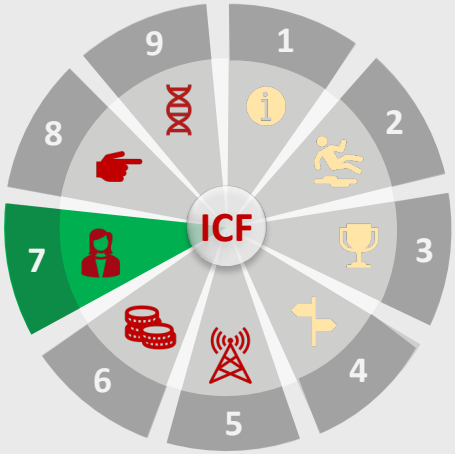


7. WHO IS THE CONTACT?

Contact information for questions or more information

What if I have questions?

If you have any questions, concerns, or complaints about the research, please contact:

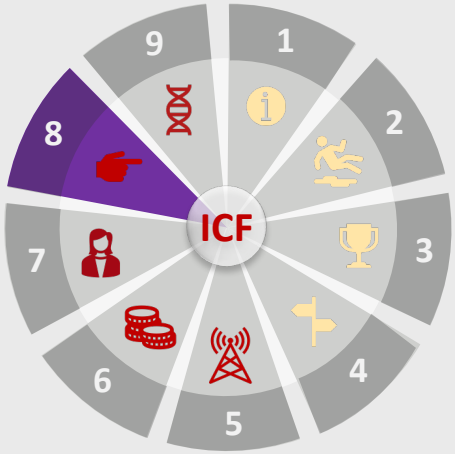
[Researcher's name]
[Department]
[Address]
[Phone]
[Email address]

If you have questions regarding your rights as a research participant, about what you should do in case of any injury or illness because of your study participation, or if you want to get information or give feedback, please contact the WCM Institutional Review Board (IRB) at:

WCM IRB, (646) 962-8200, irb@med.cornell.edu

Website: https://research.weill.cornell.edu/irb

You may also submit questions or complaints without giving your name by calling (866) 293-3077 or visiting http://www.hotline.cornell.edu/.



8. IS IT MANDATORY?

A statement that participation is voluntary

- **A statement that it is the participant's decision whether or not to join the study.**
- **Restate their rights to withdraw at any time**
- **If applicable:**
  - Discuss the process for withdrawing once the project has begun
  - How participants can request their data to be withdrawn
  - How recordings will be destroyed
  - How they may continue treatment or follow-up

Do I have to join? Can I quit the study? It is your decision whether to join this study or not. You have the right to choose not to join or to stop your participation at any time. Your decision to join in this research or stop participating will not affect your regular care nor your relationship with Weill Cornell Medicine, your doctors, or other employees. *[If applicable, discuss the process for participants to withdraw once the project has begun, including how participants can request their data not be used for research, and whether data already collected will remain in the study database (data collected will remain in the data if FDA-regulated research). Describe the process and option to continue with follow-up of their condition if applicable – how often and when this will end. If you are using audio or video recording, please state that the participant's recording will be destroyed should he/she/they decide to withdraw.]*

9. WHAT HAPPENS AFTER?

A statement about what will be done with collected information

Will my information be used in the future?
[Choose one] [For more information regarding the NIH Data Sharing policy, please set up a consult with the Library by contacting Sarah Ben Maamor (sbm4003@med.cornell.edu) or John Ruffing (jruffing@med.cornell.edu)]

[If not banking research data:]
We will destroy information about you when the study is finished. Information about you will only be kept for as long as required by regulations and WCM policy and will not be used or shared for future studies.

OR

[If banking de-identified research data:]
All information that identifies you (e.g., your name, date of birth) will be removed from the data collected in this project. We will keep your de-identified information in a library that has information from other research studies. Your information may be used in the future for other research studies without your permission. Information that cannot identify you or be linked to you will be kept for a long period of time (longer than 50 years). Some of your information may be placed on scientific databases for others to use. These may include databases maintained by the federal government. These data cannot be removed from the library.

OR

[If banking identifiable research data:]
We will keep your information in a library that has information from other research studies. Your information may be used in the future for other research studies. If you agree to this future use of your data, information that identifies you may be kept for a long period of time (longer than 50 years). Some of your information that cannot be linked to you may be placed on scientific databases for others to use without your permission. These may include databases maintained by the federal government. You may decide to have your information removed from the library at any time by contacting the researcher. All your information in the library will be destroyed but information about you that has already been shared cannot be destroyed. You may choose not to participate in the library and still be part of the main study without penalty. *[This must be the case unless the study does not have direct benefit. If there is no direct benefit, you may replace the last sentence with:* In order to be in the main study, you must agree to your identifiable information entering the library for future use. *where applicable.]*
[Include future use checkboxes in the signature section.]

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Additional Elements of Informed Consent

(1) Unforeseeable risk(s)

(2) Possibility of termination of enrollment by investigator

(3) Any additional costs to the subject

(4) Consequences of a subject's decision to withdraw and procedures to withdraw

(5) Provision of significant new findings to the participant

(6) Use of subject's biospecimens (even if identifiers are removed)

(7) Disclosure of clinically relevant research results, including individual research results

(8) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing

For Research Involving PHI

- **Prospective HIPAA authorization from participants**
- **Waiver or Alteration of HIPAA authorization**

HIPAA Authorization for Use and Disclosure of Your Protected Health Information
As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it identifies you.

Protected Health Information (PHI)
By signing this Consent Document, you are allowing the following people to use or release your protected health information for this study: [list all people or class of people (i.e. researchers and their staff) that will access PHI or you can also create a document to give participants that lists these people] .

This information may include: [list PHI, e.g. results of physical exams, medical history, body mass index, sensitive diagnoses if applicable, etc.] . We will use this information to: [include the purpose and describe each use of the requested information] . The researcher may use with and/or release the health information listed above to: [name or class of persons involved] .

In addition to the people listed in this form, there is a chance that your health information may be shared outside of the research study and no longer be protected by federal privacy laws. Examples of this include releases to law enforcement, legal proceedings, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your permission for the use and disclosure of your health information for this project shall not expire unless you cancel it. Your health information will be used or disclosed as long as it is needed for this project. However, you stop your permission at any time by notifying the WCM Privacy Office in writing. To do this, please send a letter to:

Privacy Office
1300 York Avenue, Box 303
New York, NY 10065
Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss them, please call (646) 962-6930. Please note that the research team does not have to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

If you have questions about the privacy practices of the institution, you can request a Notice of Privacy Practices from your provider.

Refusal to Sign
If you choose not to sign this consent form and permission for the use and disclosure of your PHI, you cannot be in the research study. Your decision to sign this consent form or stop participating will not affect your regular care, benefits, nor your relationship with Weill Cornell Medicine, your doctors, or other employees.

Signatures

- **If the participant is a/an:**
  - **Adult:** Their signature
  - **Minor:** Parent/Guardian signature
  - **Member of a vulnerable population:** Legally Authorized Representative (LAR) signature, as appropriate
  - **Adult who cannot read or write:** Witness signature
- **Researcher must also sign the consent**

Vulnerable populations:

- Children/neonates
- Prisoners
- Persons with limited decision-making ability
- Pregnant Participants/Fetuses
- Students or Direct Reports of a PI

Assessing Capacity to Consent

- **Approval of research involving adults unable to provide consent/with impaired decision-making ability contingent on if:**
  - **The research can reasonably be achieved without this population**
  - **There are appropriate provisions for:**
    - **Evaluating capacity**
    - **Obtaining consent/assent**
    - **Otherwise protect subjects**

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Informed Consent Waivers in HSR

45 CFR§46.116; 45 CFR§46.117

Informed Consent Process:

Describe the process (when, where, how, who) for obtaining informed consent including considerations for privacy. If applicable, include any waiting period between informing participants and consenting. Include the process to ensure ongoing consent. Describe steps that will be taken to minimize the possibility of coercion or undue influence. If applicable, describe how participant comprehension will be ensured and the process to determine whether an individual is capable of consent. Describe plans, if applicable, to use a legally authorized representative. If research involves minors, describe the assent process and how guardian permission will be obtained. If the research involves adults with diminished capacity to consent, explain how their agreement to participate will be obtained and documented. If the study includes obtaining consent electronically, explain the process and system to be used. Upload consent/assent documents/scripts as separate word documents with your submission.

or

If the study qualifies for a waiver of documentation of informed consent (absence of signature), provide information explaining why the research meets the waiver of documentation criteria at 45CFR45.117(c)(1).

If the study qualifies for a waiver of informed consent/assent, provide information explaining why the research meets the waiver criteria at 45CFR46.116(f)(3) and/or 45CFR46.408.

permission of parents or guardians/assent by children

Waiver of Documentation of Informed Consent

45CFR46.117(c)(1)

- **Allows collection of data without obtaining participants' signatures on a consent form.**
- **Granted for minimal risk research wherein documentation is the only practical barrier to conducting the study**
- **Applicable when:**
  - **Obtaining signatures may increase risk for participants**
  - **Presents logistical challenges**
- **Not applicable when research involves HIPAA**
- **Informed consent process is still necessary**

Addressing the Criteria for Waiver of Documentation of Informed Consent

45CFR46.117(c)(1)

Don't:

- **Choose the wrong waiver criteria.**
- **Just repeat the regulation without the study specific information.**

Do:

- **Select a regulatory criteria and provide a study specific explanation for the waiver**

"The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context because this research involves a survey about attitudes."

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Waiver of Consent

45CFR46.116(f)(3)

- Allows researchers to conduct a study without obtaining explicit consent from participants
- Granted when obtaining consent would be impractical, unnecessary, or could potentially harm participants
- Allowed under certain conditions:
  - Minimal risk
  - Lack of feasibility
  - Observational research
- Requirement to inform participants about their involvement

Addressing the Criteria for Waiver of Consent

45CFR46.116(f)(3)

Don't:

- **Just repeat the regulation without the study specific information.**
- **Skip over requirements.**

Do:

- **Provide study specific explanation for each regulatory requirement.**

"The research involves no more than minimal risk to the subjects because the research involves observing public behavior."

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Addressing the Criteria for Waiver of Consent

45CFR46.116(f)(3)

Don't:

- **Just repeat the regulation without the study specific information.**
- **Skip over requirements.**

Do:

- **Provide study specific explanation for each regulatory requirement.**

"The research could not practicably be carried out without the requested waiver or alteration because informing participants that they are being observed would alter their behaviors and therefore make the research data unreliable."

Addressing the Criteria for Waiver of Consent

45CFR46.116(f)(3)

Don't:

- **Just repeat the regulation without the study specific information.**
- **Skip over requirements.**

Do:

- **Provide study specific explanation for each regulatory requirement.**

"If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format – this research does not involve using identifiable information."

Addressing the Criteria for Waiver of Consent

45CFR46.116(f)(3)

Don't:

- **Just repeat the regulation without the study specific information.**
- **Skip over requirements.**

Do:

- **Provide study specific explanation for each regulatory requirement.**

"The waiver or alteration will not adversely affect the rights and welfare of the subjects because participants are engaging in this space as they normally would without the research existing."

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Addressing the Criteria for Waiver of Consent

45CFR46.116(f)(3)

Don't:

- **Just repeat the regulation without the study specific information.**
- **Skip over requirements.**

Do:

- **Provide study specific explanation for each regulatory requirement.**

"Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation – participants will be given an information sheet as they leave the venue to let them know about the research and who to contact with questions."

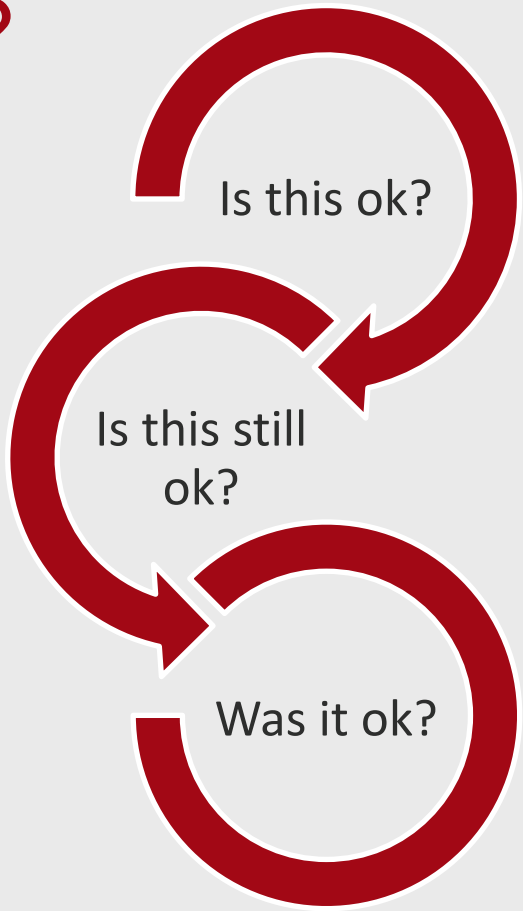
IRB Review for Waivers of Consent

- Ethical justifications: Ensure safety and welfare of participants
- Regulatory compliance
  - The Common Rule: federally funded research
  - FDA Regulations: certain clinical research
    - Planned research in emergency situations when there is no time to obtain informed consent
    - Unplanned use of an investigational drug, device, or biologic in an emergency

Is that it? Can I consent?

No.

- **Language is important**
- **The Key Information Section helps**
- **Informed Consent is a *process***
- **Proper training is key**



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The Key Information Section

What is the Key Information Section?

- **The first thing your participant sees during the IC process**

Important information for you to think about:

- **What am I being asked to do?** [Briefly describe the procedures to be followed in lay terms] .
- **How long will the study last?** If you join the research study, it will take [number of hours] hours over [include the number of times the participant will be involved in research activities, how long each activity or session will take, etc.] .
- **Any possible risks or discomforts?** [Include the most important risks] .
- **Will this study help me?** [Include the most important benefits] .
- **Do I have to join?** You do not have to be in this study. *[Include any alternatives to participating, if appropriate.]*

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Creating an ICF

ICF Language: Accessibility & Legibility

Accessible

- **Easily understood by a range of individuals**
  - Simple and straightforward language
  - Free of jargon
  - Organized
  - Tagged headings
  - Alternative text

Legible

- **Clear and easy to read and decipher**
  - Font choice and size
  - Line spacing
  - Color contrast between text and page

Utilize the WCM ICF Templates

- **WCM Assent Template**
- **WCM Biomedical ICF Template**
- **WCM Humanitarian Use Device ICF Template**
- **WCM Informed Consent Addendum Template**
- **WCM Intermediate-Size Investigational Treatment ICF Template**
- **WCM Pregnant Partner Non-Subject ICF Template**
- **WCM Pregnant Partner Research Subject ICF Template**
- **WCM Repository ICF Template**
- **WCM Social Behavioral Education Research (SBER) ICF Template**
- **WCM Single Patient Investigational Treatment ICF Template**

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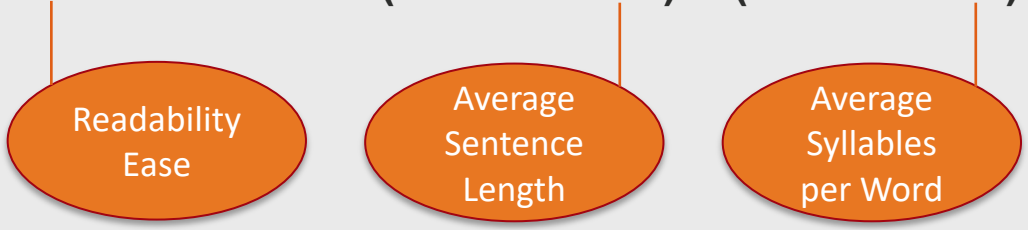
Available on our website:
https://research.weill.cornell.edu/compliance/human-su[illegible]s-research/institutional-review-board/irb-policies-and-proce[illegible]res/form-0

The Flesch-Kincaid Readability Test

- **Flesch Reading Ease Readability Formula (1948)**

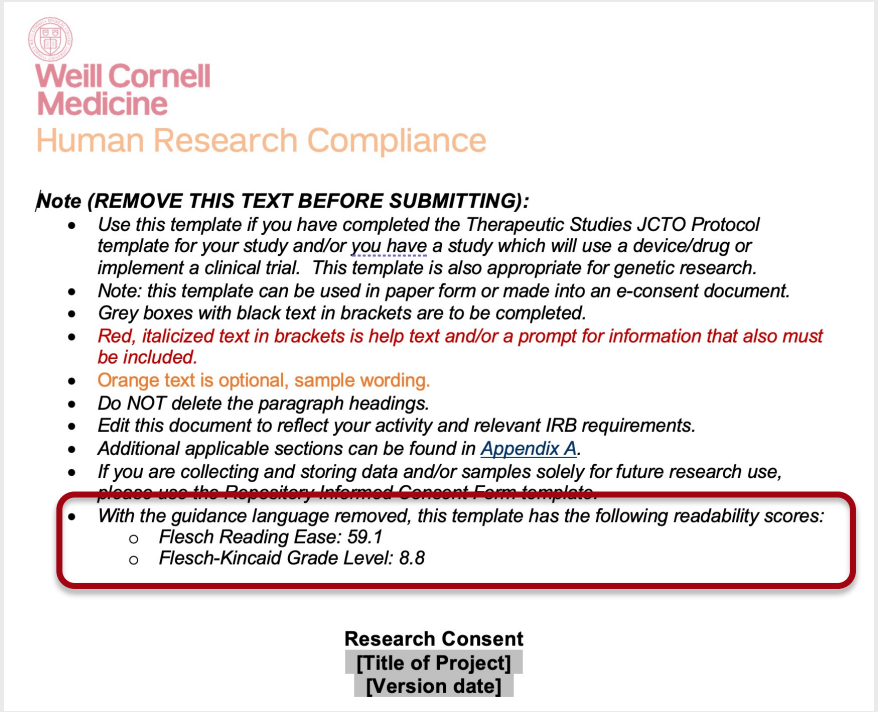
RE = 206.835 – (1.015 x ASL) – (84.6 x ASW)



- **Flesch Grade Level Readability Formula (1976)**
  - 90.0 - 100.0: average 5th grader
  - 60.0 – 69.9: 8th and 9th graders
  - 50.0 – 59.9: high school reading level

The ICF Templates are Readable

- **All informed consent forms (ICFs) must meet the Flesch-Kincaid Grade Level 6-8 readability standards**
  - Shorter sentences and words
- **ICFs that do not fall within the Level 6-8 range may be returned for revisions**



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Human Research Compliance

Note (REMOVE THIS TEXT BEFORE SUBMITTING):

- *Use this template if you have completed the Therapeutic Studies JCTO Protocol template for your study and/or you have a study which will use a device/drug or implement a clinical trial. This template is also appropriate for genetic research.*
- *Note: this template can be used in paper form or made into an e-consent document.*
- *Grey boxes with black text in brackets are to be completed.*
- *Red, italicized text in brackets is help text and/or a prompt for information that also must be included.*
- *Orange text is optional, sample wording.*
- *Do NOT delete the paragraph headings.*
- *Edit this document to reflect your activity and relevant IRB requirements.*
- *Additional applicable sections can be found in Appendix A.*
- *If you are collecting and storing data and/or samples solely for future research use, please use the Repository Informed Consent Form template.*
- *With the guidance language removed, this template has the following readability scores:*
  - *Flesch Reading Ease: 59.1*
  - *Flesch-Kincaid Grade Level: 8.8*

Research Consent
[Title of Project]
[Version date]

For more information…

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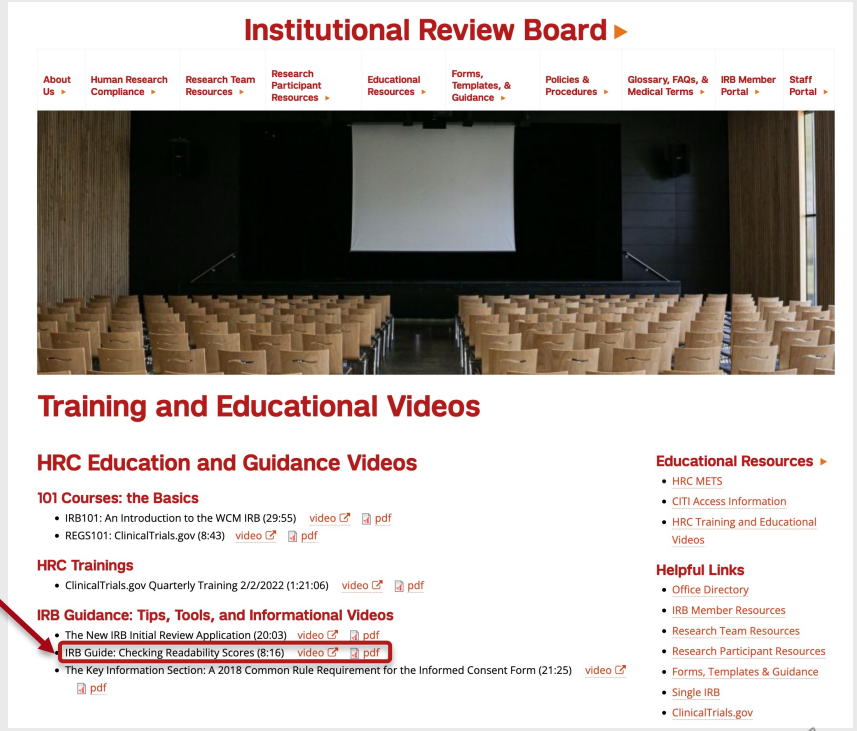
Checking Readability

The Flesch-Kincaid Grade Level Readability Test

Office of Human Research Protection & Compliance
Melissa Epstein, PhD, MBE, CIP *Executive Director*

https://research.weill.cornell.edu/irb



Tip #1: Do not use jargon

Use words familiar to the non-medical reader

- “Anticonvulsant” → a drug used to prevent convulsions/seizures
- “Lipid” → fat
- “Mortality” → death

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Tip #2: Keep it short

- If possible, keep words to 3 syllables or fewer
  - "Anticonvulsant" → a drug used to prevent convulsions/seizures
    too long! 3 syllables vs. 2 syllables
- Write short, simple, and direct sentences
- Keep paragraphs short and limited to one idea

Tip #3: Use precise language

- Use active verbs in an active voice
- Use the second person (i.e., ”you”) not the third person (i.e., “the participant”) to increase personal identification
- ~~Don’t~~ Do not use contractions
- Do not use ”e.g.,” “etc.,”
  - e.g. → ”for example”
  - etc. → ”so forth”

Tip #4: Format your document well

- Use page numbers on protocol, consent, and any other documents
- Use at least 12-point font and consider a larger font based on your audience
- Highlight important points
  - Use underlines
  - Use **bold**
  - Use boxes

Avoid *italics* or ALL CAPS,
AS THEY ARE HARDER TO READ ON THE PAGE

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Tip #5: Be clear and concise

- Avoid repetition; do not repeat yourself
- Check the text to see if each idea is clear and logically sequential
- Use photos, graphics, or tables if they will help clarify procedures

Tip #6: Be consistent

- Be consistent with the use of all terminology, such as drug names and abbreviations
- Spell out acronyms when first used
  - Abbreviations such as DNA, HIV, and AIDS that have come to be accepted as standard need not be spelled out

Tip #7: Use of Drug and Device Names

- **Brand names of drugs** (e.g., ~~Paclitaxel~~ PACLITAXEL™) **or devices** (BD ~~Vacutainer~~ VACUTAINER®) **must be capitalized**
- **Generic drug** (e.g., taxol) **or device names** (e.g., blood collection tube) **are lowercase**
- **Use the appropriate abbreviation the first time a drug name is used in the consent**

Good rules of thumb

- **Describe study design procedures when the concept(s) is/are first introduced.**
- **Do not describe investigational drugs, devices, or procedures as “new.”**
  - Use “investigational” or “experimental” and describe the term
- **When describing randomization for 2 groups use, “like the flip of a coin,” for more than 2 groups, use "like drawing numbers from a hat.”**
- **If collecting blood or other fluids, give a volume equivalent (for ml. or cc.) in teaspoons/tablespoons**

Special items

- If the **FDA may approve the study drug while the research study is in process,** include information on whether participants will be responsible for paying for the study drug if it is approved.
- For **double-blinded studies**, include a statement about unblinding.
- For **optional portions of the study** (e.g., asking permission to store samples for future research), insert checkboxes to allow a subject to indicate his/her choice.

[Include the following if audio/video recordings are being collected and are optional]:

Please check one of the following:

☐ I agree to be [audio and/or video] recorded.
☐ I do not want to be [audio and/or video] recorded.

[Include this section if you are banking identifiable data to be used for secondary future research:]

☐ **YES,** I give permission for my data and information to be kept for future unknown research. I understand that my data and information will be kept for [number] years *[or state indefinitely]*. I also give permission for my data and information to be **shared** with other qualified **researchers** for future research.

☐ **NO,** I do not give permission for my data and information to be kept or shared for future research. *[If future research is mandatory omit this option.]*

[Include the following if the study involves genetic tests for research purposes only (cannot predict a disease):]

I agree to be contacted in the future for research purposes, for information about the study results, and for information about tests on my sample that could benefit my or my family's medical care.

Name of Adult Participant	Signature of Adult Participant	Date
Name of Parent/Guardian	Signature of Parent/Guardian	Date

Word Usage

- **Do not use the words, “treatment” or “therapy”:**
  - To describe an investigational drug, device, or procedure
  - If one of the study arms will be a placebo
- **Do not use “invite”**
  - Use “you are being asked to participate in a research study because…”
- **Do not use symbols such as “>” (greater than)**
- **Use “study doctor” instead of “principal investigator”**
- **Use “research study” instead of “trial”**
- **Use “participant” instead of “patient”**

Helpful Resources

OHRP Guidance

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html

FDA Guidance

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent

Email:

WCM IRB Office: irb@med.cornell.edu

For Training Requests: hrpo@med.cornell.edu

or

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