UNIVERSITY of MARYLAND
SCHOOL OF NURSING

Informed Consent in Human Subjects Research

Part 4: Tips and Guidance on Consent Writing at UMB

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Goals

By the end of this seminar, you should have an increased knowledge of:

- UMB Consent form template "do’s" and "don’ts"
- Tips for improving participant understanding and avoiding IRB queries
- Resources available to assist in consent form readability

Warm Up!

What are your tips for improving the readability of research consent forms?

UMB Research Consent Template

- Available on the UMB HRPO website: https://www.umaryland.edu/hrp/for-researchers/consent-form-templates/
- Use is required in non-exempt studies where UMB is the IRB of record
- Includes directions on what can be changed and what cannot
- May be used to draft your own or merge with sponsor consent

UMB Research Consent Template
Recent Changes

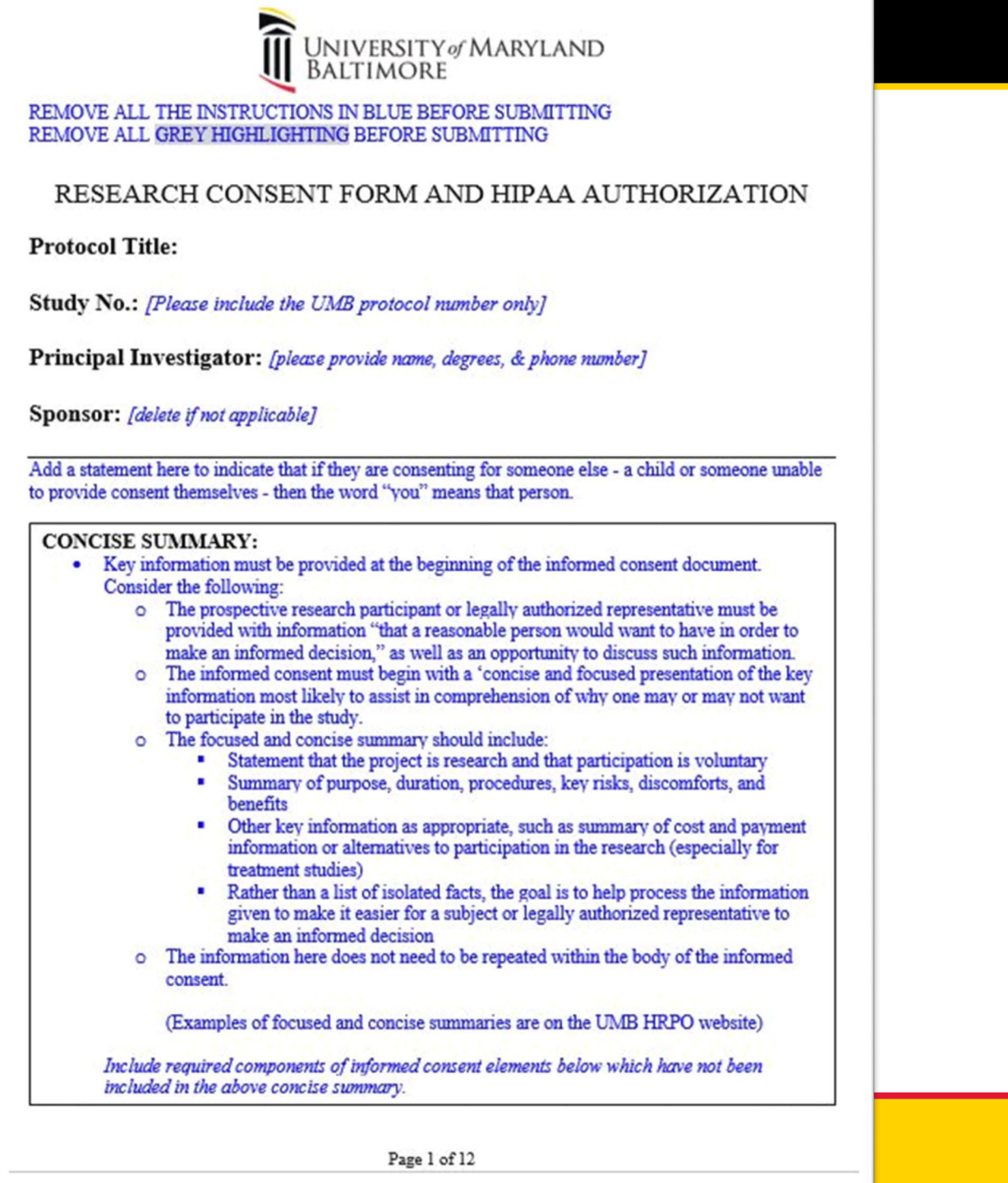
- Concise Summary required
- HIPAA consent included

Note! COVID language should not be added to the UMB consent template (unless it is a COVID related study). There is a separate UMB COVID consent that is mandatory for on campus studies that include in-person contact.

UMB Research Consent Template

What does it look like?

- UMB Header
- Concise summary
- Pagination footer
- Instructions in blue text (remove blue text before submitting)
- Grey highlighted text is mandatory (remove highlight before submitting)
- Approval stamped by HRPO in footer
- ! Version control !



UNIVERSITY of MARYLAND BALTIMORE

REMOVE ALL THE INSTRUCTIONS IN BLUE BEFORE SUBMITTING
REMOVE ALL GREY HIGHLIGHTING BEFORE SUBMITTING

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title:

Study No.: *[Please include the UMB protocol number only]*

Principal Investigator: *[please provide name, degrees, & phone number]*

Sponsor: *[delete if not applicable]*

Add a statement here to indicate that if they are consenting for someone else - a child or someone unable to provide consent themselves - then the word "you" means that person.

CONCISE SUMMARY:

- Key information must be provided at the beginning of the informed consent document. Consider the following:
  - The prospective research participant or legally authorized representative must be provided with information "that a reasonable person would want to have in order to make an informed decision," as well as an opportunity to discuss such information.
  - The informed consent must begin with a 'concise and focused presentation of the key information most likely to assist in comprehension of why one may or may not want to participate in the study.
  - The focused and concise summary should include:
    - Statement that the project is research and that participation is voluntary
    - Summary of purpose, duration, procedures, key risks, discomforts, and benefits
    - Other key information as appropriate, such as summary of cost and payment information or alternatives to participation in the research (especially for treatment studies)
    - Rather than a list of isolated facts, the goal is to help process the information given to make it easier for a subject or legally authorized representative to make an informed decision
  - The information here does not need to be repeated within the body of the informed consent.

    (Examples of focused and concise summaries are on the UMB HRPO website)

Include required components of informed consent elements below which have not been included in the above concise summary.

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Concise Summary- Refresher

Key information should:

- State that the project is research, participation is voluntary
- Summarize purpose, duration, procedures, key risks, and benefits

Also, (as appropriate):

- Summarize costs, payment, alternatives (especially in treatment studies)

Concise summary should not:

- list isolated facts
- be repeated verbatim elsewhere in the consent

Concise Summary- Writing Tips

Simplify! Pretend you are using this text to casually explain the study to someone in line at the grocery store

- Don't bullet sentences; only bullet lists
- Risks- note the most glaring ones; not the exhaustive list
- Use 1st/2nd person
- Refrain from adding information that is not required

Concise Summary Example- needs work

- This project is considered research and your participation in this research is strictly voluntary. You can refuse to participate or end your participation at any time. This decision will not impact the care you receive at Baltimore Hospital.
- The purpose of this study is to examine, using computed tomography (CT) technologies, whether persisting symptoms associated with skateboarding injuries leads to disruption in the stoke system (the system responsible for ensuring your brain is mega excited) compared to controls.
- If you choose to participate in this study, you will undergo a blood draw, and brain CT after being injected with a dye. In addition, you will be asked to participate in cognitive and outcome tests.
- The study will be conducted under standard safety precautions and all tests will be performed by trained research team members.

Key risks presented by participating in this study include the following:

- There is a small risk you may experience claustrophobia while inside the CT scanner. You will be able to contact the CT technologist during the scan at any time. The CT technologist can let you out of the scanner if you request this action.
- There is a risk that you may experience a brief sensation of pain, stinging or burning, fainting or lightheadedness, or rarely, infection during the blood draw. The venipuncture procedure will be performed by an individual certified in phlebotomy. Standard infection control procedures will be strictly followed to minimize risk of infection.
- There is a risk you may experience an allergic reaction to the CT contrast agent. You will be monitored at all times by the technologist for any adverse events following contrast injection.
- You are free to withdraw your consent at any time during the course of your participation.

Concise Summary Example Simplified

We want to see if you are interested in joining a research study because you either skateboard regularly or you do not skateboard at all. The decision to join this study is up to you, it is voluntary.

We want to compare certain brain functions between skateboarders and non-skateboarders.

If you join, you would be asked to come to Baltimore Hospital to:

- provide a one-time blood sample,
- have a CT scan, and
- complete some mental tests.

All the activities could take up to 6 hours total. They can be done in one day.

Some of the risks include irritation where the blood draw is taken, a reaction and allergy to the CT scan dye, and feeling tired from the tests.

Consent Document- Writing Tips

- Beware of complex terms. Consider replacing medical terminology or highly technical terms with lay terms or define in parenthesis.

  Example: Venipuncture (Blood work)

- Avoid information overload- Keep statements simple and to the point
- Keep words, sentences, and paragraphs short*
- Use conversational, plain speak (1st, 2nd person)

  Remember your audience!

Consent Document- Writing Tips

- Spell check! Aim for Flesch-Kincaid 8th grade level in MS Word
- Use Times New Roman or Arial font, no smaller than 11 size
- Ok to split up screening/phases (can't split up HIPAA)
- Have a non-scientist/lay person read it and give you feedback

Consent Document- Writing Tips

- Encourage use of white space!
- Don't shy away from visual aids (infographics, charts, schedules/calendars)
- **Read and follow the blue instructions found on the UMB template (don't rush!)**

Common Errors/Overlooked Information

- LAY LANGUAGE (do not copy/paste from protocol)
- 1st/2nd person, active voice consistency
- Questionnaires – are there sensitive questions being asked? Confidentiality concerns?
- Ensure consistency between protocol, CICERO application, and consent
  Updates to one section affects another

Common Errors/Overlooked Information

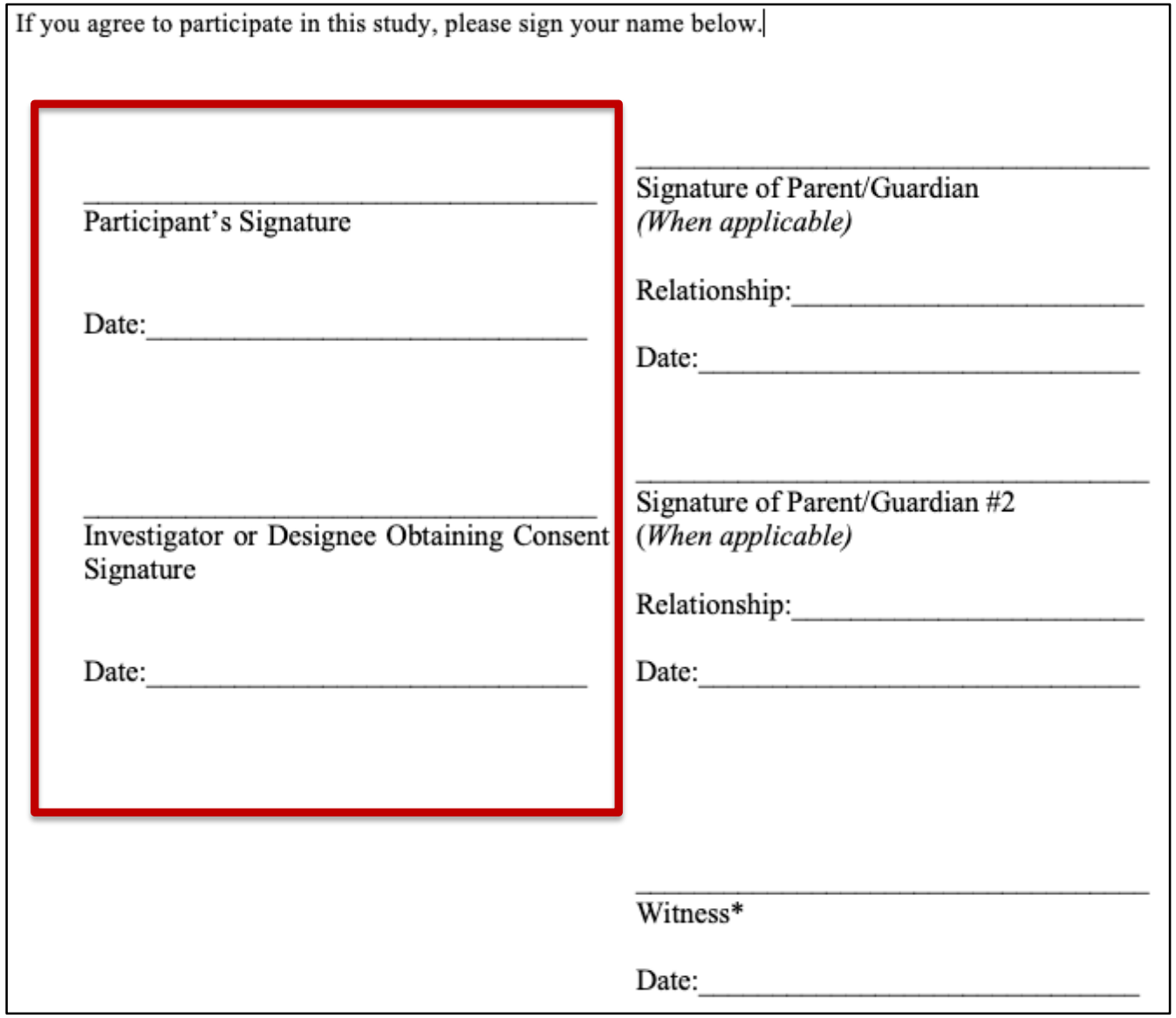
- Payment information – amount, distribution plan
- Time commitment- be clear about expectations
- Blood draws - (96 teaspoons vs. 2 cups, not cc or mL)
- Remove blue text and grey highlighting
- Version control and labeling

Consent Signature

Signature line for:

- Participant
- PI/designee
- Witness, LAR, parent/guardian

(when applicable)



If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

_____
Signature of Parent/Guardian
(When applicable)

Relationship:_____

Date:_____

_____
Signature of Parent/Guardian #2
(*When applicable)*

Relationship:_____

Date:_____

_____
Witness*

Date:_____

Example –needs work

A potential risk for participating in the interview is loss of confidentiality. However remote the possibility, it is possible that a confidentiality breach could release participant names. Also, some people feel that providing information for research is an invasion of privacy. Some people feel uncomfortable when an interview is audio recorded.

Example –simplified

The main risk to you is that someone could find out you were in this study. Also, you may be one of those people who feel uncomfortable being recorded. You may skip any question or stop the interview at any time. We will have the interview transcribed. The transcription will not contain your name. We will destroy the audio recording at the end of the study. Because of these actions, we think the confidentiality risk is very low.

Example –needs work

DrugX will be provided to you at no cost. You or your insurance company may be responsible for administration of this drug.

Edited:
You will not have to pay for DrugX. However, you or your insurance company may have to pay for how the drug gets into your body (the infusion).

Improvement Exercise

Procedures: 4-5 mL of blood will be drawn, where a needle connected to a small plastic tube will be placed on the subject's arm, prior to the first CT session. The procedure will be performed by a phlebotomy-certified individual in the imaging center. The blood samples will be shipped to Dr. Soandso's lab at the National Institute of Health (NIH), who is an expert on biomarkers. The serum levels of biomarkers such as XYZ, ABCD1, Zap, Noidea light chain and B-reactive protein will be analyzed. You will not be told the results of the biomarker testing.

Sponsor Template? Writing Your Own?

- If sponsor has a template they require, you must merge it with UMB research consent template
- If writing your own, you must use the UMB research consent template

Sponsor Template vs. Writing Your Own

Writing your own

- Social/behavioral studies, PI initiated studies, emergency use, HUD
- Use UMB consent template as a guide
- Mandated UMB legal and risk language
- Few levels of review (departmental, HRPO, IRB, maybe HSHSL)

Sponsor Template vs. Writing Your Own

Sponsor consent templates

- Treatment, device studies, social/behavioral, repository, etc.
- May see high level/technical medical writing
- Mandated sponsor legal and risk language
- Multiple levels of review (sponsor, departmental, CCT, UMB legal, HRPO, IRB, maybe HSHSL)

What About Multiple Sites?

Some sites have language requirements- how to handle local context?

- Affiliated vs non-affiliated
- It is the responsibility of the non-affiliated sites to inform the PI of local context language
- Local context should be vetted in the IRB IAA/reliance process

Resources

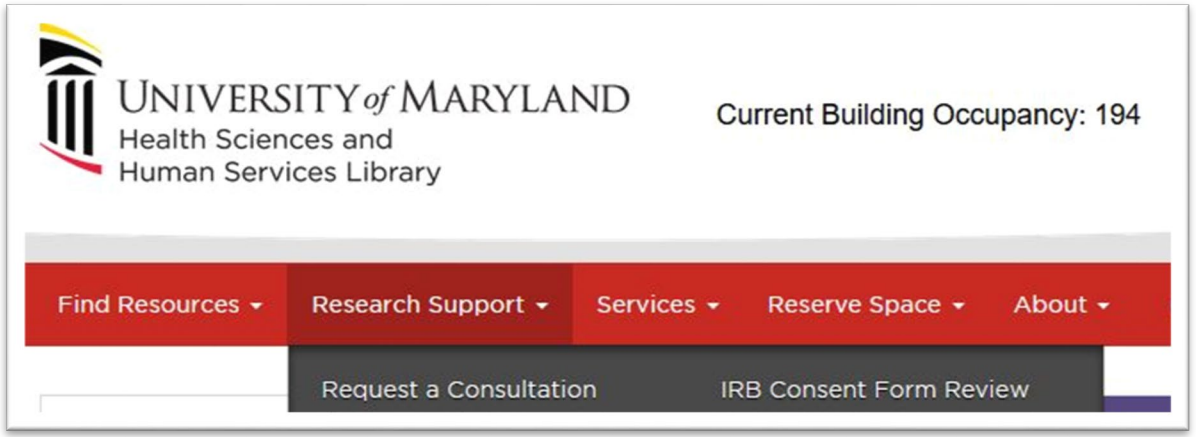
Program for Readability In Science and Medicine (PRISM) Toolkit:
https://www.nhlbi.nih.gov/files/docs/ghchs_readability_toolkit.pdf

National Cancer Institute (NCI) Consent Readability Tool:
https://ctep.cancer.gov/protocoldevelopment/docs/NCI_Informed_Consent_Template_Readability_Assessments.pdf

MRCT Consent Literacy Guide:
https://mrctcenter.org/health-literacy/tools/overview/consent-guide/#1571182455801-75d992eb-b604

HSHSL Services

Available to assist with consent writing!



- May take up to 5 business days
- For UMB/VA consents only

Note!

-HSHSL will not write it for you! They revise drafts to improve readability

-IRB may decide you need to request this service if the consent needs work

-You are still obligated to counter review their edits

Stay Tuned for Further Research Seminars!

December 2021 – winter break, no seminar!

January 2022 - Clinicaltrials.gov compliance

February 2022– Consent Seminar Series #5

Questions?