THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

NRP

Biomedical Behavioral Translational Social

Network for Research Professionals

NRP March 2026 Education Session

A QUICK WORD:

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
NRP
Network for Research Professionals

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March 18, 2026

Special Considerations In Obtaining Informed Consent

Office of Human Research Ethics

UNC Research

Objectives

Establish	General requirements for informed consent
Discuss	Coercion and undue influence during the consent process
Review	Case studies on special populations
Summarize	Elements of a well-crafted Consent Process
Provide	Updates to the investigator guidance (IG 1101)
View	A sneak peek to the consent form updates

Why Informed Consent Matters?

- Informed consent is a **process**, not just a form
- Protects the **rights, safety, and autonomy** of participants
- Required by federal regulations and ethical principles
- Must be **voluntary**, informed, and understandable

General Requirements for Informed Consent

Belmont Principle: Respect for Persons/Autonomy
Explain the study to potential participants **in a language they can understand.**
Allow participants to **freely join or decline** the study, knowing the potential risks and benefits.
Clearly document that consent is obtained **without coercion or undue influence**.
Provide **additional protections for vulnerable persons**.
Allow participants to **withdraw consent and leave the study at any time** without penalty or loss of benefits to which they are otherwise entitled.

Core Elements of Valid Consent

Valid informed consent requires that participants:

- Receive **adequate information**
- **Understand** that information
- Have the **capacity** to decide
- Decide **voluntarily**, without pressure

What Is Voluntariness?

Voluntariness means:

- Participation is free of pressure
- No threats, penalties, or improper rewards
- Participants know they can:
  - Say no
  - Withdraw at any time
  - Do so without negative consequences

Threat to Voluntariness: Coercion and Undue Influence

Impact on consent:

- Both conditions compromise voluntariness, violating the regulatory requirement that informed consent be obtained under circumstances that minimize coercion or undue influence.

Regulatory Requirements

45 CFR 46 (Subpart A)

- §46.116(a)(2): Consent must be sought under circumstances that minimize the possibility of coercion or undue influence.
- §46.111(a)(3): IRBs must ensure equitable selection and be particularly cognizant of subjects vulnerable to coercion or undue influence, with appropriate safeguards.

What is Coercion?

Coercion = real or perceived threat of harm or negative consequences is used to pressure someone into participating in research.

Examples:

- Threatening loss of services or benefits
- Implying negative consequences from refusing participation
- Pressuring employees or students due to hierarchical power

What is Undue Influence?

Undue influence = an excessive or inappropriate offer that distorts someone's ability to judge risks or benefits.

Examples:

- Extremely large payments
- Access to scarce or high-value services
- Offers that feel "too good to refuse," especially to individuals in need

Avoiding Coercion & Undue Influence

Key Mitigation Strategies:

- Utilize staff who are not in a position of authority over participants
- Ensure adequate decision time
- Use clear, simple language
- Keep incentives appropriate
- Create a no-pressure environment
- Reinforce voluntariness and right to withdraw
- Add protections for vulnerable groups

Case Studies

Case Study #1

A study seeks to collect blood and fluid samples from subjects on extracorporeal ventilation after presenting to the emergency room. The first timepoint for sampling is immediately following the subject being placed on the ventilator.

When the LAR is contacted by the study coordinator, they decline participation in the study. Therefore the sample taken prior will not be used for research and will be discarded.

Once the PI is notified of this, they want to call the LAR and talk to them about how important this study is.

Case Study #1 (cont)

What should the coordinator say to the PI?

Case Study #2

A clinical trial testing a new migraine drug recruits patients directly from a neurology clinic. Treating physicians introduce the study during routine visits and emphasize the $2,500 compensation and increased monitoring. The study starts with an overnight sleep study and the study has a lot of follow-up visits.

Many patients served by the clinic have limited financial resources.

Although patients are told participation is voluntary, recruitment occurs in the exam room immediately following clinical care. Some patients feel pressure to enroll because their migraines are so severe and the invitation comes from their physician so they think it will likely help them.

Case Study #2 (cont)

How could the recruitment process be changed to lessen the risk of coercion and undue influence?

Case Study #2 (cont)

One participant enrolls primarily due to financial need and later feels unable to withdraw despite the study drug making them feel very tired and ill.

The study coordinator who is conducting the follow-up visits identifies this as an adverse event. What action should the coordinator take?

Case Study #3

A study seeks to learn more about self-injurious thoughts and behaviors in teenagers. The study team plans to recruit participants through child psychiatrists and counselors.

Study activities consist of a survey with open-ended questions inviting participants to describe their thoughts, feelings, and circumstances before, during, and after a past incident of self-harm. In several cases, parents express strong interest in their teenagers' participation and actively pressure them to enroll as they believe talking more about their feelings will help them although there is no treatment component to this study and it is not known whether the research will have any benefit for the participants.

The study team is concerned that the teenagers may participate only due to pressure from their parent.

The study team emphasizes voluntariness to the child, however, they acknowledge that parental influence may undermine the child’s ability to provide meaningful assent.

Case Study #3 (cont)

What does the research team do to ensure voluntariness of the participant?

Case Study #3 (cont)

The teenager has now actively declined to participate.

How does the research team respond if the participant declines to participate, but the parent is saying their teen will participate?

PARENTAL PERMISSION + ASSENT = RESPECT FOR PERSONS IN RESEARCH INVOLVING MINORS

Essential Elements of a Strong Consent Process

- Low pressure environment
  - Build rapport
  - Invite rather than persuade
- Interactive approach - "teach back" model
- Culturally sensitive - group & family influences
- Adaptable to the needs of the participants
  - Literacy pre-check
  - Open-ended questioning to gauge preferences and address unique concerns
  - Multi-modal

From an IRB Chair's Perspective

- You are the content and context expert for your study
  - Where the consent process will occur
  - Practical challenges that affect when consent occurs
  - Nuanced understanding of the study population
- Many members, especially the community members, do not have these insights
- Clearly describe your reasoning for your planned approach to help members understand how you have:
  - Optimized the setting for privacy
  - Created an environment that prioritizes voluntariness

Additional OHRE Updates

Updates: Investigator Guidance (IG)

IG1101- Obtaining Informed Consent from Research Participants

Investigator Guidance: A New Look!

Objective:

Aid investigators in completing the IRB application by proactively addressing some of the most frequently asked questions and reasons for stipulations returned to the study team

What you should know:

- Companion document created to supplement regulations, established policies, and SOPs.
- Investigator Guidance (IG) will be named to link it to it's related UNC OHRE SOP
  - SOP 1101: Obtaining Informed Consent from Research Participants → IG1101
- Living document, will change over time. We recommend bookmarking the OHRE webpage and accessing the document directly when needed rather than saving a copy: you may miss important updates to the guidance

Where to find it:

Posted on the OHRE website, under "SOPS and Guidance"

Guidance Review

- Parts of the document

IG1101

Title:	Investigator Guidance- Obtaining Informed Consent from Research Participants		
Investigator Guidance #:	IG-1101	Effective Date:	3-17-2026
Previous Version Dates:			

This investigator guidance document outlines the expectations for investigators, provides frequently asked questions (FAQs), and presents various scenarios with situational applications of requirements for research conducted under the auspices of the University of North Carolina at Chapel Hill (UNC-Chapel Hill). It should be used in conjunction with SOP 1101, 45 CFR § 46.116, and 21 CFR Part 50 Subpart B.

Audience: Investigators and research staff

1 Frequently Asked Questions

Informed Consent for Screening, Recruiting, or Determining Eligibility

- Q: When is informed consent *not* required for screening research subjects?
- Q: My study does not require obtaining consent for screening, do I need to ask for a waiver of consent (for screening) in my IRB application?

Informed Consent in Exempt Research

- Q: My study is considered exempt research, do I need to obtain informed consent? Is it required, or just recommended?
- Q: If I don't need to use a full consent form for my exempt study, what should I use?

Consent and Secondary or Existing Data and Specimens

- Q: How do I obtain consent if I am only using secondary data and medical records?

  Q: Do I need to obtain new consent if the study uses secondary data from previous research?

It depends on the consent obtained for the original study. Researchers should ensure that the use of secondary data complies with the original consent agreements and ethical guidelines.

In your IRB application, please tell us in section C.1 that you have reviewed the terms under which the data you plan to use was obtained, and that your use of the data is covered under the original consent.

- Q: What if the study involves prospective collection of data* through chart review, can I obtain a waiver of informed consent and HIPAA authorization?

Expandable sections so you can find what you're looking for, and skip the rest

Links to handy worksheets, guidance docs, and templates referenced in the IG

Avoiding stips? Use these tips!

2 IRB Application Completion Tips

Help us help you! The UNC IRB would love to help you save time on your application process. This section of the guidance document will cover clarifications commonly requested by the IRB and how to better respond to application questions.

Part D (The consent process)

- **D.1.2. Will adult subjects be enrolled in your study?**
- **D.1.3. Will decisionally-impaired subjects be enrolled in your study? (includes unconscious patients, some psychiatric disorders, others who lack the capacity to give consent)**
- **D.2. Waiver of written documentation of informed consent**

3 Resources

OHRP- Informed Consent FAQs

Exempt Studies-Information/Fact Sheet Template

Waiver of Informed Consent when Using Medical Records or Other Secondary Data or Specimens

UNC-CH OHRE Guidance Document: Waiver of Informed Consent when Using Medical Waiver of Informed Consent when Using Medical Records or Other Secondary Data or Specimens.

Guidance: eSignature and eConsent

Need more help? Contact: Kim Brownley, OHRE Associate Director - Policy & Initiative
kim_brownley@med.unc.edu

Consent Form Guidance

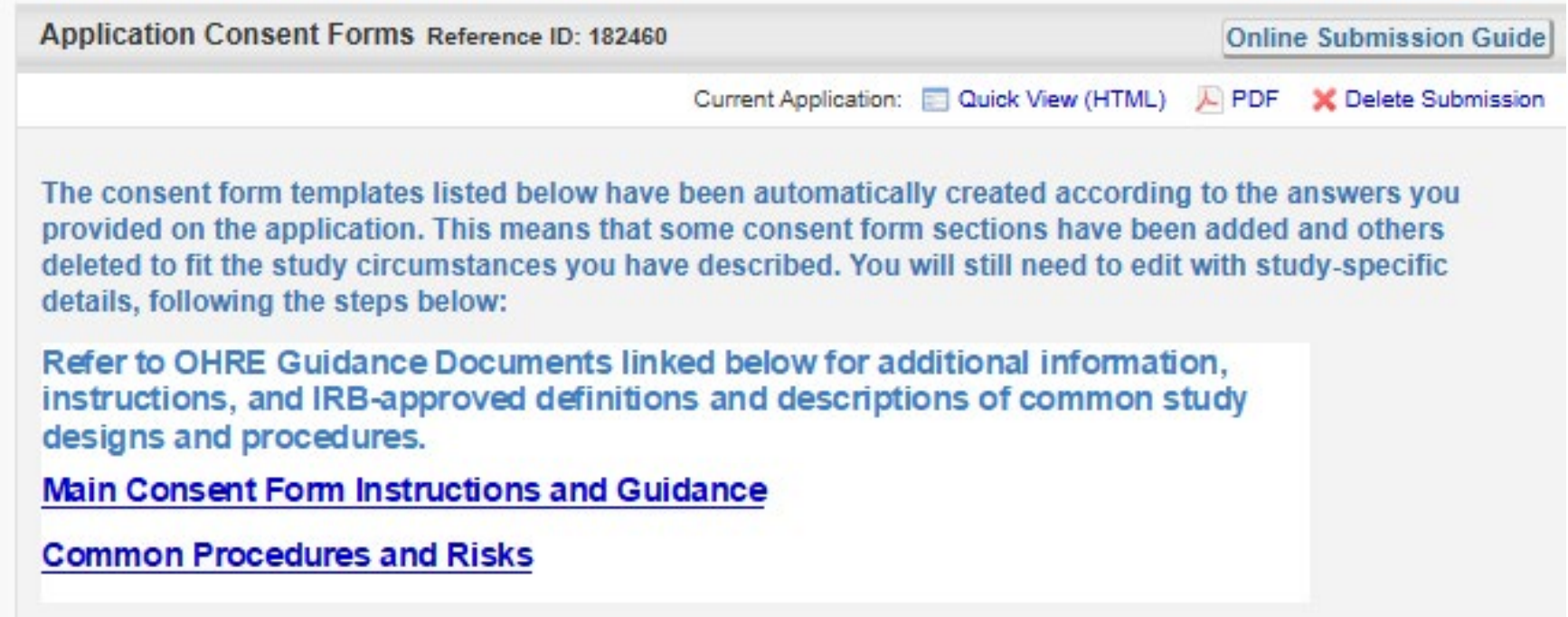
WHY ARE WE DOING THIS RESEARCH?	Provide key background information that guides the reader to an understanding of the scientific knowledge gap that the study seeks to address. Explain the main research question(s) to be addressed. You may mention, but do not overstate, the longer-term potential applications/benefits of the research to society. For example, the purpose of this study is to learn more about how differences in blood sugar levels affect brain activity. This information may eventually help researchers develop new strategies for treating diabetes. Continue to refer to the investigational nature of the drug(s) or c studied.
REASONS NOT TO BE IN THE STUDY	This section can be challenging to understand if it includes high medical eligibility criteria that are not common knowledge to p participants. It is important that this section focuses the participant's attenti factors they would easily be able to identify as pertaining to the might quickly recognize a reason or reasons they should exit th process. For example, someone is likely to know if they currently use hig pressure medication, have received a prior diagnosis of cancer, seizure event; they would know if they were not willing to refrair consumption during the study or to allow researchers to review record. On the other hand, someone would not likely know their blood or their cancer sub-type or grade, or what the medical term neu means. If the Sponsor requires all eligibility criteria to be listed, comple medical terms must be explained in lay language.

HOW MANY WILL TAKE PART?	Indicate the planned total enrollment number and if this number is only at UNC or across multiple institutions, including UNC.
HOW LONG WILL IT TAKE?	This section should help participants quickly understand the duration and frequency of study visits. Be explicit about the expected total number of hours and explain how that time will be distributed over X number of days, weeks, years, as applicable. Indicate if certain visits are much longer than others, and certain visits are in persons vs. remote, and if any visits require overnight stay at the clinic.
PROCEDURES AND RISKS	Throughout this section, it is recommended that you organize the information in order of highest to lowest risk, e.g., invasive before noninvasive, sensitive before nonsensitive. This prioritization may help a concerned person choose an off-ramp during the consent process sooner rather than later. [Describe each research activity or procedure, why it is done, what it entails, how long it will take, how often it will be done (what visits), and what risks are anticipated.] For lengthy/complex activities, consider using bullets and sub-headings rather than long narrative text. Keep the relevant sections/subheadings and delete any that are N/A for the study. Refer to OHRE document "Common Procedures and Risks" for recommended language to use in this section. Customize and complete the Table of Events; alternatively, the Table of Events may be submitted as a separate Addendum to the Informed Consent Form.

Procedures and Risks Examples

	A	C	D
1	**Procedure**	**Risks (Consent-Ready Language)**	
18	**Electromyography**	Possible minor side effects include possibly itching where the elecrodes are placed or temporary soreness or bruising at the needle insertion site. There is a small risk of bleeding, infection and nerve injury where a needle electrode is inserted. When muscles along the chest wall are examined with a needle electrode, there's a very small risk that it could cause air to leak into the area between the lungs and chest wall, causing a lung to collapse (pneumothorax).	
19	**Exercise test**	The exercise test(s) may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs.	
20	**Finger stick blood test**	You may feel a small pinch and brief bleeding.	
21	**Focus Groups**	To respect the privacy of your fellow participants, do not repeat what is said in the focus group to others outside of the group. Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. Please be as honest and open as you can but keep this in mind when choosing what to share in the group setting.	
22	**General Anesthesia (revise to what is applicable)**	The most common side effect is a sore throat from the tube in your throat. Other risks include allergic reactions to anesthesia medications such as skin rash, nausea and vomiting, difficulty breathing, confusion, memory problems, and effects on heart function and blood pressure. You may get a cut on the lip or a chipped tooth from placing the tube in your throat. This medication may show up on a urine or blood drug screen.	
	Heart monitor (ECG)		

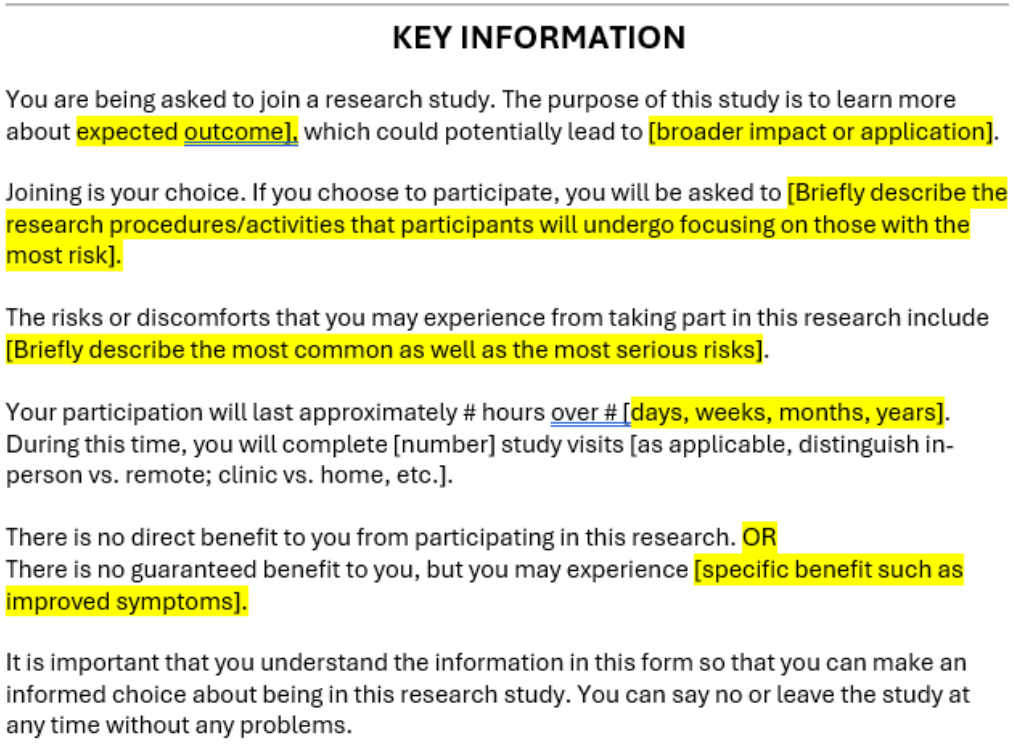
Link to Consent Form Instructions and Guidance



Consent Template Updates

Concise Summary

- Only needed if consent form > 5 pages
- Renamed to align with regulations
- Easy to use prompts
- No more guessing what to include



KEY INFORMATION

You are being asked to join a research study. The purpose of this study is to learn more about expected outcome], which could potentially lead to [broader impact or application].

Joining is your choice. If you choose to participate, you will be asked to [Briefly describe the research procedures/activities that participants will undergo focusing on those with the most risk].

The risks or discomforts that you may experience from taking part in this research include [Briefly describe the most common as well as the most serious risks].

Your participation will last approximately # hours over # [days, weeks, months, years]. During this time, you will complete [number] study visits [as applicable, distinguish in-person vs. remote; clinic vs. home, etc.].

There is no direct benefit to you from participating in this research. OR
There is no guaranteed benefit to you, but you may experience [specific benefit such as improved symptoms].

It is important that you understand the information in this form so that you can make an informed choice about being in this research study. You can say no or leave the study at any time without any problems.

Section Headers

- Questions removed
- Brief descriptive header
- Should facilitate verbal consent

STUDY DESCRIPTION:
[In simple language, provide sufficient background information that will help the participant understand the gap in scientific understanding or the unmet need that the research will address]
By conducting this study, we expect to learn more about [Explain the anticipated immediate outcomes of the study]. The researchers hope to use the new information learned from this study to [Identify the longer-term implications of the study].

You are being asked to be in the study because [describe the reason]. About [total number] people will take part at this University. OR About [total number] people will take part at all research sites.

REASONS TO NOT BE IN THE STUDY:
[List reasons that are recognizable to the potential participant. Avoid listing reasons that are beyond the participant's immediate knowledge, e.g., specific laboratory values]
You should not be in this study if:

[As applicable]If you agree to be in the study and sign this consent form, the study team will do an in-depth assessment to be sure you are eligible to participate. If they find any reason you are not eligible, they will let you know.

RESEARCH PROCEDURES AND RISKS:
[For studies with multiple visits and procedures, it is HIGHLY RECOMMENDED to include a Time and Events Schedule/Table in this section or as an addendum to this form.]

Compound Consent

Addition of HIPAA Authorization to Privacy and Confidentiality section

PRIVACY AND CONFIDENTIALITY:
If you take part in this study, we cannot guarantee complete privacy and confidentiality.

To protect your privacy during our interactions with you, we will [Describe how you will maintain privacy during telephone calls, in-person visits, etc].

To protect the confidentiality of your information that we collect, we will [Edit for accuracy; see Companion Document for additional prompts to consider].

- Remove your name and other personal details from your data prior to analysis.
- Not print your name or private information in any reports or publications.
- Store the list that matches names and codes on a secure private server hosted at the University of North Carolina at Chapel Hill.
- Store all electronic data on a secure, password-protected computer system at the University of North Carolina at Chapel Hill. Only approved research staff can access it.
- Keep any paper records in a locked cabinet at the University of North Carolina at Chapel Hill. Only approved research staff can access the cabinet.
- Ask you to sign a separate form allowing us to review your medical records.

Participants will/will not [select one] be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH PURPOSES

Participation in research may involve some loss of privacy. However, to the extent possible the University of North Carolina at Chapel Hill ("University") is committed to respecting your privacy and keeping health information that identifies you safe. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), a federal law, provides additional protections of your medical records and related health information. One of those protections requires your written authorization for your health information to be used in this research study. This form ("HIPAA Authorization") is intended to inform you about how

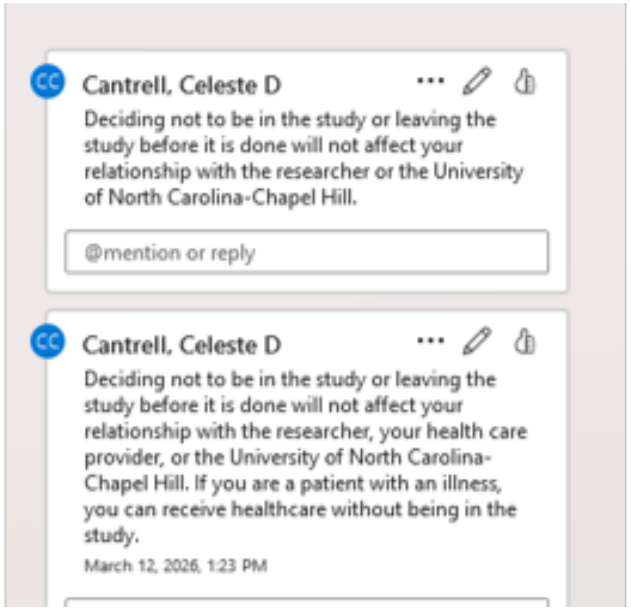
Increased Use of "Tags"

There is no guaranteed benefit to you, but you may experience [specific benefit such as improved symptoms].

It is important that you understand the information in this form so that you can make an informed choice about being in this research study. You can say no or leave the study at any time without any problems. [UNC] [UNCHC]

The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your family, friends, and doctor before deciding.

If you are interested in learning more about this study, please continue reading the rest of this document.



RESEARCH PROCEDURES AND RISKS:
[For studies with multiple visits and procedures, it is HIGHLY RECOMMENDED to include a Time and Events Schedule/Table in this section or as an addendum to this form.]

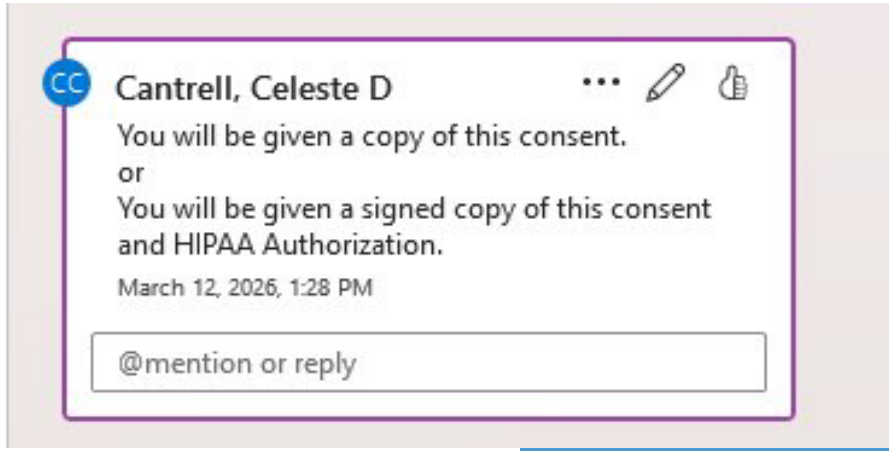
[BIOMEDICAL-GENETICS][INTERVIEW][FOCUS GROUPS][QUESTIONNAIRES]

OTHER PROCEDURES AND ACTIVITIES:[e.g., study diaries, diet/lifestyle changes]

[FOLLOW-UP PROCEDURES]

Signed Copy of Consent

QUESTIONS ABOUT THE STUDY:
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.
[COPY][COPY WITH HIPAA][CLINICALTRIALS.GOV]



Stored Specimens Changes

If storing specimens already collected as a part of the main study

- Specimen sections included in main consent form
- Optional storage can be described and indicated with a checkbox/initials

Optional Specimen Collection and Storage

- Shortened to describe only optional collection and storage
- Removed sections that are already in the main consent form
- Single form for both storage with and without identifiers

Specimen "Addendum"

University of North Carolina at Chapel Hill
Optional Collection and Storage of Biological Specimens

DELETE THIS AND ALL OTHER INSTRUCTIONS IN ITALICS AND YELLOW HIGHLIGHTS. The consent form must be written in 2nd person (e.g., You are being asked to take part in a research study about)

Consent Form Version Date:
IRB Study #
Title of Study:
Principal Investigator:

Study Contact Telephone Number:
Study Contact Email:

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child.

This document describes procedures for collecting and storing additional specimens in addition to those collected in the main portion of the study. Your specimens will be stored with other specimens from other people in what's called a biobank. You do not have to agree to participate in this optional specimen collection and storage to be in the study.

PURPOSE OF THE BIOBANK
Research with specimens can help researchers understand how the human body works. Researchers may develop new tests to find diseases, or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store specimens to use them for different kinds of research or share them with other scientists in a biobank.

- State the type and amount of specimens to be collected.
- Describe purpose for the specimen collection and storage and what you hope to learn from the stored samples.
- Provide a specific description of the research to be conducted with the specimens if known.

RESEARCH PROCEDURES AND RISKS
- Provide specific details about how the specimen will be collected, including frequency and size/amount.

STORAGE AND FUTURE USE
Address specific areas about how the sample will be used and stored:

- Provide a clear description of the operation of the specimen biobank
  - Where will the specimen be stored?
  - Who will have access to the link?
  - When will the specimens be destroyed?
- If applicable, please describe how clinical or study data will be linked to the specimens for future use.
- Inform subjects of conditions under which data and specimens will be released to other investigators.

Insert any contract, grant or agreement language related to specimen ownership or modify the following boilerplate.
UNC-Chapel Hill [or replace with the organization that will retain the specimens] will own your specimens and may use them for research that may lead to a profit. You [will/will not] get any of the money if UNC-CH [or organization] or companies use your samples to make money.

POTENTIAL BENEFITS
Benefits to you are unlikely. Studies that use specimens from this biobank may provide additional information that will be helpful in understanding (specify if biobank focus known).

PRIVACY AND CONFIDENTIALITY
Indicate how privacy and confidentiality will be protected.

- Include protection of identifiable data.
- Describe methods to be used: coding, etc.
- Describe how the records will be secured.
- Include who may have access to the records, if names will be used, or if there will be ID numbers only, and a linkage file.

[if using study data only with no new medical information collected] Information from your study and/or medical record may be stored along with your specimens(s).

[if applicable] The specimens may be shared with researchers at this or other institutions [include name of other institutions, if known]. Research studies may be done at many places at the same time. Your personal identifying information will not be sent to other researchers.

Specimen "Addendum"

RESEARCH RESULTS

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally.

[*If identifiers/codes*] There are no plans to re-contact you or other subjects with information about research results.

[*If no identifiers*] In this case that would be impossible, because the researchers have no information that identifies you.

WITHDRAWING YOUR SPECIMENS

[*If no identifiers*] You may not withdraw your specimen in the future because there are no identifiers on the specimen and the researchers will not know which specimen is yours.

[*If have identifiers/codes*]If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing.

The researchers will use data from any study in progress or already done before you withdraw your specimens. Once the researchers have been notified, your remaining specimens will be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

Contact us

- 919-966-3113

UNC Research

Evaluation

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
NRP Network for Research Professionals

Post-session evaluation:

https://go.unc.edu/NRPMarEducEval

or scan the QR code.

Attendance Certificate: An option to **download** certificate, BEFORE submitting the eval, is located within the post session eval survey.

Email: NRP@unc.edu if further questions or suggestions for future education.