**NSU Biomedical Template for Waiver of Documentation of Informed Consent (v2023-08-31)**

**Read all instructional pages prior to beginning your consent form.**

**When should this template be used?**

This template is intended for studies that meet **all** of the following criteria:

1. Will enroll adult participants over the age of 18 who are able to provide consent to participate in a research study.
2. Investigators will seek IRB Waiver of the requirement that participants must sign the consent form. In order to be granted a waiver of documentation the IRB must determine either:
	1. The principal risk to participants is a potential loss of confidentiality and a signed consent form is the only record linking participants to the study. **OR**
	2. The study does not involve procedures that would require written consent outside of a research context.
3. The study is considered a “biomedical research study,” which is defined as:
	* A study testing prospective interventions (which may include placebos or other controls) to evaluate the biomedical or behavioral health-related outcomes.

**Instructions for completing Consent Form Template**

* This consent form should be written in 2nd person, this is the “you” perspective.
* **Read all instructions** prior to drafting your Informed Consent Form.
* All instructional text is in RED or is Yellow Highlighted.
* RED text in brackets [ ] should be replaced with information relevant to your study. For example, [your name here] would be replaced with your name. Change all text to black before submitting.
* Yellow Highlighted text provides instructions and helpful information for completing the section.
* Some sections may not apply to your research study. The instructions for these sections will indicate whether or not you can delete them if they do not apply to your study. Delete or revise those Sections as needed. Some Sections cannot be revised or deleted because they contain regulatory or institutional language. Contact your College Representative for guidance if you feel certain sections do not pertain to your study.
* **Do not** copy/paste directly from your research protocol, proposal, grant application, etc.
* **Do not** alter the letterhead, header/footer, side margins, font size (11 point), or font style (Arial) of this template.

**Readability**

* Write the consent form in laymen terms and aim for an 8th grade reading level on the Flesch-Kincaid (FK) grade level readability test. Review the [**NSU IRB Readability Level of Consent Documents**](https://www.nova.edu/irb/manual/readability-level-of-consent-documents.pdf) guidance sheet for more information.
* For reference, this entire document has been written at an 8.9 reading level on the Flesch-Kincaid (FK) grade level readability test.

**Before you attach the Consent Form to your IRB submission, you MUST:**

1. Delete this instructions page, all Yellow Highlighted instructional text, remove all [ ] and any RED text not relevant to your study.
2. Change all RED text to BLACK.
3. Remove all Comments, Notes, and/or Track Changes.

**Waiver of Documentation of Informed Consent (v2023-08-31)**

**NSU Consent to be in a Research Study Entitled**

[*Title of Study (in Italics)*: must match title listed on New Protocol Submission xForm]

**Who is doing this research study?**

College: [List the Principal Investigator’s College. You may also list both College and Department/Academic Sub-Unit]

Principal Investigator: [Name of Principal Investigator, along with earned degrees, DO NOT LIST DEGREES IN PROCESS]

Faculty Advisor/Dissertation Chair: [insert Faculty Advisor/Dissertation Chair or GME Resident Program Director along with earned degrees] If you are not a student or GME Resident, delete this field.

Co-Investigator(s): [insert names of Co-Investigator(s), along with earned degrees.]

Site Information: [List name, contact information, and addresses for all research sites.]

Funding: This study is funded by [insert name of sponsor, such as NSU Grant, For-Profit Company, Non-Profit or Federal Agency].

If there is no funding, delete previous statement and list: This study is unfunded.

**Conflict of Interest Disclosure:**

Include if any of the investigators are the participants’ treating physician, otherwise delete. Your doctor is doing this research study. They are interested in both your clinical care and the research study. You have the right to talk about this study with someone else who is not part of the research team before deciding if you want to be in this research study.

**Introduction:**

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to decide about participating. You can discuss your decision with your family, friends and other trusted people.

**What is this study about?**

This is a research study, designed to test and create new ideas that other people can use. The purpose of this research study is to [Limit explanation to why study is being done. Explain in lay language in 1-3 sentences.]

For studies involving an investigational drug and/or device, include this statement, otherwise delete: This research involves an [investigational drug and/or device] that is not approved by the U.S. Food and Drug Administration or has not been approved for the purpose being used in this research study.

**Why are you asking me to be in this research study?**

You are being asked to be in this research study because [Explain why the person may qualify to participate in the study. Do not repeat the inclusion criteria. For example:

* They have the disease being studied. Explain why this person may want to participate.
* They are already scheduled for the procedure being studied.
* They have not responded to the standard care etc.]

This study will include about [list total number to be enrolled] people. If this is a multi-center study and only some people will be recruited at this location, include the following sentence, delete if not applicable. It is expected that [insert local number to be enrolled] people will be from this location.

**What will I be doing if I agree to be in this research study?**

While you are taking part in this research study, [Give a 2-3 sentence summary of what participant will be doing. For example: *After watching a presentation you will take a survey then participate in a focus group*.].

You will be in this study about [insert number of days, weeks, months or years]. You may have to come back to the [study site] every [insert number of days/months/years]. (For example: *You may have to come back to the clinic once a week for 3 weeks.*) [Delete if not applicable]

**Research Study Procedures** – If you choose to be in this study:

Explain what will be happening to the participant or what they will be asked to do during the study. Use simple, non-scientific language. Describe the time commitment for each part of the study. Include a total time for participation. All procedures that involve participants listed in the protocol should be described here. All experimental procedures (e.g., interventions, manipulations, treatments) should be specifically noted. Using bullets or numbered lists helps readability for participants.

* Describe the screening process and how participant eligibility will be determined.
* Describe all the procedures/visits and their purpose. Only describe what involves the participant.
* Describe in chronological order.
* Use layman terms. Define all terminology and acronyms the first time they are used.
* Describe all hospitalizations and outpatient visits.
* Describe all telephone, virtual, or written follow-up with participants.
* If there is more than one group of study participants, describe how they will be assigned to study groups, such as the randomization method, by location, etc.
* Identify the procedures which are Standard of Care. Standard of Care is any procedure that would have been done if the participant was not in the study.
* Identify which procedures are experimental and are being done solely for research purposes.
* Quantify procedures – for example:
	+ Number of each procedure per visit and total for study
	+ Be as specific as possible (For example: “1 hour survey”, not “a short while”).
	+ Average length of time to complete each survey or questionnaire
	+ Volume of blood, saliva, or other samples per visit and total volume for entire study
* Describe the length of each visit or describe the length of time the research procedures will add to a routine care visit. It is not necessary to state time needed to complete each research procedure. It is important that participants know the time requirement for each study visit.

Delete if the study does not include Whole Genome Sequencing of biospecimens.

This study includes Whole Genome Sequencing as part of the planned analysis of your biospecimens. Whole Genome Sequencing is a laboratory method used to determine the entire genetic makeup of a specific person.

Insert the below section only if participation may be removed early by the investigator or sponsor.

**Could I be removed from the study early by the research team?**

There are several reasons why the researchers may need to remove you from the study early. Some reasons are: [Describe any reason a participant could be removed from the study. i.e., if it appears that the participant may be in danger, no longer meets inclusion criteria, fails to follow study interventions, etc.]

If applicable, add:

The researchers will tell you how you can get medical care when you are no longer in the study.

**Are there possible risks and discomforts to me?**

This research study involves little risk to you. To the best of our knowledge, the things you will be doing have no more risk of harm than you would have in everyday life. [Revise this statement based on your study design.]

Some of the most likely risks of being in this study include:

* List risks in bullet points.
* Risks may be physical, emotional, legal, social, economic, or group/community. Do not include a risk if it does not apply to your study.
* Note the difference between study risks and risks that would happen even if they are not in the study.
* Do not include results of animal studies unless there is no other known risk information and including would aid participant understanding.

Include the following statement if the research involves any procedures which could cause possible emotional or mental harm:

You may find some questions we ask you (or some things we ask you to do) to be upsetting or stressful.

Choose one of the below options.

If the researcher is prepared to offer referrals to appropriate support services, add: If so, we can refer you to someone who may be able to help you with these feelings.

If the researcher is prepared to offer materials to help participants with these feelings, add: If so, we can provide you materials to help you with these feelings.

**What other options are there to being in this research study?**

[Option 1] If there are other procedures or treatments that might be beneficial to the participant.

You do not have to participate in this study. There are other options available to you. Your other choices may include:

Select relevant options from the list below and add other available alternatives.

* Getting treatment or care for your condition without being in a study. [Describe other procedures or treatments that might be beneficial to the participant.]
* Taking part in another study if there is one available.
* Getting no treatment or receiving comfort care to relieve your symptoms and discomfort.
* The FDA approved the study treatment. You may receive [study treatment] outside of this study.

These options may have risks. Discuss the possible risks and benefits with study staff.

[Option 2] If there are no other procedures/treatments that might be beneficial to the participant and the only alternative is to not participate.

If you do not want to be in the study, there are no other choices except not to take part in the study.

**What happens if I am injured because I took part in this study?**

The researchers have taken steps to minimize the known or expected risks. You may still have problems or get side effects even though the researchers were careful to avoid them. Contact Principal Investigator right away if you think you have suffered a research-related injury or a bad reaction. Their contact information can be found in the contact section at the end of this form.

For research involving more than minimal risk:

If there's payment, medical or other treatment, etc. available FROM SPONSOR, put that language here. If not, delete. Include whether payment, medical, or other treatments are available if injury happens. Describe treatment or where further information may be found. Specify how the treatment will be paid for, i.e., provided by sponsor or from PI funds. NOTE: NSU does not have a program to provide compensation if injury occurs due to participation in a research study.

For clinical trials, include the following: Nova Southeastern University does not have a program to pay you if you are hurt or have other bad results from being in this study. Medical care at Nova Southeastern University is open to you as it is to all sick or injured people. The cost for such care will be billed to you or your insurance company.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed because of participation in this study.

**What happens if I do not want to be in this research study?** Choose one of the following options:

[Option 1] If the participant CANNOT request that their data not be used, use the following:

You can leave this research study at any time or refuse to be in it. There will be no penalty or loss of services. Any information about you that was collected **before** the date you leave the study will be kept in the research records for 36 months from the end of the study. This data may be used as a part of the research. [All records must be kept for a minimum of 36 months but may be kept longer if stated here].

[Option 2] If the participant **CAN** request that their data not be used, then it should read:

You can leave this research study at any time, or not be in it. There will be no penalty or loss of services. Any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the end of the study. You may request that it not be used. [All records must be kept for a minimum of 36 months but may be kept longer if stated here].

**Are there risks if I leave the study early?**

Tell the study doctor if you are thinking about stopping or have decided to stop. They will tell you how to stop your participation safely. Choose one of the following options:

[OPTION 1] If there are risks if participants leave the study early, discuss the following:

* Describe any safety or risk concerns about leaving the study.
* Explain what procedures will be completed if leaving the study early. Describe the risks if these procedures are not followed.
* Address any issues regarding continued treatment.]

[OPTION 2] If there are no risks if participants leave study the early, include “There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.”

**What if there is new information learned during the study that may affect my decision to remain in the study?**

Any information that may impact your decision to remain in this study will be given to you by the investigators. You may be asked to sign a new Informed Consent Form if the information is given to you after you have joined the study.

**Are there any benefits for taking part in this research study?** Choose one of below options, monetary compensation is NOT a benefit.

[Option 1] If there are direct diagnostic benefits or direct therapeutic benefits, insert:

The possible benefit of your being in this research study is [describe the benefits related to the intervention or procedure and/or benefits which is likely to contribute to the well-being of the participant]. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this research study will benefit other people with similar conditions in the future.

[Option 2] If there are no direct benefits, insert:

There are no direct benefits from being in this research study. We hope the information learned from this study will [describe any indirect benefits participants will receive or how it will help others with conditions similar to theirs.]

**Will I be paid or otherwise compensated for being in the study?** Choose one of below options:

[Option 1] If there is no compensation insert:

You will not be given any payments for being in this research study.

[Option 2] If there is study related compensation or reimbursement insert the information below. Keep in mind that reimbursement is repayment for costs to the participant because they agree to be in the study, such as car mileage, airfare, hotel accommodations, etc.

* Describe the amount or type (cash/check/gift card). Specify retailer for gift cards),
* When it will be paid/provided. Provide details on frequency of compensation and timing.
* Provide a schedule or timetable if the compensation will be prorated when participants do not complete the study.

Delete if no commercialization of a product derived from biospecimens is planned.

You will not be given any share of the money from any commercial product derived or developed from your biospecimens used as part of this research study.

**Will it cost me anything?**

There are no costs to you for being in this research study.

Revise the above statement only if there are costs to the participant for enrolling into the study. Describe any study related costs the participant may be responsible for paying.

Ask the researchers if you have any questions about what it will cost you to take part in this research study. This could include bills, fees, or other costs related to the research.

**Will clinically relevant research results be shared with me?** Choose one of the options below that best describes your study.

[Option 1] The study investigators plan to share some research results with certain people who are in the study. These results will only be shared if they think they are important for you to know. The results will be shared with you in an [individualized, aggregated] format, meaning that the results [apply only to you; apply to an entire group of people]. The study team will share these results by [Describe plan, including timing, resources, and method. Include a description of the results to be shared and the reasons why they are clinically relevant.]

[Option 2] The study investigators do not plan to share research results with people in the study.

**How will you keep my information private?**

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. [Describe procedures for protecting privacy].

Only people who need to review your information will have access to study files. Organizations or people that may review and copy your information include:

* Members of the research team
* NSU Institutional Review Board and other representatives of this institution responsible for overseeing the research
* [Include if applicable:] People who do tasks for the study, such as scheduling tests, performing procedures, and billing.
* [For federally funded studies only, include the funding agency and:] The U.S. Office for Human Research Protections
* [For FDA-regulated studies only, include:] The U.S. Food and Drug Administration (FDA)
* [Include if applicable:] Regulatory Authorities from other countries
* [Include if applicable:] The study sponsor, [name of sponsor]
* [Include if applicable:] Collaborating researchers outside of NSU, including researchers at [name collaborating institutions]
* [Include if applicable:] Companies or groups performing services for the study, such as [add examples of services, e.g.: laboratories outside of NSU]
* [Include any other individuals or entities who may access study records.]

Your personal information may also be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. All confidential data will be kept [describe where and how data will be stored]. All data will be kept for 36 months from the end of the study. [all records must be kept for a minimum of 36 months but may be kept longer if stated here] They will be destroyed after that time by [describe how data will be destroyed].

For all FDA regulated drug (including biological products) and device clinical trials the following statement must be included **EXACTLY AS WRITTEN. DO NOT** change this statement: A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. The Web site will include a summary of the results. You can search this Web site at any time.

If no audio or video recording is used during the study, this section may be deleted.

**Will there be any Audio or Video Recording?**

This research study involves audio and/or video recording. This recording will be available everyone listed in the section above, as applicable. The recording will be kept, stored, and destroyed as stated in the section above. Because a recording could be used to find out that it is you, it is not possible to be sure that the recording will always be kept confidential. The researcher will try to keep anyone not working on the research from listening to or viewing the recording.

Delete this section if no student/academic information will be used in the research study.

**What Student/Academic Information will be collected and how will it be used?**

The following information will be collected from student educational records [records being collected]. These records will be used to [describe how these records will be used]. These records will be given to the Principal Investigator by [indicate how the records will be obtained].

If your study involves banking biological materials (tissues/specimens) for future use, pick the statement below that best describes your study and delete the other option. If your study does not involve banking biologic material, delete this section.

**Will my biological specimens be used in future research studies?** Choose one of below options:

[Option 1] There is a possibility that the [data/tissues/specimens/blood] collected from you may be shared with other investigators in the future. If that is the case, the [data/tissues/specimens/blood] will not contain information that can identify you. You will not be contacted or asked to provide consent for the use of this data and/or specimens.

[Option 2] The research team will not re-use or share your study data and/or specimens for use in future research studies.

**Whom can I contact if I have questions, concerns, comments, or complaints?**

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Primary contact:

[Insert name and degrees] can be reached at [provide telephone number(s), with area code, that will be readily available during and after normal work hours]

If primary is not available, contact:

[Insert name and degrees] can be reached at [provide telephone number(s), with area code, that will be readily available during and after normal work hours]

**Research Participants Rights**

For questions/concerns regarding your research rights, please contact:

Institutional Review Board

Nova Southeastern University

(954) 262-5369 / Toll Free: 1-866-499-0790

IRB@nova.edu

You may also visit the NSU IRB website at [www.nova.edu/irb/information-for-research-participants](http://www.nova.edu/irb/information-for-research-participants) for further information regarding your rights as a research participant.

**All space below was intentionally left blank.**

Use the above statement if there is significant blank space left at the end of this document before the signature page. If there is no blank space, delete.**Do not edit any of the content on this page except for this highlighted text.** This section MUST be on a separate page from rest of consent document exactly as it appears here except for deletion of yellow highlighted help text.

**Research Consent & Authorization Signature Section**

Voluntary Participation - You are not required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

**AGREE TO THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:**

* You have read the above information.
* Your questions have been answered to your satisfaction about the research.

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