NYCHP Biomedical Template for Waiver of Documentation of Informed Consent

Read this entire instructional page prior to beginning your consent form.

Who can use this template?

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:
    a. 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**
    b. 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 research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Instructions for completing Waiver of Documentation of Consent Form Template

- 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 pertinent to your study, e.g., [your name here]. All text should be changed to black before submitting.
- Yellow Highlighted text provides instructions regarding the inclusion or deletion of sections, along with helpful information for completing the section.
- Some sections may need to be revised in order to meet the needs of your research study (i.e. replacing template language where necessary, deleting sections that do not pertain to your study). Contact your College Representative for guidance if you feel certain section do not pertain to your study.
- Consent form needs to be written in laymen terms with around an 8th grade reading level when tested against the Flesch-Kincaid (FK) grade level readability test. Review the **NYCHP IRB Readability Level of Consent Documents** guidance sheet for more information.
- **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.

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

- Delete this instructions page, all Yellow Highlighted instructional text, and any RED text not relevant to your study.
- Change to BLACK all RED text you replaced with your study information.

- Remove all Comments, Notes, and/or Track Changes.

Waiver of Documentation of Informed Consent
NYCHP 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 academic department under which you are conducting this research study. If you are in a sub-department, 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 CEME Resident Program Director along with earned degrees] If you are not a student or CEME Resident, delete this field.

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

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

Funding: If funded by an institution or agency, add the following statement and note funding source. This study is funded by [insert name of NYCHP Grant, For-Profit Company, Non-Profit or Federal Agency]. If there is no funding, list: Unfunded

Conflict of Interest Disclosure:
Include if any of the investigators are the participants' treating physician, otherwise delete. Your doctor, who is also doing this research study, is 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.

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 [Provide a brief (3-5 sentences) background of the research study. See guidelines below].

- Briefly describe in lay-terms the purpose of the research study.
- Explain any potential benefits to others or reasons why this study needs to be done.
- Explain technical terms so that information is clear to participants. Use lay terms first, followed by any medical terms in parentheses, if applicable.

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 candidate or person may qualify to participate in the study. This is not intended to be a repetition of the inclusion criteria]. For example,

- because they have the disease being studied and if applicable, why it is reasonable for this particular participant to participate;
- they are already scheduled for the procedure being studied,;
- they have not responded the standard care etc.]

This study will include about [insert anticipated total number to be enrolled] people. If this is a multi-center study and only a portion of participants will be recruited at this location, include the following sentence. It is expected that [insert anticipated total 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, [Outline how many sessions, and how long each will take]. (e.g. 3 consecutive sessions, 1 per week, for 15 minutes each, PLUS final session for 30 minutes)].

You may have to come back to the [study site] every [insert number of days/months/years].

Research Study Procedures - as a participant, this is what you will be doing:

[Describe study procedures, in paragraph form, using the guidelines listed below]

- Discuss in lay language, all the procedures/visits in chronological order and their purposes. When listing procedures, be as specific as possible (i.e. “1 hour of survey”, not “a short while”).
- Describe all screening procedures used to determine eligibility to participate in research study.
- If there is more than one group of study participants, describe how they will be assigned to study groups and whether it is with or without randomization.
- Identify the procedures which are standard and that would have been done, even if they were not in the study (in the same timing and frequency) and which procedures are experimental (done solely for research purposes).
- Quantify procedures – for example
    - Number of each procedure per visit and total for study
    - Average length of time to complete each survey or questionnaire
    - Volume of blood samples optional unless:
        a) volume obtained exceeds 550 ml in an 8-week period from healthy, non-pregnant adults, or
        b) volume obtained from other (not healthy, or pregnant) adults and children, the amount drawn exceeds the lesser of 50 ml or 3 ml per kg in an 8-week period
- All hospitalizations, outpatient visits and telephone or written follow-up.
- 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, but it is important that participants be informed of 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.

Insert the below section only if participation may be terminated by the investigator/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 anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent, for example, 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 about how you can get medical care when you are not in the study any more.

Are there possible risks and discomforts to me?

This research study involves minimal 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.

Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks of procedures may be presented in a table form.

- Physical risks
- Psychological risks
- Privacy risks
- Legal risks
- Social risks
- Economic risks
- Group or community risks

Distinguish between the risks presented by participation in the research and the risks associated with any procedures or treatments that would occur regardless of participation in the research. Also, in general, do not include results of animal studies, unless there is no other known risk information and inclusion would aid with understanding.

If the research involves any procedures, which could cause possible emotional or mental harm, include the following statement:
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 treatment options are there to being in this research study?
Insert this section only if there are alternative courses of treatment or procedures, that might be advantageous to the participant, otherwise delete this section. There are other options available to you. Your other choices may include: [Provide a disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant, if applicable, otherwise delete this section. Consider the following options: 1) getting treatment or care without being in a study, 2) taking part in another study, 3) getting no treatment.]

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still have problems or get side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you have a bad reaction, please contact Principal Investigator right away. See the contact section at the end of this form for phone numbers and more information.

For research involving more than minimal risk, include whether compensation or medical (or other) treatments are available if injury occurs. If such treatment will be provided, indicate what it consists of, or where further information may be obtained. Specify how the treatment will be paid for, i.e. provided by sponsor or from PI funds. NOTE: NYCHP does not have a program to provide compensation if injury occurs due to participation in a research study.

For clinical trials, include the following: New York College of Health Professions does not have a program to pay you if you are hurt or have other bad results from being in this study. However, medical care at New York College of Health Professions is open to you as it is to all sick or injured people. If you have health insurance, the costs for any treatment or hospital care you receive as result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you. If you do not have health insurance, you will be billed for the costs of any treatment or hospital care you receive because of a study-related injury.

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?
If the participant does NOT have the option to request that their data not be used, then it should read:
You have the right to leave this research study at any time or refuse to be in it. If you decide to leave or you do not want to be in the study anymore, you will not get any penalty or lose any services you have a right to get. If you choose to stop being in the study before it is over, 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 and 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].

If the participant has the option to request that their data not be used, then it should read:
You have the right to leave this research study at any time, or not be in it. If you do decide to leave or you decide not to be in the study anymore, you will not get any penalty or lose any services you have a right to get. If you choose to stop being in the study, 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 but 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 related to withdrawing from the study early? If there are risks involved with early withdrawal from the research study, include this section; otherwise delete this section.

If you decide to stop being in the study before it is over, please talk to the principal investigator about why you don't want to be in the study any more. [State here whether participants might be at risk if they stop study participation early.

- Describe any safety/risk concerns relating from withdrawing from study.

- Explain what procedures will be performed for early study withdrawal and the risk to the participant if withdrawal procedures are not followed.
- If there are no risks associated with early withdrawal, please 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."

Address any issues regarding continued treatment if applicable.]

What if there is new information learned during the study that may affect my decision to remain in the study?
If significant new information relating to the study becomes available, which may relate to whether you want to remain in this study, this information 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.

If there are direct diagnostic benefits or direct therapeutic benefits, insert:
The possible benefit of your being in this research study is [consider adding the benefits related to the intervention or procedure and/or benefits related to a research monitoring procedure 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.

OR 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 be given compensation for being in the study?

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

Modify the above statement and include the following information if there is study related compensation or reimbursement. 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 nature (provide details such as cash/check/gift card, If using a gift card as payment, please specify what retailer),
- When it will be paid/provided (provide details on frequency of compensation and timing)
- When the compensation will be prorated if the participant does not complete the study, provide a schedule.

Delete if no commercialization of a product derived from biospecimens is planned.
You will not be given compensation or a 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.

Modify the above statement and include the following if there are study related costs the participant may be responsible for.
[Describe the possible costs to the participant that may be incurred due to participation in the research study.]

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

Will clinically relevant research results be shared with me?

Choose the option that best describes your study.
The study investigators plan to share certain research results with people who are in the study 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.]
OR
The study investigators do not plan to share research results with people in the study.

How will you keep my information private?

Information we learn about you in this research study will be handled in a confidential manner, within the limits of the law and will be limited to people who have a need to review this information. [Describe procedures for protecting privacy]. Organizations that may review and copy your information include the Institutional Review Board and other representatives of this institution. [Add to this list other organizations that may have access to participants' records such as Federal and other regulatory agencies, study sponsors, funding agencies or collaborating institutions]. If we publish the results of the study in a scientific journal or book, we will not identify you. All confidential data will be kept securely [Specify 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] and destroyed after that time by [specify how data will be destroyed].

For 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. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will there be any Audio or Video Recording?
If no audio or video recording is used during the study, this section may be deleted.
This research study involves audio and/or video recording. This recording will be available to the researcher, the Institutional Review Board and other representatives of this institution, and any of the people who gave the researcher money to do the study (if applicable). The recording will be kept, stored, and destroyed as stated in the section above. Because what is in the 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.

What Student/Academic Information will be collected and how will it be used? If no student/academic information will be used in the research study, this section may be deleted.
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].

Will my biological specimens be used in future research studies?

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.
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.
OR
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
New York College of Health Professions
(516) 000-000 / Toll Free: 1-800-922-7337
IRB@nycollege.edu

You may also visit the NYCHP IRB website at https://nycollege.edu for further information regarding your rights as a research participant.

All space below was intentionally left blank.
Please include the above statement if there is significant blank space left at the end of this document before the signature page, otherwise delete.

Do not edit any of the content on this page. 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.

Waiver of Documentation of Informed Consent Signature Section

The Participant has voluntarily decided to take part in this research study.

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date