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|  | |  | | --- | | NEW YORK INSTITUTE OF TECHNOLOGY | | Institutional Review Board for the Protection of Human Participants  Northern Blvd, Old Westbury, NY 11568 | | 516-686-7488♦http://www.nyit.edu/ospar/irb/ | |

**LONG CONSENT FORM-Template**

* You are being asked to join a research study.
* This consent form explains the research study and your part in the study.
* Please read it carefully and take as much time as you need.
* Ask questions about anything you do not understand now, or when you think of them later.
* You are a volunteer. If you do join the study and change your mind later, you may quit at any time without fear of penalty or loss of benefits.
* While you are in this study, the study team will keep you informed of any new information that could affect whether you want to stay in the study.
* If children may join this study, the word “you” in this consent form will refer to both you and your child.
* If you have any questions about this study, please contact the Principal Investigator. If you have questions about your rights as participant in this research study, contact the Institutional Review Board (IRB).

**Principal Investigator**:Name, Terminal Degree

Department

Address

Telephone; Email

**Other Researchers:** Name; Terminal Degree

**Institutional Contact:** Institutional Review Board

Office of Sponsored Programs and Research

New York Institute of Technology

Northern Boulevard, Old Westbury, NY 11568

Tel: 516-686-7488 or [grants@nyit.edu](mailto:grants@nyit.edu)

|  |  |
| --- | --- |
| **Contact in case of injury resulting from this study:** | On-Call Physician / Hallie Zwibel D.O., MPH, Medical Director, 516-686-3771 *[Inclusion of Dr. Zwibel’s name and phone number here requires his prior approval.]* |

**Title of Research:** *The title should conform to the title of any grant application/protocol.*

**A. Purpose of the Study**

*[Note to PI: Instructions are written in ITALICS. Sample text is shown in* ***black****. Delete and replace the sample text as necessary. Text should be written in language understandable to the general public. NYIT IRB recommends an 8th grade reading level. Use this website for guidance: https://www.webfx.com/tools/read-able/]*

*[In addition to stating the purpose of the study, the investigator should provide the rationale for performing the study (e.g. results of previous studies, what the study is designed to discover or establish, etc.)]*

The purpose of this study is …………

*[Describe the basic eligibility criteria, but DO NOT state that the participant has been selected for the study:]* People with ………………. may join this study.

**B. Subject Participation**

We estimate that the following number of subjects will enroll in this study:

Male: Female: At this site: Total at all sites:

*Inclusion/Exclusion Criteria*

Your participation will involve \_\_\_\_\_\_ number of visits, which will take place over\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*[Indicate the approximate total length of the subject’s proposed participation by the number of days, months or years (from screening to final termination).]*

Each of these visits will take \_\_\_\_\_\_ minutes/hours.

*[Indicate the approximate length of each visit in minutes or hours. (For example, Visits 1, 3 and 5 will each involve approximately 2 hours; visits 2 and 4 will each involve approximately 30 minutes.)]*

**C. Description of the Research**

*[Start with the statement:]* If you agree to be in this study, we will ask you to do the following things:

*[Describe the procedures chronologically using lay language, short sentences, and short paragraphs. Use subheadings and bulleted items. Identification of any procedures that are experimental; A statement that significant new findings developed during research which may relate to the subject’s willingness to continue will be provided to the subject. Also, describe the process whereby subjects will be notified of significant new findings.]*

**D. Potential Risks and Discomforts**

The following are risks and discomforts that you may experience during your participation in this research study:

*[Be accurate and reasonable; identify each intervention with a subheading and then describe any reasonable risks, discomforts, inconveniences, and how these will be managed. Review any risks related to procedures and tests relating solely to research and any tests that carry a risk of morbidity/mortality. Inform the subject of previously reported adverse events.]*

*[In addition to biomedical risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result. For example, address the risk for the loss of confidentiality of sensitive information; effect on financial standing, employability or insurability; feelings of sadness or anxiety, and legal risks that may require reporting to authorities, etc.]*

*[If appropriate, identify procedures to be followed in the event of a study-related medical emergency, such as: The site where this study will be conducted does not have emergency room facilities. In the event of a study-related medical emergency, dial 911 and NYIT Security (Telephone: 516-686-7789) immediately. In addition, please contact the on-call physician and/or the Medical Director, Hallie Zwibel, DO, MPH, (Clinic Telephone: 516-686-3771), the Principal Investigator Dr. … (Telephone: 516-686-….), and your personal physician, right away. If the study is being conducted off-campus and it has emergency room facilities and/or site-specific emergency procedures, please describe these.]*

*[If appropriate to the study, end with the statement: There may be risks and discomforts that are not yet known.]*

**E. Potential Benefits**

*[State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there are no direct benefits, state****:*** *There is no direct benefit to you from being in this study. Describe the generalizable or societal benefits and use a sentence such as: If you take part in this study, you may help others in the future.]*

*[Do NOT include financial rewards for participation in the study. Any payment to participants should be included in the “Compensation” section. Results of tests given to participants are not considered a benefit.]*

**F1. Confidentiality**

**IF YOU ARE RECRUITING FROM THE ACADEMIC HEALTH CARE CENTER or USING ANY AHCC FACILITY, YOU MUST INCLUDE THIS TEXT, MODIFIED AS INDICATED. OTHERWISE USE THE ALTERNATE SECTION F2. BELOW.**

1. **Consent to Use Your Protected Health Information for Treatment, Payment and Health Care Operations.**

You hereby consent to the use or disclosure of your health information in order that the Academic Health Care Center (herein after referred to as the Practice) may carry out treatment, payment, or health care operations. For purposes of this consent, health information shall mean any and all information relating to health care services provided to you bythe Practice, including, without limitation, information relating to services provided to you prior to this date (referred to herein as “Protected Health Information”).

The Practice has provided you its Notice of Privacy Practices (the “Notice”) that explains, among other things, the definitions of treatment, payment, and health care operations and the types of uses or disclosures that the Practice can make. You acknowledge that you have had an opportunity to review the Notice before you sign this Consent and Authorization Form. You further understand that the Practice may change the terms of the Notice from time to time and that you may contact the person designated in Section K below, at the address listed below, to obtain a revised version of the Notice at any time.

You understand that you may at any time submit a request in writing to the person designated in Section K below, at the address listed below, that the Practice restrict how your health information is used or disclosed to carry out treatment, payment, or health care operations. The Practice is not required to agree to your requested restriction. In the event that the Practice does agree to the requested restriction, however, the restriction will be binding on the Practice.

2. **Authorization to Use and Disclose Your Protected Health Information for Research Purposes.**

The Practice may use or disclose your Protected Health Information for research purposes other than carrying out treatment, payment, or health care operations, as follows:

2.1 **Your health Information.** The health information that is subject to this Section includes all health information about you created or received by the Practice.

2.2 **Authorized Persons.** You authorize the following person(s) or class of persons to request use or receipt of your health information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

2.3 **Recipient.** The Practice may disclose your health information described in this Section above to the following: ­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The address of the Recipient or where your health information should be delivered is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

2.4 **Purposes of Use or Disclosure.** By your signature below, you hereby authorize the Practice to use or disclose to the Recipient your health information described in this Section above for the following specific purpose(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

2.5 **Expiration Date.** You authorize the Practice to use or disclose your health information in accordance with the terms and conditions of this Consent and Authorization Form:

**** Until you revoke it in writing.

**** From the date of this Compound Consent and Authorization Form until the \_\_\_\_\_ of, 202\_\_.

**** Until the following event occurs:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**** None.

2.6 **Re-disclosures to Third Parties.** You understand that once the Practice discloses your health information to the Recipient in accordance with the terms and conditions of this Section, the Practice cannot guarantee that Recipient will not redisclose your health information to a third party. The third party may not be required to abide by this Compound Consent and Authorization Form.

2.7 **Refusal to Sign/Revocation of Authorization.** You understand that you may refuse to sign or may revoke (at any time) your authorization for the Practice to use or disclose your health information described in this Section above for any reason. The Practice can use or disclose your health information for the purposes of that Research Study. If you refuse to sign this Compound Consent and Authorization, the Practice may deny you participation in this Research Study. If you revoke this Compound Consent and Authorization, your participation in this Research Study will be terminated by the Practice.

2.8 **Effect of Revocation.** You understand that this authorization will remain in effect until you provide a written notice of revocation to the person listed in Section K below at the address listed below. The revocation will be effective immediately upon the Practice’s receipt of your written notice, except that the revocation will not have any effect on any action taken by the Practice in reliance on this authorization before it received your written notice of revocation.

2.9 **Other persons and organizations,** including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of NYIT will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

When your study information will be disclosed outside of NYIT as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. NYIT will not disclose the code key, except as required by law.

**F2. Confidentiality IF YOU ARE NOT USING THE AHCC, USE THIS TEXT FOR SECTION F.**

**INCLUDE THE HIPAA SECTION BELOW IF REQUIRED**

This section of the consent form describes how your information will be used and shared in this research, and the ways in which NYIT will safeguard your privacy and confidentiality. If you agree to be in this research program, Dr. [PI name] and [his/her] study team will ask you to [detail according to what project entails]. [He/She] will use these test results to [detail according to what project entails].

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of NYIT will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

When your study information will be disclosed outside of NYIT as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. NYIT will not disclose the code key, except as required by law.

By signing this form you authorize the use and disclosure of the following information for this research: *[Modify as applicable.]*

* *Your research records*
* *Observations/findings/interviews that you participate in during the course of this study*
* *Medical records.*

HIPAA Authorization

[Include if HIPAA Authorization is required. Otherwise, delete this section.]

[If included, do not alter any of the following text, except as indicated.] We are committed to

respecting your privacy and to keeping your personal information confidential. When choosing to take

part in this study, you are giving us the permission to use your personal health information including

the health information in your medical records and information that can identify you. For example,

personal health information may include your name, address, phone number or social security number.

The health information we may collect from you and use for this research includes: [Modify the list

below to reflect all health information that may be used or disclosed for research purposes.]

• All information in a medical record

• Results of physical examinations

• Medical history

• Lab tests, or certain health information indicating or relating to a particular condition as

well as diaries and questionnaires

• Records about study medication or drugs

• Records about study devices

• Billing information

• HIV testing results

• Substance abuse information: [Specify.]

• Mental health information: [Specify.]

• Genetic health information: [Specify.]

**G. Privacy/Data Security:**

*Explain briefly and in lay terms how you will protect the participant’s privacy and/or confidentiality.*

*How will sensitive data be kept secure in an electronic environment; who will have access to identifying information? Use the survey disclaimers for Qualtrics and REDCAp.*

**H. Compensation**

*[State whether the participant will be paid or offered other financial rewards. If not, state so.]*

*[List rates of payment or other financial rewards (transportation, etc.)]*

*[List method and timing of payment, and provisions for partial payment if a participant leaves the study early.]*

**I. Alternatives to Participating in the Study**

*[Describe any alternatives that should be considered before deciding whether to be in the study. Any alternative procedures or treatments that may be advantageous to the subject, thus giving the subject a full range of available options. If applicable, explain why these procedures are being withheld. When appropriate, a statement that supportive care with no additional disease specific treatment is an alternative.]*

*[Avoid suggesting that participation in the research is the only way to obtain awareness, attention, etc.]*

*[End with the statement:]* You do not have to join this study. You are free to choose not to participate in the study.

**J. Voluntary Participation and Authorization.**

Your decision to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study, it will not affect the care or services you receive and will not result in any loss of benefits to which you are otherwise entitled and that the subject may discontinue at any time.

You will be told of any significant new developments during the course of the research that may influence your willingness to continue to participate in the research.

**K. Withdrawal from the Study and/or Withdrawal of Authorization**

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. A clear statement of the consequences of a subject’s decision to withdraw from the research, and, if so, how to withdraw safely. *[In addition, if applicable, a description of circumstances under which the subject’s participation could be terminated by the investigator without the subject’s consent].*

If you decide to withdraw your consent, we ask that you contact Dr. [PI name] in writing and let [him/her] know that you are withdrawing from the study. [His/Her] mailing address is [address].

Dr. [PI name] will discuss with you any considerations involved in discontinuing your participation in the study. Dr. [PI name] may also decide to remove you from the study if he feels that to do so would be in your best interest. [He/she] will discuss with you the reasons for withdrawal.

**L. Costs/Reimbursements**

[For research involving more than minimal risk, an explanation should describe compensation; medical treatment and who bears financial responsibility; where the subject may obtain further information. *List any costs to participants for the study procedures.]*

*[List all related costs, such as parking. If none of the costs will be the responsibility of the participant, state:]* There are no costs involved to participants in this study. In case of research-related injury, the costs for care will be billed to you or your insurance. No funds have been set aside for research-related injuries. The specific office, name, and telephone number(s) of whom to contact for further information regarding the research subject’s rights, the research study, or for research-related injury.

**M. Identifiable private information or identifiable biospecimens:**

1. *A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.*

**OR**

1. *A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.*

*(if applicable) A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

*For research involving biospecimens whether the research will (if known) or might include whole genome sequencing (that is, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.*

**N. Clinical Trials** *[if applicable, the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act.* **A description of this clinical trial will be available** [**http://www.ClinicalTrials.gov**](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.**

* + *Also, a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*

**O. Audio/Video Recording**

*If audio and/or video recording devices will be used, explain why the recordings are needed for the research and what will be done with them upon completion of the research (e.g. kept indefinitely, archived after transcription, destroyed after X years.)*

*Provide a separate signature line on the consent form for the participant to be audio/video recorded, if the recording is optional for participation. For example:*

*Please sign below if you are willing to have this interview recorded (specify audio or video). You may still participate in this study if you are not willing to have the interview recorded.*

1. *I do not want to have this interview recorded.*
2. *I am willing to have this interview recorded.*

*Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; Dated\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*If you plan to take photographs or make audio, video, or other types of recordings, and you want to use the photographs/record for activities beyond research analysis (e.g., in publications, presentations, or other promotional purposes), you will need to include a section that*

* *Informs the participant that you are making a [type(s) of media used] recording in which the person’s name, likeness, image, and/or voice will be included;*
* *Asks the participant to grant you the right to make, use and publish Recordings completely or in part in media forms now known (such as film, slides, and digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;*
* *Explains the limitations on reproduction, distribution, performance, or display of images/recordings;*
* *Explains that the participant does not have rights to inspect or approve the finished product or printed/published matter that uses the images/recordings or versions of the images/recordings; and*
* *Explains that the participant will not receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images/recordings.*
* *The same signature line above may be used for this performance release information. The information provided may be altered, but you should contact the IRB office to verify it does not present any compliance or liability problems.*

**P. Additional Information**

*[Include any additional information here.]*

**Agreement to Participate in Research Study**

I have read this consent form OR

It was read to me by:

Any questions I had were answered by:

I voluntarily agree to participate in this research program

Yes

No

I understand that I will be given a copy of this signed Consent Form.

*[Include the appropriate signature lines below. Delete those that do not apply to your project]*

**FOR ADULTS CAPABLE OF GIVING CONSENT:**

Name of Participant (PRINT):

Signature: Date: / /

Signature of Person Obtaining Consent: Date: / /

**(Investigator or IRB Approved Designee)**

**FOR ADULTS NOT CAPABLE OF GIVING CONSENT:**

Name of Participant (PRINT):

Signature of Surrogate/Guardian: Date: / /

Relationship of Surrogate to Participant:

Signature of Person Obtaining Consent: Date: / /

**(Investigator or IRB Approved Designee)**

**FOR CHILDREN NOT CAPABLE OF GIVING CONSENT:**

Child’s Name (PRINT):

Name of Parent/Guardian (PRINT): Date: / /

Signature of Person Obtaining Consent: Date: / /

**(Investigator or IRB Approved Designee)**

**Note: A copy of the signed, dated consent form must be kept by the Principal Investigator and a copy must be given to the participant.**