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**Consent Form-Biomedical Research**

1. **Why am I being invited to take part in a research study?**

You are being invited to participate in this research study because:

Enter your response here

1. **What should I know about a research study?**

In this research study:

- Someone will explain the study to you.

- Your participation is voluntary; you can decide not to participate or withdraw at any time.

- Your decision will not affect your current or future medical care or other rights.

- You may ask as many questions as you need before deciding to participate.

1. **Why is this research being done?**

The purpose of this research is: *(Explain the research goals and background.)*

Enter your response here

This study aims to: *(Describe any potential benefits to others.)*

Enter your response here

1. **How long will the research last and what will I need to do?**

You are expected to participate in this research study for approximately: *(Provide specific duration.)*

Enter your response here

During the study, you will:

*(Provide a high-level summary of the procedures involved, such as receiving an investigational drug, attending study visits, providing blood samples, and completing questionnaires.)*

Enter your response here

1. **Is there any way that participating in this study could be bad for me?**

Participation in this study may involve risks such as: *(List important risks or discomforts participants may experience.)*

Enter your response here

1. **Will being in this study help me in any way?**

Participation in this study may benefit you by: *(Describe any direct benefits to participants.)*

Enter your response here

**Note: *We cannot guarantee benefits to you or others from participating.***

1. **What happens if I do not want to be in this research?**

Participation is voluntary. If you choose not to participate, alternatives include:

*(List any available alternatives or standard treatment options.)*

Enter your response here

**Note: *Your decision not to participate will not affect your current medical care or rights.***

1. **Who can I talk to?**

If you have questions, concerns, or complaints about the research, please contact the research team at: *(Insert contact information.)*

Enter your response here

*Note: You may also reach out to the Institutional Review Board (IRB) at* [*irbhelp@dyc.edu*](mailto:irbhelp@dyc.edu)*.*

1. **How many people will be studied?**

We expect approximately     people at this site.

A total number of     nationally or     internationally to participate in this research study.

1. **What happens if I say yes, I want to be in this research? (Address all the points below in the space provided below.)**

If you decide to participate, you can expect the following:

- A timeline of procedures will be provided.

- You may receive investigational drugs or biologics.

- Devices and procedures will be used as described.

- Details about hospitalizations, outpatient visits, and follow-ups will be provided.

- Some procedures are part of standard medical care.

- Indicate the study’s start date and end date.

- Blood draws will occur*. (Specify amount and frequency.)*

Enter your response here

- You will interact with: (*List individuals involved.)*

Enter your response here

- The research will take place at: *(Provide full location details.)*

Enter your response here

- Describe any experimental procedures or therapies.

Enter your response here

1. **What are my responsibilities if I take part in this research?**

If you choose to participate, you will be responsible for:

*(Describe any specific responsibilities of participants.)*

Enter your response here

1. **What happens if I say yes, but I change my mind later?**

You can leave the research at any time without consequences. If you withdraw:

*(Describe any implications or procedures related to withdrawal.)*

Enter your response here

1. **Is there any way being in this study could be bad for me? (Detailed Risks)**

*(If there are no known risks, including confidentiality issues, then state them in the appropriate areas below.)*

There are no known risks associated with these procedures.

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

• **Physical risks:** There may be potential physical harms such as discomfort, pain, injury, or adverse health effects from procedures.

|  |
| --- |
| Enter your response here |

• **Psychological risks:** There may be potential emotional or psychological discomfort, distress, or anxiety.

|  |
| --- |
| Enter your response here |

• **Privacy risks:** There is a small chance that someone who is not authorized could see your private study information.

|  |
| --- |
| Enter your response here |

• **Loss of confidentiality:** If identifiable information is collected, there is a risk of loss of confidentiality.

|  |
| --- |
| Enter your response here |

• **Legal risks:** There may be potential legal consequences related to participation in the study.

|  |
| --- |
| Enter your response here |

• **Social risks:** There may be potential impacts on your social relationships or reputation.

|  |
| --- |
| Enter your response here |

• **Economic risks:** There may be potential financial costs or loss due to participation.

*(Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise, state clearly that there are no foreseeable economic risks.)*

|  |
| --- |
| Enter your response here |

* **Other possible risks:** In addition to the risks identified above, this research may harm you in ways that are currently unknown. These harms could range from minor inconveniences to severe outcomes such as death.

*(Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise, state clearly that there are no other foreseeable additional risks.)*

Enter your response here

The procedures in this research are known to potentially harm a pregnancy or fetus in the following ways: *(Type “Not applicable” in the space provided if there are no such known risks.)*

Enter your response here

The research may also harm a pregnancy or fetus in ways that are currently unknown. These harms could range from minor inconveniences to severe outcomes such as death. *(Type “Not applicable” in the space provided if there are no foreseeable risks.)*

Enter your response here

You should not be or become pregnant (or father a baby) while on this research study. *(Type “Not applicable” in the space provided if there are no foreseeable risks.)*

Enter your response here

1. **Taking part in this research study may lead to added costs to you.** *(Include for research that may result in additional costs to the subjects. Include for a clinical trial. Describe what these costs are. If there are no foreseeable additional costs, type “Not applicable” in the space provided.)*

Enter your response here

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance provider to see what services will be covered by your insurance and what you will be responsible for paying.

1. **What happens to the information collected for the research?**

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Data collected during this study will be stored securely. Identifiable information will be kept confidential and stored separately from research data. Access to this information will be restricted to authorized personnel only. Data will be retained for       (S*pecify duration, e.g., 3 years.)* after the study concludes.

If information that identifies you is removed from your study information, it could be used for future research studies or given to other researchers without your additional consent.

1. **Can I be removed from the research without my permission?**

The person in charge of the research study or the sponsor can remove you from the research study without your approval for reasons including *(Specify reasons, if applicable):*

Enter your response here

We will inform you about any new information that may affect your health, welfare, or choice to continue participating in the research.

1. **What else do I need to know?**

Enter your response here

1. **Who is paying for this research?**

This research is being funded by *(Insert name of sponsor, if any):*

Enter your response here

1. **What medical costs am I responsible for paying?**

You and your private or public health insurance company will not be charged for any of the tests or procedures done for this study.

Enter your response here

1. **Who will pay for my medical care if participating in this research harms me?**

If you are injured or become ill because of this study, medical treatment will be provided. However, *(Insert the name of applicable institution(s))* makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research.

Enter your response here

Will I get paid for my participation in this research? Yes No If yes, how much?

1. **What happens when I am released from incarceration?** *(Explain or type “Not applicable”)*

Enter your response here

1. **What are my alternatives to participating in this research study?**

Instead of being in this research study, your choices may include *(Describe alternatives, if applicable)*:

Enter your response here

1. **Important risks and possible benefits of these alternatives include:**

*(Describe risks and benefits of alternatives, if applicable)***:**

Enter your response here

1. **What will happen to my information and samples?** (Explain or type “Not applicable.”)

*Example: Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.*

Enter your response here

1. **What will I be told about clinically relevant research results?** (Explain or type “Not applicable.”)

*Example: Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.*

Enter your response here

**HIPAA Authorization for the Use and Disclosure of**

**Identifiable Health Information for Research Purposes**

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

**A. What individually identifiable health information will be collected about you as part of this research study?**

*(Check all that apply and DELETE any option that does not apply.)*

Information from your full medical records: This includes records related to your medical history, treatments, and diagnostic tests.

New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

**B. Who is authorized to create or provide this information for research use?**

*(Must include all legal entities creating or providing the information to the researcher; Check all that apply)*

|  |  |
| --- | --- |
|  | KALEIDA Health, Buffalo NY |
|  | ECMC Healthcare Network, Buffalo NY |
|  | Other(s): (Specify other entities if applicable.) |
| Enter your response here | |

**C. Who is authorized to receive the information from the information providers identified in (B)?**

*(Check all that apply.)*

|  |  |
| --- | --- |
|  | Principal Investigator or designee |
|  | Other(s) (identify): [Specify other authorized recipients if applicable]: |
| Enter your response here | |

**D. With whom may your protected health information be shared?**

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to: *(Check all that apply.)*

|  |  |
| --- | --- |
|  | The sponsor of this research study (Name the specific sponsor.), cooperative group, or its agents, etc.: (Insert list specifying sponsor or cooperative group.) |
| Enter your response here | |
|  |  |
|  | The organization(s) responsible for administering this research: (Insert list specifying organization(s); e.g., Roswell Park Cancer Institute, Catholic Health, etc.) |
| Enter your response here | |
|  |  |
|  |  |
|  | Other medical investigators/centers/institutions participating in this research study: (Insert list specifying centers, institutions, etc.) |
| Enter your response here | |
|  |  |
|  | Other entities, if applicable: (Insert list specifying all other specific organizations, people, etc.) |
| Enter your response here | |

Your information may also be shared with individuals or entities responsible for general administration, oversight, and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

**E. How long are the information providers listed in (B) authorized to provide your information for this research project?**

*(Choose one (a, b, or c) THEN delete the other 2 options)*

a. This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

*-or-*

b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

*-or-*

c. This authorization will expire, and your protected health information will no longer be collected for the purposes of this study after: (Select date.) Click to select a date.

*(ALSO check (d), if applicable. Delete (d) if not applicable.)*

d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

**F. What are your rights after signing this authorization?**

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you choose to withdraw this authorization, you must do so in writing to the following individual(s):

(Insert name(s) and address(es) of individual(s) or position(s) associated with the research study who will be responsible for handling such requests.)

|  |
| --- |
| Enter your response here |

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with to collect your individually identifiable health information. (Providing copies of such written authorization revocations to the institutions providing information, which are identified in section B, is mandatory unless their contact information has been provided in the previous paragraph.)

**G. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

The following sections in other parts of this template must be present for this document to constitute a valid HIPAA Authorization:

• A description of each purpose (the research purpose) for the disclosure of information being requested from entities identified in Section B.

• Signature of the individual and a date. If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual must also be provided. Addressed in “Signature Block” sections attached to this document below.

• Copies of every signed authorization must be provided to each external institution that will rely on them to release their information to researchers. Consult with those institutions for the procedures governing how to accomplish this.

*(For studies where the consent form will be uploaded into the EMR, include the following language:)*

Should you agree to participate in this research, this consent document will be placed in your medical record.

***(There are four signature pages attached to this biomedical research consent form. Use the signature page or pages appropriate to your study. The IRB requires that you make separate consent documents for each signature page to be used. (Exception: One consent document may be used when the IRB approves the use of a Legally Authorized Representatives (LAR) signature page & assent of an adult legally unable to consent.))***

***(Omit the signature page if there is no written documentation of consent.)***

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

**Printed name of capable adult:**

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**Signature of person obtaining consent**

**Date signed:** Select a date.

**Printed name of person obtaining consent:**

**Signature Block for Use with the LAR of an Adult Unable to Consent**

*(When approved by the IRB, this section should be used if the participant does not have the decisional capacity to consent to their participation.)*

The following are considered to qualify as Legally Authorized Representatives (LAR) and may act on behalf of decisional incapacitated adults in New York State (listed in descending order of priority). Please select the category that describes your relationship with the study participant. (CHECK ONE.)

A health care agent properly designated on a health care proxy form

A court-appointed guardian or committee under the New York Surrogates Court Procedure Act Article 17-A

The spouse

An adult son or daughter

A parent

An adult brother or sister; or

A close friend: “…an adult (l8 years or older) who has a close personal relationship with the subject and provides a signed written statement that they are a close friend of the subject and that they have maintained such regular contact with the subject as to be familiar with the subject’s activities, health, religious or moral beliefs, and some means of corroborating such familiarity.”

Briefly explain your relationship as a “close friend” of the study participant in the box below:

*Enter your response here*

Your signature as the LAR documents your permission for the named subject to take part in this research. By signing this form, you are not waiving any of the subject’s legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research:

**Printed name of subject:**

**Printed name of legally authorized representative:**

|  |
| --- |
|  |

**Signature of legally authorized representative**

**Date Signed:** Select a date.

**Printed name of person obtaining consent:**

**Assent Obtained from Subject**

*(The Assent Box, which is applicable to the subject named in this consent document, must be checked if the subject does not have the decisional capability to consent for themself.)*

Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

**Witness to Consent Process, If Applicable**

*(Check the box below and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. Note: You must have prior IRB approval to utilize the short form of consent documentation.)*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the legally authorized representative, and that their consent was freely given.

**Printed name of witness to consent process:**

|  |
| --- |
|  |

**Signature of witness to consent process**

**Date Signed:** Select a date.

**Signature Block for Parental Permission**

Your signature documents your permission for the named child to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Your relationship to child:

Parent

Individual legally authorized to consent to the child’s general medical care

*(Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.)*

*(Note: if the IRB determines that the permission of two parents is required, you will be directed to add a second parent signature line.)*

**Printed name of child:**

**Printed name of parent or individual legally authorized to consent to the child’s general medical care:**

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| --- |
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**Signature of parent or individual legally authorized to consent to the child’s general medical care**

**Date Signed:** Select a date.

**Assent Obtained from Parent or Individual Legally Authorized to Consent**

*(The Assent Box, which is applicable to the subject named in this consent document, must be checked.)*

Assent Obtained

Assent not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

**Date Signed:** Select a date.

**Printed name of person obtaining consent:**

**Witness to Consent Process, If Applicable**

*(Check the box below and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. Note: You must have prior IRB approval to utilize the short form of consent documentation.)*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

**Printed name of witness to consent process:**

|  |
| --- |
|  |

**Signature of witness to consent process**

**Date signed:** Select a date.