UNIVERSITY AT BUFFALO

HUMAN RESEARCH PROTECTIONS PROGRAM

**Authorization for the Use and Disclosure of
Identifiable Health Information for Research Purposes**

You have been asked to be part of a research study under the direction of (***insert name of Principal Investigator)***, the Principal Investigator,and his or her research team. The study is called ***(insert title of study).*** The purpose of the study is ***(insert one or two sentences to describe the study).***

This authorization form 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.

1. **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: ***[Provide a description of the information that will be collected in a specific and meaningful fashion]***

\_\_\_\_\_ 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 and delete the option(s) that do not apply:]***

\_\_\_\_\_ KALEIDA Health, Buffalo NY

\_\_\_\_\_ ECMC Healthcare Network, Buffalo NY

\_\_\_\_\_ UBMD Clinical Practice Plan(s) (identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_ University at Buffalo School of Dental Medicine

 \_\_\_\_\_ Principal Investigator or designee ***[May only be checked when data is being created by the UB researcher or designee as part of their UB job function; this cannot be checked for data created or provided by legal entities external to UB that the researcher may also belong to, such as UBMD practice plans or affiliated hospitals]***

\_\_\_\_\_ Other(s) (identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

***[Check all that apply and DELETE the option(s) that do not apply]:***

\_\_√\_ Principal Investigator or designee

\_\_\_\_\_ Other(s) (identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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 and DELETE the option(s) that do not apply]:***

\_\_\_\_\_ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

\_\_\_\_\_ The sponsor of this research study ***(list specific sponsor),*** cooperative group, etc., or its agents ***[insert list]***:

\_\_\_\_\_ The organization(s) responsible for administering this research ***[insert list – e.g., Research Foundation of SUNY, UB Foundation Services, Inc.]***:

\_\_\_\_\_ Other medical investigators/centers/institutions participating in this research study ***[insert list of centers, institutions]****:*

\_\_\_\_\_ The following ***[insert list of all other specific organizations, people, etc.]***:

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?**

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

***(2) ALSO – Check “d” if applicable OR Delete “d” if it does not apply]***

\_\_\_\_\_ 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 ***[date]***

***[ALSO – Check here (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. The researchers may continue to rely on this authorization to acquire protected health information about you unless you revoke this authorization in writing.

**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 chose to withdraw this authorization, you must do so in writing to the following individual(s):

***[Insert name and address of individual or position associated with the research study that will be responsible for handling such requests.]***

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order 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 in order 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 in section B. Addressed in “Title of research study” section.***
* ***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.***
* ***Copies of every signed authorizations must be provided to each external institutions that will rely upon them to release their information to researchers. Consult with those institutions for the procedures governing how to accomplish this.]***

This document constitutes a direct request on my part to the entities identified above to provide the protected health information described in this document in accordance with 45 CFR 164.524 *Access of individuals to protected health information*, and authorizes the release of this information to the authorized recipients identified above. Furthermore this document authorizes the recipients identified above to act on my behalf as my personal representative in seeking this information.

**Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

After signing, you will be provided with a signed copy of this authorization form.

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

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| --- |
| *[When approved by the IRB, this section should be used if the participant does not have the decisional capacity to consent to his/her participation]* The following are considered to qualify as Legally Authorized Representatives and may act on behalf of decisionally 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Your signature documents your permission for the named subject to take part in this research. |
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| Printed name of subject |  |  |
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| Signature of legally authorized representative |  | Date |
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