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. Health information is considered "protected health information" when it may directly identify you as an individual. 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. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

1. What protected health information will be collected about you as part of this research study?

☐ information from your medical records:
☐ new Health Information created from study related tests, procedures, visits, and/or questionnaires as described in the attached consent form.

General description of information:

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2. Who is authorized to provide and collect this information?

☐ KALEIDA Health, Buffalo NY
☑ Principal Investigator or listed designee
☐ ECMC Healthcare Network, Buffalo NY
☐ University at Buffalo School of Dental Medicine

☐ Other:_____

3. 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:

☐ 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]***:
☐ 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 responsible for general 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, 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.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization 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.

4. How long will this information be kept by the Principal Investigator?

[choose one: a, b, or c]

☐ 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 by *[date or "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 by *[date or "end of the research study"]*. After that time, this authorization may not be used to acquire additional information about you and the protected health information collected on you for the purposes of this study will be destroyed.

[check if applicable – note: only applies if a) or b) above are checked]

☐ Your protected health information will be held confidentially by the researcher 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.

5. 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. You may also withdraw this authorization directly with those institutions by writing to the following:

[Insert name, address of Privacy Officers of any covered entities from which information is being acquired (information not being provided directly by subject) from #2 above.]

6. 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.

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.

Section for Personal Representatives:

Name (please print) _____

Signature_____

Date: _____

You must provide a description of the personal representative's authority to act for the individual: