SAMPLE CONSENT FORM ADDENDUM- USE OF STUDY DATA FROM EU AND EEA (GDPR COMPLIANT)

Instructions: Review comments to determine required and optional statements. Include this document in your OneAegis submission. Remove this box (using the border feature) and other instructional text, examples, and comments in [brackets]. Do not alter hyperlinks. You may update email addresses.

This Notice/ Informed Consent is required when the research collects or creates Personal Data[1] from subjects located in the EU or EEA. If the research is obtaining "Sensitive Data[2]," explicit consent is required.

Please leave a space 2 inches wide and 1 inch tall in the bottom right corner for the IRB stamp.

Brigham Young University
NOTICE / INFORMED CONSENT ADDENDUM FOR USE OF STUDY DATA
(EUROPEAN UNION (EU) /EUROPEAN ECONOMIC AREA (EEA))

[Title of Study]

RESEARCH TEAM
Principal Investigator
[Name and Title]
[Department]
[Telephone number]
24-Hour Telephone Number/Pager [Required for medical studies and clinical investigators]

Other Researchers [If not applicable, please remove]
[List only those researchers qualified to be involved in the informed consent process]

STUDY LOCATION(S):

STUDY SPONSOR(S):

This research will collect data about you that can identify you, referred to as Study Data. The General Data Protection Regulation ("GDPR") requires researchers to provide this Notice / Consent to you when we collect and use Study Data about people who are located in a State that belongs to the European Union or in the European Economic Area.

We will obtain and create Study Data directly from you or from [insert the data sources, including repositories, collaborators, publicly available sources, etc.] so we can properly conduct this research. As we conduct research procedures with your Study Data, new Study Data may be created.

The Research Team will collect and use the following types of Study Data for this research:

[1] Article 4 of the GDPR states "'personal data' **means** any information relating to an identified or identifiable natural person ('**data subject**')"
[2] According to Article 9 of the GDPR applies additional conditions for processing Personal Data about racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation is prohibited unless additional requirements are met such as informed consent from the data subject.

[Delete any categories of information that you will not collect or create]

- Contact Information
- Health information
- Your racial or ethnic origin
- Your political opinions
- Your religious or philosophical beliefs
- Your sexual orientation or beliefs
- Genetic data
- Information about your response to the research procedures

[Insert the categories of any additional data that you will collect]

[Include, if applicable, otherwise delete] The Research Team will enter data about you and your health into a computer and a computer program will help the study team decide if you meet requirements to be in this study.

[Include, if applicable, otherwise delete] The research protocol requires the Research team to enter data about you and your health into a computer. A computer program will be used to assign you to one of the following specific study treatments: [list study treatments]. If you sign this consent form, you are consenting to the use of this automated process to determine the treatment you receive. [Describe any other procedures that use an automated process to make decisions about the subject]

Please initial one of the boxes below to indicate whether you consent to use of the automated processes described above.

I agree	I do not agree

This research will keep your Study Data for [insert the time the data will be maintained by the research team- be mindful of recordkeeping requirements] after this research ends.

The following categories of individuals may receive Study Data collected or created about you: [Delete any category that is not applicable]

- Members of the research team so they properly conduct the research
- Brigham Young University Institutional Review Board for Human Subjects staff will oversee the research to see if it is conducted correctly and to protect your safety and rights
- The research Sponsor who will monitor the study and analyze the data
- Agents of the Sponsor who will assist the sponsor with data monitoring and analysis
- Representatives of the U.S. Office of Human Research Protections (OHRP) who oversee the research
- Other researchers, so they can perform procedures required by this research
- Other researchers, including researchers in other countries, so they can conduct additional research on [condition] and other, unrelated diseases and problems

[List the additional categories of individuals who may receive access to Personal Data and describe the reason for the disclosure.]

[Include, if applicable, otherwise delete] The research team will transfer your Study Data to our research site in the United States. The United States does not have the same laws to protect your Study Data as States in the

EU/EEA. However, the research team is committed to protecting the confidentiality of your Study Data. Additional information about the protections we will use is included in the consent document.

The GDPR gives you rights relating to your Study Data, including the right to:

- Access, correct or withdraw your Study Data; however, the research team may need to keep Study Data as long as it is necessary to achieve the purpose of this research
- Restrict the types of activities the research team can do with your Study Data
- Object to using your Study Data for specific types of activities
- Withdraw your consent to use your Study Data for the purposes outlined in the consent form and in this document (Please understand that you may withdraw your consent to use new Study Data but Study Data already collected will continue to be used as outlined in the consent document and in this Notice)

Brigham Young University located in Provo, Utah, USA, is responsible for the use of your Study Data for this research. You can contact the BYU Principal Investigator by phone at: [phone number] or by email at [xxxx@byu.edu] if you have:

- Questions about this notice
- Complaints about the use of your Study Data
- If you want to make a request relating to the rights listed above

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, please sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent