

Instructions: This Notice is required when the research collects or creates Personal Data<sup>1</sup> from participants located in the European Union (EU) or European Economic Area (EEA). If the research is obtaining “Sensitive Data<sup>2</sup>,” explicit consent is required. **Delete all language in blue type before submitting this Notice for review.**

## Notification/Consent for Collection and Use of Study Data

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 to you when we collect and use study data about people who are located in a country that belongs to the European Union (EU) or in the European Economic Area (EEA). If you reside in the EU or EEA during your participation in the study, your study data will be protected by the GDPR, in addition to any other laws that might apply.

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:

(Delete any categories of information that you will not collect or create)

- Contact information
- Health information relating to [provide some information about the type of health information collected/used]
- Your racial or ethnic origin
- Your political opinions
- Your religious or philosophical beliefs
- Your sexual orientation or beliefs
- Genetic data relating to [provide some information about the type of genetic data collected/used]
- 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 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 into a computer. A computer program will be used to assign you to one of the following specific study interventions: (list study treatments). If you sign this consent form, you are

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<sup>1</sup> Article 4 of the GDPR states “personal data’ **means** any information relating to an identified or identifiable natural person (**data subject**)”

<sup>2</sup>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.

## GDPR Notice and Consent

IRB protocol #: \_\_\_\_\_

consenting to the use of this automated process to determine the intervention you receive.  
(Describe any other procedures that use an automated process to make decisions about the subject)

This research will keep your study data for (insert the time the data will be maintained by the research – Chapman University requires the data to be maintained for at least 3 years following completion of the research) 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 can conduct the research
- Chapman University Office of Research staff who 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
- Representatives of the Food and Drug Administration (FDA) who will use the data to determine whether a marketing application for the investigational device can be approved
- 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.)

The research team will transfer your study data to a research site in the United States. The United States does not have the same laws to protect your study data as countries 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.

If you reside in the EU or EEA during your participation in the study, the GDPR gives you rights relating to your study data, including the right to:

- Access, correct or withdraw your study data; note that the research team may need to keep a copy of your study data, though it may not be used in reporting any research results
- 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.

## GDPR Notice and Consent

IRB protocol #: \_\_\_\_\_

Chapman University is responsible for the use of your study data for this research. Please contact the Office of Research at [irb@chapman.edu](mailto:irb@chapman.edu) or (714) 628-2833 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.
- [If the data will be used for sponsored research or research authored by another research institution, where a non-Chapman University researcher or non-Chapman University institution is determining the data to be collected and scope of research, and Chapman University is acting at the direction of the non-Chapman University researcher or non-Chapman University institution]: [name and contact information of sponsor/institution; sponsor/institution's Data Protection Officer and Representative, if any, and their contact information; if no DPO or Representative, provide name and contact information of sponsor/institution privacy official.]

Please sign below to indicate that you agree to the information contained in this notice.

\_\_\_\_\_  
Printed Name of Participant or Legal Guardian

\_\_\_\_\_  
Signature of Participant or Legal Guardian

\_\_\_\_\_  
Date