INSTRUCTIONS: This template was developed by a multi-stakeholder group led by the Multi-Regional Clinical Trials (MRCT) Center at Harvard and is intended to provide language that can be used in consent forms in order to describe to participants how their data are protected and how they may then be used or shared. Such language anticipates research practices and/or regulations requiring that participant-level clinical trials data be made available by sponsors to third-party researchers and to the public. The following language can be inserted as the "privacy" section of an informed consent form and has been drafted to enable broad use of the coded data for downstream research purposes. While this language seeks to provide "best practice" guidance in this area, each study site will need to consider whether customization of this language is required based on applicable national law and the research and privacy policies of individual study sites.

INFORMED CONSENT LANGUAGE FOR CONFIDENTIALITY AND DATA SHARING

What information about me will be used in the study?

If you join the study, information about you will be used for the study. This information may include your name, address, or birth date. It may also include information from your medical record. As part of the study, new information about you will be collected, such as heart rate, blood pressure and results of study tests, for example tests on your blood and other samples.

Who may see and use information about you and your health?

Information that directly identifies you is held at the study site. Study doctors and other people at the site who are assisting with the study or your care will be able to see this information. In certain cases other persons may need to see this information, for example, the ethics review committee (sometimes called an institutional review board) that reviews the study to ensure that it meets scientific and ethical standards. In addition, people from regulatory agencies overseeing the study, and persons engaged by the study site to help with the study, such as the site's attorneys and data storage companies, may also need to see your information. The study site will use care to protect your privacy when sharing information and data, as described in the next paragraph. Some people or groups who receive your health information might not be required by law to follow the same privacy rules that the study doctors and study site must follow.

As part of the study, information and data will need to be transferred from the study site to SPONSOR and other researchers working with SPONSOR. Before this transfer takes place, researchers at the study site (the "Site Study Team") will give your information a unique study number. This number will then be

used in place of your name and other information that directly identifies you. We will call this information "Your Coded Information." The Site Study Team will keep the link between your directly identifiable information and Your Coded Information. The Study Site Team gives only coded information to SPONSOR unless there is a regulatory reason that SPONSOR needs to see information that directly identifies you.

How will my Coded Information be used and protected?

SPONSOR will protect Your Coded Information as described here and will follow laws that protect the use of health information. SPONSOR and those working with SPONSOR will use Your Coded Information for health research purposes only. SPONSOR and those working with SPONSOR may use Your Coded Information in the following ways:

- Keep it electronically and analyze it to understand the study and the study results.
- Share it with regulatory agencies that approve new medicines and others as required by law. For example, it is possible that as part of efforts to make research data more widely available to researchers, regulatory agencies in some countries may require that Your Coded Information be made publicly available on the internet or in other ways.
- Combine it with data from this study or other studies to learn more about [DISEASE/CONDITION] or other conditions, to develop new commercial products, medicines or devices, and to advance science and public health.
- Use it to improve the quality of this study or other studies.
- Publish summaries of the study results in medical journals, on the internet or at meetings so that other researchers may learn about this study. Your name or other data that directly and easily identifies you will not appear in any of these publications without your specific permission.

SPONSOR may also share Your Coded Information with other researchers for the purposes of researching [DISEASE/CONDITION] or other conditions, to develop new commercial products, medicines or devices, and to advance science and public health. If SPONSOR makes Your Coded Information available to other researchers, SPONSOR will take additional steps to safeguard your privacy. For example, before allowing other researchers to access Your Coded Information, SPONSOR will replace the unique code assigned to the information by the Site Study Team with a new unique code and may remove other information that may indirectly identify you. Despite these and other

precautions, however, your privacy cannot be guaranteed.

Your Coded Information may be sent to another country where SPONSOR or researchers with whom SPONSOR shares Your Coded Information are located. This may include countries where the data protection laws are not as strict as the rules in the country where you live. In such cases, Your Coded Information may be protected less strongly and securely by the data protection laws of these foreign countries, as compared to those of your own country.

What other general information about this clinical study is shared?

A general description of this clinical study will be available on the SPONSOR Clinical Study Register: <insert web address>. Information about the study may also appear in clinical trial/study registries in countries in which the clinical study is conducted or in other countries where regulatory agencies require information about the study to be made available on a website known as a clinical trial registry. These websites may contain Your Coded Data, but they will not include information that can directly identify you.

[*IF THE STUDY IS SUBJECT TO CLINICALTRIALS.GOV REGISTRATION REQUIREMENTS, INCLUDE THIS LANGUAGE:*][“A description of this clinical trial will be available on http://ClinicalTrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”]

Do I have to participate in this study?

No. You do not have to participate. You have the right not to sign this form. If you do not sign it, you cannot take part in this research study. It is your choice to sign this form. You should feel that all your questions about the study and the use of your data have been answered before you sign.

For how long will my data be used?

Your data may be used and shared as described in this form for as long as they remain useful for research purposes.

Can I change my mind about participating in this study?

Yes. You have the right to withdraw your permission for us to use or share your information for this research study. If you withdraw your permission, you will no longer be able to participate in the study and no further information will be collected about you. However, all of the information collected before you withdraw your permission will still be used. We will not be able to take back information, including Your Coded Information, that has already been used or

has been shared with others. We cannot remove your information that is already part of larger data sets that have been and are being shared for further research. If you wish to withdraw your permission, you must notify your study doctor.

[Note to researcher and SPONSOR: This section on withdrawal of permission to share information relates to the United States; other jurisdictions may not allow the retention of information once a subject withdraws from the study. Please review the laws of the jurisdiction in which the study takes place before using this language.]

OPTIONAL: The below table may be included in addition to the above text to provide a summary of how information will be used and protected.

Type of information	**How will it be used**	**How will it be protected**
Information that directly identifies you e.g. name, address and date of birth.	Information that directly identifies you will be used: • For study purposes. • To ensure the study is being conducted correctly.	Access will be granted only to the following persons who need access to complete the research: • Doctors and other people who are assisting with the study or your care. • People who ensure the study is done correctly such as the ethics committee and regulatory agencies.
Coded information (Your name and other information that directly identifies you are removed and replaced with a code).	Coded information: • Will be transferred from the study site to people who are working with SPONSOR. • Will be used to understand the study and study results. • May be used by SPONSOR and other researchers for health research purposes including to learn more about other diseases/conditions and to	SPONSOR will protect coded information by: • Following laws that protect the use of information stored electronically. • Taking additional steps when sharing data with third-party researchers, for example, removing data fields that are not needed by the third party and/or assigning a new code number.

Type of information	How will it be used	How will it be protected
	improve the conduct of clinical trials in general. • May be used by SPONSOR and other parties to develop new commercial products, medicines, or devices, and to advance science and public health. • May be sent to other countries where the data protection laws are not as strong as those in your country of residence.	
Results Summaries (combined statistical data and results of the study)	Results summaries may: • Help other researchers learn more about the study. • Be provided in medical journals, on the internet or at meetings.	SPONSOR will: • Not include information in the results summaries that directly identifies you without first obtaining your explicit permission to do so.

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