

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

14

15 **INFORMED CONSENT LANGUAGE FOR CONFIDENTIALITY AND DATA SHARING**

16 **What information about me will be used in the study?**

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

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

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

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

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

46 **How will my Coded Information be used and protected?**

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

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

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

78 precautions, however, your privacy cannot be guaranteed.

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

85 **What other general information about this clinical study is shared?**

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

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

99 **Do I have to participate in this study?**

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

104 **For how long will my data be used?**

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

107 **Can I change my mind about participating in this study?**

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

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

118  
 119 *[Note to researcher and SPONSOR: This section on withdrawal of permission to share*  
 120 *information relates to the United States; other jurisdictions may not allow the retention of*  
 121 *information once a subject withdraws from the study. Please review the laws of the jurisdiction*  
 122 *in which the study takes place before using this language.]*

123  
 124 **OPTIONAL:** The below table may be included in addition to the above text to provide a  
 125 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: <ul style="list-style-type: none"> <li>• For study purposes.</li> <li>• To ensure the study is being conducted correctly.</li> </ul>	Access will be granted only to the following persons who need access to complete the research: <ul style="list-style-type: none"> <li>• Doctors and other people who are assisting with the study or your care.</li> <li>• People who ensure the study is done correctly such as the ethics committee and regulatory agencies.</li> </ul>
Coded information  (Your name and other information that directly identifies you are removed and replaced with a code).	Coded information: <ul style="list-style-type: none"> <li>• Will be transferred from the study site to people who are working with SPONSOR.</li> <li>• Will be used to understand the study and study results.</li> <li>• May be used by SPONSOR and other researchers for health research purposes including to learn more about other diseases/conditions and to</li> </ul>	SPONSOR will protect coded information by: <ul style="list-style-type: none"> <li>• Following laws that protect the use of information stored electronically.</li> <li>• 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.</li> </ul>

Type of information	How will it be used	How will it be protected
	<p>improve the conduct of clinical trials in general.</p> <ul style="list-style-type: none"> <li>• May be used by SPONSOR and other parties to develop new commercial products, medicines, or devices, and to advance science and public health.</li> <li>• May be sent to other countries where the data protection laws are not as strong as those in your country of residence.</li> </ul>	
<p>Results Summaries (combined statistical data and results of the study)</p>	<p>Results summaries may:</p> <ul style="list-style-type: none"> <li>• Help other researchers learn more about the study.</li> <li>• Be provided in medical journals, on the internet or at meetings.</li> </ul>	<p>SPONSOR will:</p> <ul style="list-style-type: none"> <li>• Not include information in the results summaries that directly identifies you without first obtaining your explicit permission to do so.</li> </ul>