

Re: Independent (Commercial) IRB Consent Form Language

Washington University has reliance agreements with WCG IRB (Formerly Western IRB/WIRB) and Advarra IRB. As a part of these agreements, these independent IRBs are responsible for inserting institutionally required consent form language into a limited number of sections in the consent document. This is expected to occur when the PI submits the site's application to the independent IRB.

Study teams should not be responsible for creating site specific consent forms or inserting the approved language in to template consent documents. The expectation is that the independent IRBs will insert the agreed upon language and, if required, provide for sponsor review prior to approving the consent document.

The currently approved institutionally required language is provided below for review by study teams and sponsors as needed. Washington University will not negotiate changes to this language.

NOTE: Study teams and sponsors should not insert this language in to the consent documents if possible. The Independent IRBs should insert the required language they have on file.

Compensation for Injury

Sponsors will be asked to choose between the 2 options below. No changes are permitted to this language.

Option A:

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at the telephone number listed on the first page of this form and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University and [insert Industry Sponsor's name]. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

Option B:

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at the telephone number listed on the first page of this form and/or the Human Research Protection Office at 1-(800)-438-0445.

The sponsor will reimburse your reasonable and necessary medical costs for treatment for a research-related illness or injury through Washington University in St. Louis if the injury or illness:

- is a direct result of the [choose one: drug/device] being studied or the properly performed study procedures*
- is not a medical condition that you had when you started the study;*
- is not the direct result of a failure to follow the study plan; and*

- *is not the direct result of proven negligence of Washington University in St. Louis.*

The sponsor does not plan to provide any other form of compensation to you for any illness or injury resulting from this study. Washington University in St. Louis does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.

Cost Language

HRPO will determine the appropriate language to add to the consent form.

Option A:

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

Optional statement that may be added to the Option A language only:

The sponsor is providing the [insert drug(s) name] at no cost to you.

Option B:

You will not have any costs for being in this research study.

Optional statement that may be added to the Option B language only:

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

Option C:

You will have costs for being in this research study. You will be asked to pay for:

- *[Insert procedures]*

Optional statement that may be added to the above Option C language only:

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

HIPAA Language

This language replaces all other HIPAA language. This language is to be embedded in the body of the consent form. Changes or additions are not permitted.

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research, [WCG IRB ONLY {for example, past and

present medical records, research records, and records about study visits and phone calls made as part of this research.}] Some of these records could contain information that personally identifies you.

- *Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities*
- *The U.S. Food and Drug Administration*
- *[sponsor name]*
- *[If applicable the site will add: The sponsor (give company name) may also inspect any part of your medical record for the purposes of auditing the conduct of the study.]*
- *[For registry studies, the site will add: People who use the registry]*
- *[If applicable the site will add: Your primary care physician if a medical condition that needs urgent attention is discovered]*
- *[If applicable the site will add: Public health agencies to complete public health reporting requirements.]*
- *[If applicable add: Siteman Cancer Center]*
- *Hospital or Washington University representatives to complete their responsibilities*
- *Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.*
- *The Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Washington University Human Research Protection Office. The Institutional Review Board has reviewed and approved this study. {this varies slightly by IRB}*
- *Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.*
- *[The site will indicate other entities with whom PHI may be shared and the purpose of sharing, for example, a data safety monitoring board or data coordinating center]*

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed above.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA and may further be shared without your permission.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- *your treatment or the care given by your health provider.*
- *your insurance payment or enrollment in any health plans.*
- *any benefits to which you are entitled.*

However, it will not be possible for you to take part in the study.

If you sign this form:

- *You authorize the use of your PHI for this research*
- *This authorization does not expire.*
- *You may later change your mind and not let the research team use or share your information (you may revoke your authorization).*
- *To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <http://hrpo.wustl.edu/participants//withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.*

If you revoke your authorization:

- *The research team may only use and share information already collected for the study.*
- *Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.*
- *You will not be allowed to continue to participate in the study.*

Emailing/Texting PHI Language

This language is included if the study team will be emailing or texting participants.

Can we contact you by email or text message?

We would like to contact you by email or text message for the purposes listed below. Some of these emails may contain health information that identifies you.

- *[specify types of transactions available by email and/ or text, e.g. patient education, prescription refills, and appointment scheduling containing PHI].*

Only the research team will have access to your email and text communications. We will only communicate in this method by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email or text.

- *Text messaging is not a secure communication method.*

•*There is always a risk that the message could be intercepted or sent to the wrong email address or phone number. To avoid sending messages to the wrong email address, the first email we send you will be this we will send a test message to ensure we have the correct email address or phone number.*

•*When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.*

•*If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.*

•*Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.*

•*If you lose your phone, others may be able to access the messages that we send.*

Do you agree to allow us to send your health information via email?

 Yes No
Initials Initials

Do you agree to allow us to send your health information via text?

 Yes No
Initials Initials

myChart Required Language

This language is included if the study is a clinical trial AND the study team wishes to communicate through MyChart

If you have a MyChart account we may use this as a way to communicate with you for the following purposes: [Describe the types of communications that will be sent through MyChart].

Questions section

This language must be added after the contact information of the IRB.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wusm.wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Signature Line

This Language will replace other signature blocks and associated language.

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

Subject's Printed Name

Subject's Signature

Date

Printed Name of the Person Conducting the Consent Discussion

*Signature of the Person
Conducting the Consent Discussion*

Date