

Please review all of the categories below and select the language applicable for your study. Cut and paste the appropriate language into your consent form. For questions, contact your Managing Analyst at 503-494-7887 or Susan Bankowski, IRB Chair, at 503-494-3036. For more information regarding research injuries see: [Why OHSU does not allow billing of research related injuries to subjects or their third party payers.](#)

1. Industry Sponsored and either: Phase I-III Clinical Trial (except Category B devices); or Phase IV clinical trial of marketed drugs or devices for new use under an IND/IDE

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day].***

You, or your medical insurance, will be billed for expenses resulting from your condition. However, if you are harmed by the ***[study drug(s), study device(s)]*** or study procedures, you will be treated. This treatment will be provided at no cost to you or your insurance company if the harm is caused by the ***[study drug(s), device(s)]*** or study procedures and would not have been expected from the standard treatment for your condition.

You have not waived your legal rights by signing this form. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

2. Industry Sponsored Clinical Trials with Category B Devices

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day].***

You, or your medical insurance, will be billed for expenses resulting from your condition. However, if you are harmed by the study device(s) or study procedures, you will be treated. This treatment will be provided at no cost to you or your insurance company if the harm is caused by the study device(s) or study procedures and would not have been expected from the standard treatment for your condition.

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3. Industry sponsored clinical trial using non-research care with research procedures *(example: a cancer study comparing two approved therapies but involving additional CT scans performed for research purposes)*

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact [study team info, if study involves physical risks that may be immediate provide a phone number that is available 24-hours a day].

You, or your medical insurance, will be billed for expenses resulting from your condition. However, if you are harmed by the study procedures, you will be treated. This treatment will be provided at no cost to you or your insurance company if the harm is caused by the study procedures and would not have been expected from the standard treatment for your condition.

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4. Industry sponsored and either: clinical trial with marketed drug or device used per labeling; or compassionate use drug/device or humanitarian use device

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day]***.

You have not waived your legal rights by signing this form. If you are harmed by the study drug(s), study device(s) or study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

5. Industry sponsored with physical contact with subject but no medical intervention i.e., does not involve a drug, device, supplement, or biologic, but may involve blood or tissue sampling or other procedures not required for medical care

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You, or your medical insurance, will be billed for expenses resulting from your condition. However, if you are harmed by the study procedures, you will be treated. This treatment will be provided at no cost to you or your insurance company if the harm is caused by the study procedures and would not have been expected from the standard treatment for your condition.

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6. Investigator designed study of drug or device, regardless of level/type of support provided by industry sponsor

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You have not waived your legal rights by signing this form. If you are harmed by the ***[study drug(s), study device(s)]*** or study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

7. Industry sponsored and data collection only (including phone screen), no physical risk

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day]***.

You have not waived your legal rights by signing this form. If you are harmed by the study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

8. Non-industry Sponsored clinical research (Includes federally funded)

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves***

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physical risks that may be immediate provide a phone number that is available 24 hours a day].

You have not waived your legal rights by signing this form. If you are harmed by the ***[study drug(s), study device(s)]*** or study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

If the protocol is sponsored by a cooperative group add:

[Insert sponsor name (for example, The Children's Oncology Group)] does not offer compensation for injury.

If federally funded, add the following statement:

It is not the policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

9. Non-industry Sponsored non-clinical research (Includes federally funded) (non-clinical research that does not involve an experimental treatment, but may involve minimal physical risk activities like cheek swabs, minor blood draws, interviews, etc.

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day].***

You have not waived your legal rights by signing this form. If you are harmed by the study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

If the protocol is sponsored by a cooperative group add:

[Insert sponsor name (for example, The Children's Oncology Group)] does not offer compensation for injury.

If federally funded, add the following statement:

It is not the policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

10. Establishing a Repository Only (storage of data or biological samples for future research or analysis) regardless of funding source

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If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info]***.

You have not waived your legal rights by signing this form. Any claim you make against the Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have further questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

If the repository includes prospectively collected biological samples and is industry funded, add:

You, or your medical insurance, will be billed for expenses resulting from your condition. However, if you are harmed by the study procedures, you will be treated. This treatment will be provided at no cost to you or your insurance company if the harm is caused by the sample collection and would not have been expected from the standard treatment for your condition.

11. Any study with genetic component include this additional language

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day]***.

Oregon Health & Science University is also subject to the Oregon Genetic Privacy law (ORS 192.531 through ORS 192.549) and its requirements concerning confidentiality and the legal remedies provided by that law for breach of its requirements. You have not waived your legal rights by signing this form. For clarification on this subject, or if you have further questions, please call the OHSU Research Integrity Office at (503) 494-7887.

12. Media Consent

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day]***.

You have not waived your legal rights by signing this form. Oregon Health & Science University does not offer to compensate you for any harm you may experience from the use of your [photographs, videotapes, audiotapes]. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

13. Shriners Hospital for Children

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If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact ***[study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day]***.

Any physical injuries or adverse reactions arising from participation in this study can be treated by the Shriners Hospitals for Children or by a combination of medical services at the Shriners Hospitals for Children and any other hospital you choose. You will not be charged for medical treatment and other services provided by Shriners Hospitals for Children. If you receive medical care for adverse reactions arising in this study from another hospital or healthcare provider, these providers may seek reimbursement for the cost of that care from your medical insurance coverage. Shriners Hospitals for Children is not able to offer financial compensation for a study related injury or other problem.

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