

Guidelines for Subject Injury Language

The clinical trials contract is a contract between the sponsor and the institution, not the participant and the sponsor. The consent form should be used to convey what a participant may expect if they are injured because of participating in a clinical trial. Please follow the templated language provided below whenever possible.

The following language is suggested for all informed consent forms:

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research.

[For industry sponsored trials where the sponsor will offer injury coverage, include the following statement below without revision.]

The study sponsor [enter sponsor name] may pay for the cost of medical treatment. The treating institution and the study sponsor will be responsible for determining what costs may be covered by the study sponsor. You or your insurance company will still be responsible for costs that are not covered by the study sponsor.

[If the industry sponsor does not offer injury coverage, do not include the language in the paragraph above and instead refer to the paragraph below.]

These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury. However, you do not give up any of your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender and sex assigned at birth, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

Info Sheet - Policy

When the sponsor requires revisions or additions to the templated language, the following should be addressed:

- It is acceptable to exclude progression of the underlying disease and to limit the sponsor's liability to injury directly caused by study procedures and products (e.g., limited to the properly followed protocol).
- The consent form should outline the sponsor's obligations in lay language without exculpatory phrases and should remind participants of their continuing legal rights.
- If the amount of coverage is limited to direct medical costs and specifically excludes lost wages, it should be followed by the statement, "but you do not waive any of your legal rights by participating in this trial."
- The [Medicare Secondary Payer](#) rule should **not** be violated by suggesting that the sponsor will pay the cost of injury after a third party payer is billed (for example, exclude comments such as "The sponsor may pay for the reasonable cost of medical treatment for the injury that your insurance does not pay.>").
- The language should **not** attempt to impose standards of behavior on participants (for example, "Sponsor will pay your costs if you followed the study team directions."). Such statements will generally be required to be removed.
- The consent **should avoid** legalistic language in favor of lay-friendly terminology and should not appear to contractually obligate the participant (for example, "Sponsor will not pay if the investigator was negligent or engaged in willful misconduct.>").
- The language must **not** be potentially exculpatory (for example, "You agree that Sponsor is not responsible.") and should avoid "you must agree" or other contractual language.
- **Please Note:** Subject injury language is an element of consent that is required only for research that is greater than minimal risk.