Required 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 cannot be used to convey sponsor clinical trials contract language to the participant that attempts to define what is a research related injury, imposes any standards of behavior, limits the amount of coverage, includes legal language, includes sponsor or institution obligations, appears contractual or is potentially exculpatory.

The following language is expected in all consents without edit:

> **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. These treatments may be billed to your insurance company. You will be responsible for deductibles and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up 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, 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.*

For industry sponsored studies, the following language may be included after the third paragraph:

> *The study sponsor might pay for medical treatment needed to treat your injury. You or your insurance company will still be responsible for costs that are not covered by the study sponsor.*

The DFCI IRB will not approve a study without this template subject injury language as written. If a sponsor requests changes to this language, the IRB may consider the changes but will not approve language that:

- Attempts to define a research-related injury (for example, by specifically excluding pre-existing conditions and underlying disease

- Attempts to impose standards of behavior on participants (for example, “Sponsor will pay your costs if you followed the study team directions”)

- Attempts to limit the amount of coverage that will be provided (for example, “Sponsor will pay your reasonable medical costs only,” or “Sponsor will not pay for lost wages”)

- Includes legal or not lay-friendly terminology (for example, “Sponsor will not pay if the investigator was negligent or engaged in willful misconduct”)

- Discusses the Sponsor’s obligations versus the institution’s (for example, “Sponsor will not pay if the study team did not follow the protocol”)

- Appears contractual or is potentially exculpatory (for example, “You agree that Sponsor is not responsible”)]

Note:
In most cases the DFCI IRB will require that the consent form include the template subject injury language, without revision, for the research to be IRB approved.