



Subject Injury Language Guidance Document

Updated January 11, 2024

The purpose of this Guidance Document is to provide the Informed Consent Model Subject Injury Language . This is not required for non-interventional studies or expanded access.

MODEL LANGUAGE

You may have medical problems or side effects from taking part in this research study. If you have any side effects after taking the study drug or are injured during the study, tell your study doctor right away. Once you tell your study doctor, he will either provide you with or refer to you proper medical treatment.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- George Washington University Hospital (GWU Hospital) and/or the George Washington University Medical Faculty Associates (GWU MFA); or
- your physician; or
- treatment center of your choice.

The study sponsor, _____ will provide payment for the reasonable medical expenses needed to diagnose and treat the research-related injury if the injury or illness is directly related to the (*study drug, placebo, name of comparator, etc.*) or the study procedures **and** your injury was not caused by:

- Failure by *GWU Hospital*, GWU MFA, the study doctor, or study staff to follow the sponsor's written instructions, the study protocol, or applicable laws, guidance, and regulations; or
- The negligence or misconduct of *GWU Hospital*, GWU MFA, the study doctor study or study staff.
- A standard of care procedure that you would have undergone even if you were not participating in the study;
- The normal progression of your disease or condition; and/or a pre-existing condition not made worse by the study drug or study procedures

There are no plans for *GWU*, GWU Hospital and/or the GWU MFA to pay you for any injuries or illnesses. By signing this form you will not give up any legal rights.

If the sponsor covers these expenses they will need to know some information about you such as your name, gender, date of birth, Medicare Claim Number (if you have one), and social security number (if you do not have a Medicare Claim Number). This information will be used to check to see if you receive Medicare, and if you do, report the payment they make to Medicare. This information may be collected directly from you, or from the



Office of
Clinical Research

School of Medicine
& Health Sciences
THE GEORGE WASHINGTON UNIVERSITY

study doctor, study staff, or other health care providers who treated your illness or injury. This information may be shared with others, including the sponsor's representatives and the Centers for Medicare & Medicaid Services (the government agency responsible for administering the Medicare program). The sponsor and its representatives will not use this information for any other purpose.