

# Subject Injury Language

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# Subject Injury Language in the Informed Consent

- As of April 2018 the UNC has approved standard subject injury language
- OIC is required to obtain certain subject injury language in the CTA with industry sponsors
- Language will be different for PI initiated and Federally or non-profit funded clinical trials
- Current OHRE SOP requires an “official” email to be included in your submission to an external commercial IRB
- Official email and letter comes from OCT, Christine Nelson
- Official Letter kept on a shared drive, all analysts have access

# Standard Subject Injury Language

## What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.

The Sponsor of the study, [INSERT SPONSOR NAME], has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, [select either drug or device] or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study.

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The sponsor has no plans to provide additional financial compensation for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

If you think you have been injured from taking part in this study, call Dr. (PI Name) at (24 hour phone number). He/she will let you know what you should do.

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## **Acceptable Medicare Reporting language:**

To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you are injured and a claim is submitted to the Sponsor to pay medical expenses.

# Unacceptable Language for Subject Injury

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- UNC has two position statements
  - Subject not following instructions
    - Sponsor can refuse to pay
  - Submitting claims to insurance before sponsor pays
    - Burden on subject
    - Co-pays, lifetime limitations

# Example – IRB # 19-0884

- If you become ill or are hurt directly because of this drug (Solosec) or procedures described in this consent form in accordance with the protocol, you will be paid back for your out-of-pocket (not paid by insurance or someone else) costs for reasonable standard medical expenses. In order for you to be paid back, you must tell the study doctor of your illness/injury as soon as possible and follow the directions of the study doctor and staff and this informed consent form. If it is determined that you did not follow the protocol or other study instructions, you may not be paid back for such costs. You will not be paid back for treatment of illnesses or injuries that you had before you started the study, unless the study drug or procedure worsened your previous illness or injury. In order to receive payment, you should keep a record of all of your expenses, including where and when you received treatment for your illness or injury. The offer to provide the payment described above does not mean that the illness or injury is the fault of the sponsor or the study doctor/facility. There is no provision for compensation for injuries beyond that specified above. The sponsor has no plans to provide additional financial compensation for lost wages or any other losses or expenses.