



# Human Research Ethics Training Tips: ICF Injury Language for More than Minimal Risk Research Studies

## Injury Language in Consent Forms

Injury language is required to be inserted into the consent form for every more than minimal risk study. It is usually part of the contract negotiations for that study. Depending on when the negotiations are completed, the correct language may be in the consent form at the time of IRB review or may not be available till after IRB review is completed. Thus the consent you review could be the template language supplied by the sponsor and would need to have the injury language replaced with one of the 3 choices below.

The injury language for federally funded studies is part of the consent template and is generally the same across all federal studies.

### **The following 3 scenarios are possible options for non-federally funded studies:**

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

***This section cannot be modified without the approval of the Office of Industry Contracting. Doing so may result in approval delay. Contact OIC at 919-962-3630 if you have questions.***

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, 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.

The Sponsor has not set aside funds to pay 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.

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.

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.

**2. If required by Sponsor, ONLY the following Medicare Reporting language is acceptable:**

*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.*

**3. The standard UNC injury language**

**For UNC-Chapel Hill Investigator-initiated studies, insert only the following:**

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. Any costs for medical expenses 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.

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.

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.

**IRB Member Review Responsibility**

Those negotiating contracts should only use of the 3 options listed above. If IRB Members see that something different is used, a stipulation(s) should be prepared to switch to the appropriate, approved language.

**Exculpatory Language in Consent Forms**

It is important that the consent not contain any exculpatory language where it appears that subjects are giving up any rights.

**Exculpatory language:** *“Specific language or clause within an agreement that excuses one party from certain actions or behavior relative to that agreement.”*

*“What Is Exculpatory Language?: In a contract, exculpatory language is language that frees one party of certain liability that may occur as a result of the agreement and waives the rights of the other party. The word exculpatory is based on a Latin words ex- (remove) and culpa (guilt), put together they mean 'to remove guilt.’”*

**45 CFR 46.116:** No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or

releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**Examples of Exculpatory Language:**

- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.
- **No compensation is available from the sponsor of this study to pay for your injuries.**

**Examples of Acceptable Exculpatory Language:**

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.