



HRPP *Working Together*

Research-Related Injury Clauses & Consent Forms

What is acceptable??

Clinical research sponsors often propose language in agreements stating the sponsor will pay for treatment for a subject's research-related injury if the subject's insurance does not pay for it. One frequently asked question is, "Are these types of clauses permitted?"



UNMC discourages these types of "conditional payment clauses" where the sponsor has no legal obligation to pay for the injury-related service if the subject's insurance covers the service. Most private insurance managed care contracts have provisions denying payment or provisions for obtaining reimbursement (called subrogation) from 3rd parties who are primarily responsible for the insured's injuries. Similarly, Medicare has "Medicare Secondary Payer" rules where the

3rd party primarily liable for the subject's injuries must be billed first. CMS has issued guidance over the last several years indicating that Medicare cannot be billed for a clinical research injury-related service if a clinical research sponsor has paid for the same service for a subject with private insurance.

If you have questions about this topic, please contact Sheila Wrobel at (402) 559-6767.

INFORMED CONSENT, MEDICAL RECORDS & LETTERHEAD

For any research where any research procedure or interventions may result in a billable charge from the hospital or clinic, the subject's medical record must contain a **copy** of the signed research informed consent form(s) (per The Nebraska Medical Center Medical Records Policy #MS22). However, consent/addendum forms for genetic research are **not** to be placed in the subject's medical record when the IRB has concerns over: 1) third party accessibility and subject confidentiality, 2) the subject's health insurance status or employability may be jeopardized, and 3) the subject's medical safety will not be compromised by excluding the consent form from the medical record (e.g., biochemical/molecular studies which have predictive implications; family history studies). The IRB reserves the right to require that consent forms not be maintained in the research record for other studies where breach of confidentiality constitutes a risk.

INTERNAL ADVERSE EVENTS...WHEN DO THEY GET REPORTED TO THE IRB?

Internal AEs must be reported to the IRB if the PI determines that 1) the AE is unexpected **and** 2) the AE is related to, or possibly related to, the research intervention or procedures. This reporting requirement applies while the subject is on study and for 30 days after the subject has completed study interventions.

All internal AEs that meet the conditions listed above must be reported promptly to the IRB no later than two business days following PI notification that the event occurred. In addition, if the internal AE involves a fatal event that meets the conditions listed above, the IRB must also be notified by either telephone or email within 24 hours.



TIPS & TRICKS

IRB ELECTRONIC SUBMISSION SYSTEM

1. PHARMACY & THERAPEUTICS (P&T) COMMITTEE REVIEW

If you have a study that needs to be reviewed by the P&T Committee, you must indicate that by checking the box in Section III of the IRB application in order for the P&T Committee to have access to view the application electronically.

2. INFORMED CONSENT COPY FUNCTION

After you have created an informed consent document, there is now a COPY function that allows you to copy the one you made and create a new one. This will allow you to create an identical consent form and make the changes you need to rather than creating a new consent form from scratch.

3. EXIT VS SIGN OUT BUTTONS

The EXIT button in the application has a different function than the SIGN OUT function for the electronic system. EXIT closes the application to allow someone else to go into the application in edit mode. SIGN OUT takes you out of the electronic system completely. When you are finished working on an application, ALWAYS hit EXIT before signing out. If not, then the next person to sign in will see a LOCK icon (to tell who is still logged into the application, scroll over the LOCK icon) next to the application and will not be able to edit until you EXIT out of the application.

4. SIGNING AN APPLICATION

To sign an application, the person signing must log into the electronic system. The application that is ready to be signed will have a GREEN PENCIL next to it. If there is no GREEN PENCIL or a LOCK icon, then the application cannot be signed. The LOCK icon indicates that someone else is editing the application. To determine who is editing the application, simply put your cursor over the LOCK icon. All questions must be answered (including the COI questions in Section I) prior to signing an application. The person signing can click on the orange arrow next to the section in the application where their assurance statement is (i.e. a PI would click the "Principal Investigator Assurance" section, Scientific Reviewer would click the "Scientific/Scholarly Merit" Certification section). Once in that section, click to sign next to your name.

5. RED X's

Clicking the red X next to someone's name will remove them from the application.

6. CORRECT SPACING BETWEEN PARAGRAPHS IN CONSENT FORMS

Prior to submission to the IRB, please review the pdf versions of the application and consent forms. You may notice too much or not enough spacing in the pdf version, but it looks correct in the application. To correct spacing between paragraphs, put your cursor at the end of the paragraph. Click SHIFT and ENTER and that should correct the spacing issue.

7. TAKE THE TIME TO READ

Read the educational notes under the question and the information in dialogue boxes that pop-up.

8. QUESTIONS?

Don't hesitate to contact the IRB Office if you have any questions about or issues with the system! The main number is (402) 559-6463 or contact Sue Logsdon at (402) 559-3779.

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IRB EDUCATION SERIES - UPCOMING EVENTS

August 21 - "IRB Review of Research with Human Biological Materials" presented by Bruce Gordon, MD

September 11 - "How to Identify and Manage Conflicts of Interest" presented by Sheila Wrobel, JD, MBA

All lectures are in Sorrell 1005 from 12:00pm-1:30pm.
To RSVP, [CLICK HERE](#)