



Sponsor Payment for Costs Related to Subject Injury in Industry- Sponsored Clinical Trials Guidance

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Approved by: Human Protections Administrator,
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DEFINITIONS:

- I. "Subject Injury Costs" are the costs that a subject in a study must pay for medical treatment of illness or injury that directly results to the subject from his/her participation in the trial.

POLICY:

- I. For research involving more than minimal risk, the Federal regulations require informed consent documents to contain information on the availability and nature of compensation and medical treatments available if injury occurs, what they consist of and where further information may be obtained.
- II. Industry (or Commercial) Sponsors of Clinical Trials (Sponsors) often agree to pay for Subject Injury Costs that arise from research-related injuries.
- III. Sponsors are not legally required to volunteer to pay for Subject Injury Costs for any subject. A Sponsor may offer to pay for all Subject Injury Costs. However, commonly; the promise to pay is conditioned upon the receipt of a denial from another payer or stated as a conditional payment if the services are not otherwise covered by other payers.
- IV. The Centers for Medicare and Medicaid Services (CMS) has taken a position that a promise to pay for Subject Injury Costs in a contract (even conditional payment), of itself, is sufficient to be considered a liability insurance policy or plan such that Medicare would not be the primary payer (Medicare Secondary Payer (MSP) provisions).
- V. As a result, CMS requires that if a Sponsor chooses to pay Subject Injury Costs for subjects covered by Medicare, then the Sponsor must be treated as the primary payer for those costs. The MSP provisions require that Medicare is the secondary payer. The same principles apply to Medicaid, the payer of last resort.
- VI. UIC and its investigators share responsibility for complying with the laws, rules, regulations, and operating guidance relating to treatment of research -related injury and compensation for Subject Injury Costs. The purview of the IRB is to provide an ethical and regulatory review of the research, including evaluating the subject injury language for greater than minimal risk research.
 - A. UIC will NOT agree to initially bill Medicare, Medicaid HMO plans or any other governmental healthcare insurance for Subject Injury Costs, and then bill the Sponsor for what the governmental healthcare programs do not pay. The reason for the above is that we accept funding from Medicare and other governmental health care programs and under the National Coverage



- Determination (NCD) for Routine costs in Clinical Trials (310.1), Medicare provides coverage for *items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications*. Additionally, because Medicare may pay for certain costs in the study, but other payers will not and the sponsor provides those items or services for those study participants, Medicare must not be billed for those items and services provided for non-Medicare study participants.
- B. UIC does not agree to pay medical expenses for Subject Injury Costs that result from a subject's participation in a trial or to provide other forms of compensation (e.g. lost wages or pain and suffering).
 - C. The U.S. Veterans Administration is required by law to provide medical treatment for subjects who are injured in clinical trials conducted under its regulations.
 - D. The purview of the IRB is to provide an ethical and regulatory review of the research, including evaluating the subject injury language for greater than minimal risk research. This review may involve a determination that compensation for subject injury is required.

PROCEDURE:

- I. Options Regarding the Subject Injury Cost Provisions in Clinical Trial Agreements:
 - 1) Full Payment (Preferred):
 - The Sponsor may choose to pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.
 - 2) Partial Payment (First Fallback Option)
 - The Sponsor may choose to pay for Subject Injury Costs for uninsured subjects or subjects with Medicare, Medicaid HMO plans or any other governmental healthcare insurance and to pay any part of Subject Injury Costs for subjects insured by third party commercial insurance that are not covered and/or paid by their third party commercial insurance.
 - 3) No Payment (Requires Unit Head Endorsement):
 - The Sponsor may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.
- II. Options Regarding the Subject Injury Cost Language in Informed Consent Form:
 - 1) Sponsor Paying ALL
 - If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. ___ at telephone number ___. [For research involving greater than minimal risk, emergency contact information should be included here].

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek



treatment with information they may need if they want to contact the research doctors.

If you get ill or injured as the direct result of being in this study, the [Insert sponsor name] will pay the costs for your medical treatment of the illness or injury if it:

- (a) Is not a medical condition that you had before you started the study;
- (b) Is not the result of the natural progression of your disease or condition;
- (c) Is not caused by your failure to follow the study plan; and
- (d) Is not proved to be directly caused by the negligence of a UIC employee. "Negligence" is the failure to follow a standard duty of care.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

2) Sponsor Partially Paying

- If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. ___ at telephone number ___. [For research involving greater than minimal risk, emergency contact information should be included here].

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

If you have a private health insurance plan, your plan will be billed for the costs of treatment. If there are any costs that are not paid by your plan, the [Insert sponsor name] will pay these costs. You will still be responsible for any co-payments or deductibles required by your health insurance plan.

If you are covered by Medicare, Medicaid HMO plans or any other governmental healthcare insurance or if you are not covered by a health insurance plan, the [Insert sponsor name] will pay these costs. If you have Medicare or another governmental insurance plan, the Sponsor may request your Social Security number, as the Sponsor may have mandatory



reporting requirements under the Medicare Mandatory Reporting provisions.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

3) Sponsor NOT Paying

- If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. ___ at telephone number ___. [For research involving greater than minimal risk, emergency contact information should be included here].

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. [*Include if applicable* - The study staff will assist you in obtaining pre-authorization from your insurance company.] Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.



III. Option Selection and Wording of Clinical Trial Agreement and Informed Consent Documents:

- 1) A Sponsor who wants to enter into an agreement with UIC must select one of the foregoing OPTIONS with respect to the manner in which payment for Subject Injury Costs will be handled under such agreement. Option #3 is the least desirable for the institution and subjects and should be reserved only after Options #1 and #2 are rejected. No other options are available.
- 2) If the Sponsor elects not to pay for any Subject Injury Costs (Option 3), additional endorsement of the research must be obtained from the Department/Unit Head justifying that the research subjects should bear the financial burden of participation in the development of products for companies, and including the possible assumption by the Department of any costs that may arise as a result of research-related injury.
- 3) The wording of the agreement and the information consent form must be consistent, e.g., if the agreement says that the Sponsor will not pay for Subject Injury Costs, then the informed consent form must tell that subject that the Sponsor will not pay and that the subject must pay these costs.
- 4) The agreement should be compared to the informed consent form that is approved by the IRB to ensure that the language between the two documents is consistent. If the language is inconsistent, one of the documents should be modified appropriately to reflect the agreement of the parties.
- 5) In the event of an inconsistency between an executed contract and the IRB approved informed consent document, the informed consent document will not be released to the Investigator until both documents are aligned.

REFERENCES:

45 CFR 46.116(a) (6)
 21 CFR 50.25(a) (6)
 National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
 Centers for Medicare & Medicaid Services - Mandatory Insurer Reporting, Mandatory Insurer Reporting for Non-Group Health Plans (NGHP)
 Medicare Learning Network (MLN) Matters SE0822 Revised, "Clarification of Medicare Payment for Routine Costs in a Clinical Trial"
 Local Coverage Article: Clinical Trials- Medical Policy Article (A49286), 9/1/2014

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.0, 11/13/2014	NA	Policy created.
1.1, 11/21/2014	1.0, 11/13/2014	Consent template language updated to include exclusionary language applicable when payment for subject injury costs are available.
1.2, 3/27/2015	1.1, 11/21/2014	Update consent template language to align with NCD for Routine Costs of Clinical Trials.