Lifespan
Delivering health with care.

Clinical Trials Quarterly

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Lifespan

Office of Research Administration

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Patient Injury Language in the Informed Consent Document and the Clinical Trial Agreement

Lifespan is committed to protecting the rights and ensuring the safety of research participants in industry-sponsored clinical trials conducted at our hospitals.

Most industry sponsors offer compensation for the reasonable and necessary medical care required to treat a "research injury." A research injury is defined as any physical or mental injury or illness caused by being in the study. This includes injuries resulting from a drug, device, or medical procedure that is required by the protocol that the subject would not have had but for their participation in the study.

The details of the sponsor's obligations in relation to subject injuries are defined in the Clinical Trial Agreement (CTA,) which is negotiated by the Clinical Trials Office (CTO.) The information communicated to the participant in the Informed Consent Document (ICD) must be consistent with the language in the CTA, in language appropriate for the ICD. The CTO will review the language in the ICD when it is submitted to the IRB for review. At that time, the CTO will communicate to the Study Coordinator and the IRB any language that needs to be corrected. *The study cannot be activated by the CTO until the injury language in the ICD is correct.*

In order to avoid any delays in study activation due to incorrect injury language in the ICD, the CTO has written a memo detailing our position on patient injuries in Industry-Sponsored clinical trials. The memo was distributed to the Clinical Research community on December 10, 2015. The CTO requested that this memo be sent to the Sponsor as soon as our participation in a study has been confirmed, and before the study is submitted to the IRB. By doing so we hope to have a draft consent whose research injury language is consistent with the stance outlined in the memo at the time of IRB submission.

The memo in its entirety is included below. Please send any questions or comments to Gina Johnson at gjohnson@lifespan.org.

Resources:

clinicaltrials.gov:

ClinicalTrials.gov resource that provides access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.

National Institutes of Health

https://www.nih.gov/health-information/nih-clinical-research-trials-you/educational-resources

fda.gov

The FDA ensures that drugs, vaccines and other biological products and medical devices intended for human use are safe and effective.

In Next Quarter's Issue:

"The Internal Budget"

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Rhode Island Hospital
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Bradley Hospital
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December 1, 2015

MEMORANDUM

TO: Clinical Trial Sponsors

FROM: Peggy McGill, MA, CRA
Administrative Director
Lifespan Office of Research Administration

RE: Required Subject Injury Language in the Clinical Trial Agreement (CTA) and the Informed Consent Document.

The purpose of this document is to establish Lifespan's position in regards to subject injury coverage for all industry-sponsored clinical trials conducted at Lifespan affiliate hospitals. We offer this information in advance of CTA negotiation and submission of a draft informed consent to our Institutional Review Board.

Lifespan's position is that responsibility for the cost of treating research-related injuries caused by a sponsor's drug, device, or non-standard of care protocol-required procedure falls to the Sponsor. We understand that exceptions, such as negligence of the study site or its personnel, and the progression of the study participant's underlying disease will be addressed in the CTA.

Lifespan will not accept the following language or similarly worded exceptions in the informed consent or CTA Documents:

- that requires Lifespan or any of its affiliates to request payment from a participant's insurance or any other 3rd party payer for a research-related injuries.
- that states Sponsor will only reimburse costs for research-related injuries not covered or denied by participant's insurance or another 3rd party payer.
- which limits reimbursement for research-related injuries to immediate or emergency care, or similarly worded exceptions.

Our position reflects our commitment to the safety, welfare and equitable treatment of all persons who volunteer to participate in studies for the development of products for companies. Consistent with this commitment, our position on subject injury language is not negotiable and is applicable to all industry-sponsored clinical trials conducted by Lifespan affiliates.

NEWS:

Recruitment and Retention of Clinical Trial Subjects is at an all-time low.

According to an article published in the Wall Street Journal on April 13, 2016, The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are proposing some changes to streamline and simplify the protocol creation and informed consent processes. They are hoping to attract more patients who may be reluctant to participate due to the arduous process and oftentimes overwhelming amount of information provided to them.

Read more online at The Wall Street Journal. http://www.wsj.com/articles/clinical-trials-need-more-subjects-1460407076.

Items to Note:

- Our new indirect rate for non-federal clinical trial agreements as of October 1, 2015, is 30% across all affiliates.
- At the close of an active clinical trial, the remaining balance of funds will be assessed the applicable indirect costs.
- Your Research Administrator can provide the research discount rate for Lifespan tests and procedures. Call or email Gina Johnson or Kim-Marie Lawrence.
- Training is available at your site! Call or email Gina Johnson. Topics include Coverage Analysis, Internal Budget, LifeChart billing review, and much more…