



**CLINICAL TRIAL AGREEMENTS -**

**DETAILS IN THE SUBJECT  
INJURY PROVISION YOU  
SHOULDN'T OVERLOOK**



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## What is a “Subject Injury”?

- An adverse event/reaction occurring to Study participants as a result of their participation in the Study
  - Caused by the Study Drug/Study Device (or implementation thereof)
  - Caused by Protocol-mandated procedures/activities

## In the context of the CTA...

- The “Subject Injury” provision addresses how Subject Injury-related costs will be handled
- This topic should always be addressed in CTAs
  - Allocates risk between Sponsor/Site
  - Not necessarily covered if not explicitly stated in the CTA
  - Ok to acknowledge subject injury doesn't apply in the case of studies that carry ZERO risk of subject injuries

## Subject Injury Expenses

- Subject Injury-related expenses (costs of diagnosis, hospitalization, and/or treatment) should be the **Sponsor's** responsibility
- Exceptions may be acceptable...
  - Expenses resulting from Site's failure to comply with the Protocol or negligence/misconduct
  - Expenses resulting from the **normal/expected progression** of the participant's underlying illness/pre-existing condition

## Why is this Sponsor's responsibility?

- Study participants acknowledge some degree of risk, but consenting doesn't mean they should be on the hook financially for these risks as well
- Sponsors need Study data from these participants, and will ultimately benefit commercially from such data
  - Sponsors are must better situated to take responsibility for such expenses than individuals

### SUBJECT INJURY DEFINITION

“A “Subject Injury” shall mean an unanticipated, immediate, physical injury suffered by a Study participant as a direct result of the Study Drug, as determined by Sponsor.”

### WHAT'S CONCERNING?

- “Unanticipated”
- “Immediate”
- “Physical injury”
- “Direct result”
- “of the Study Drug”
- “as determined by Sponsor”

## ORIGINAL

“A “Subject Injury” shall mean an unanticipated, immediate, physical injury suffered by a Study participant as a direct result of the Study Drug, as determined by Sponsor.”

## MODIFIED

“A “Subject Injury” shall mean an ~~unanticipated, immediate, physical~~ injury ~~and/or illness~~ suffered by a Study participant as a ~~direct~~ result of the Study Drug ~~or any procedure required by the Protocol~~, as determined by the ~~Sponsor~~ Investigator.”

### SPONSOR RESPONSIBILITIES

“...Sponsor shall pay for the reasonable and necessary expenses incurred at Site and resulting from emergency care required for any Subject Injury, which are not covered by a Study participant's insurance.”

### WHAT'S CONCERNING?

- “Expenses incurred at Site”
- “Emergency Care”
- “Which are not covered by a Study participant's insurance”

## ORIGINAL

“... Sponsor shall pay for the reasonable and necessary expenses incurred at Site and resulting from emergency care required for any Subject Injury, which are not covered by a Study participant's insurance.”

## MODIFIED

“...Sponsor shall pay for the reasonable and necessary expenses ~~incurred at Site and~~ resulting from the ~~emergency care for~~ diagnosis, hospitalization, and/or treatment of any Subject Injury, ~~which are not covered by a Study participant's insurance.~~”



### EXCEPTIONS TO SPONSOR RESPONSIBILITIES

“...Sponsor shall not be responsible for any Subject Injury expenses arising from (i) Site's negligence, recklessness, or willful misconduct; (ii) Site's failure to comply with the Protocol or Sponsor's written instructions, recommendations, or suggestions, (iii) a Study participant's pre-existing condition or underlying disease, (iv) a Study participant's early withdrawal from the Study, or (v) a Study participant's failure to comply with the Protocol or informed consent form.”

### WHAT'S CONCERNING?

- “Site's failure to comply with Sponsor's recommendations or suggestions”
- Exceptions around pre-existing conditions/underlying diseases need to exclude exacerbations related to the Study
- “Study participant's early withdrawal”
- “Study participant's failure to comply...”

## ORIGINAL

"...Sponsor shall not be responsible for any Subject Injury expenses arising from (i) Site's negligence, recklessness, or willful misconduct; (ii) Site's failure to comply with the Protocol or Sponsor's written instructions, recommendations, or suggestions, (iii) a Study participant's pre-existing condition or underlying disease, (iv) a Study participant's early withdrawal from the Study, or (v) a Study participant's failure to comply with the Protocol or informed consent form."

## MODIFIED

"...Sponsor shall not be responsible for any Subject Injury expenses arising from (i) Site's negligence, recklessness, or willful misconduct; (ii) Site's failure to comply with the Protocol or Sponsor's written instructions, ~~recommendations, or suggestions~~, or (iii) a Study participant's pre-existing condition or underlying disease, ~~except to the extent exacerbated by the Study~~ (iv) ~~a Study participant's early withdrawal from the Study~~, or (v) ~~a Study participant's failure to comply with the Protocol or informed consent form~~."

## CONDITIONAL LANGUAGE

**Be cautious** with language saying that Sponsor's obligations will only apply "IF" certain situations occur – if concerned, remove!

- e.g. Site immediately providing notice of such injuries to Sponsor
- e.g. Site being the entity providing care to the Study participants

## EXPIRATION OF SPONSOR'S OBLIGATIONS

**Remove time limits** as to Sponsor's obligations – i.e. language stating that Sponsor's obligations apply "during the Study".

Watch out for sneaky ways of incorporating this "time limitation," such as not including the subject injury provision within the survival provision.

## SILENCE

Some Sponsors try to claim that if they are indemnifying for injuries/illnesses/death to Study participants, this is the same thing.

### **NOT TRUE!**

- Sponsor's indemnification obligations related to Subject Injuries would be triggered upon the Study participant (or their family member) filing a lawsuit against the Institution/Sponsor regarding the adverse event.
- Subject Injury obligations would not require a lawsuit; the Study participant's bills are simply paid by Sponsor without any formal legal processes required.

***EXCEPTION:*** Sometimes OK to remain silent on Subject Injury compensation for Studies involving zero risk to Study participants (chart review studies, registry studies, etc.). Check the Protocol!!

## TAKE YOUR TIME

ALWAYS CONSIDER THE FOLLOWING:

- **How does this language impact the Site?**
  - Does this make sense knowing what happens in the real-world setting when adverse events occur?
  - Does this create operational hurdles for the Study/billing team?
- **How could this language impact Study participants?**
  - Is the language removing any protections that exist in the ICF?
  - Is the language asking the Site to agree to reducing patient rights?

## ASK QUESTIONS!

DON'T BE AFRAID TO ASK THE SPONSOR – WHAT DO YOU MEAN??

# Questions?



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Manager, Clinical Research Contracts & Compliance

Jody's background includes both the healthcare and legal industries, and she brings a sense of compassion and knowledge when helping bridge the divides between the research industry's various business interests, operational abilities, and legal limitations. She has collaborated with an extensive variety of research sites, from large academic and non-profit healthcare systems to the smaller dedicated research facilities and community hospitals, providing her with a well-rounded perspective of the contracting needs of each type of research site.

Jody strives to make the clinical research industry more efficient, more conscientious, and more supportive.

Thank you!

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