This worksheet is used to determine whether a clinical trial contract with a third party sponsor or CRO meets AAHRPP requirements.

1. Requirements (All must be met)

1.1 ☐ Research-related injury is not possible

1.1 ☐ All of the following are true:

1.1.1 ☐ The contract indicates who will provide care and who is responsible to pay for it (see Footnotes 1 and 2)

1.1.2 ☐ The terms specified in the contract and in the consent document are consistent

1.2 ☐ The sponsor will not conduct monitoring of its site

1.2 ☐ The contract indicates the sponsor must promptly report to the organization any findings from the monitoring that could affect the safety of subjects or influence the conduct of the study (see Footnotes 3 and 5)

1.3 ☐ The IRB-approved protocol does not include a data and safety monitoring plan

1.3 ☐ The contract requires the sponsor to send data and safety monitoring plans and reports to the organization (see Footnotes 4 and 5)

1.4 ☐ The organization does not have policies and procedures regarding the publication of findings from sponsored research

1.4 ☐ The contract’s provisions for dissemination of research findings do not contradict the organization’s policies and procedures regarding the publication of findings from sponsored research (see Footnote 6)

1.5 ☐ All of the following are true:

1.5.1 ☐ The contract requires the communication of findings from a closed research study to the investigator or organization when those findings directly affect subject safety (see Footnote 7)

1.5.2 ☐ The contract specifies the length of time following closure of a study to which this requirement applies

1.5.3 ☐ The contract indicates that this requirement survives the contract

2. Notes

3. Footnotes

3.1 There is no requirement that sponsors or organizations be responsible for paying for care for research-related injury. The contract should define whether there is payment for research-related injury before research starts so subjects can consider this information during the consent process. The laws of some countries require that the sponsor pay for care for research-related injury, in which case, contracts should specify the specific obligation of the sponsor.

Sample language:

3.2 [The sponsor] will provide payment to the institution for reasonable, unreimbursed medical expenses, including hospitalization, which the institution may incur as a direct result of the treatment of a subject’s injuries that directly result from the study drug or its administration during the clinical trial, as determined by [the sponsor] and the principal investigator.

3.3 Research-Related Injury. [The sponsor] shall be responsible for payment of the actual and reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a study subject that results from the administration of the study drug [or device] in accordance with the protocol or the proper performance of any Protocol procedure.

Sample language:

3.4 [The sponsor] shall conduct or CRO conducts monitoring of sites on a periodic basis throughout the study. If a monitor finds non-compliance at the site that affects safety or materially affects the proper conduct of the study, [the sponsor] shall in a timely manner notify the investigator and, if non-compliance is serious or continuing, the site.

Sample language:

3.5 [The sponsor] agrees to report promptly to the principal investigator and the IRB any findings obtained from on-site monitoring activities or from study results obtained as part of the study or for two years after the study has closed that could affect the safety or medical care of a study subject or a study subject’s willingness to continue participation in the study, influence the conduct of the study, or alter the IRB’s determination of whether or not the study should be conducted. The IRB will determine whether and how the reported information, or part of it, should be provided to study subjects by the principal investigator or, in the principal investigator’s absence, by the organization. The sponsor will cooperate with the IRB and the organization in carrying out the IRB’s determination.

Sample language:

3.6 [The sponsor] shall promptly notify investigator of any findings of (1) new and unexpected serious adverse safety events arising from [the sponsor’s] monitoring of the study that could affect the safety of subjects, and (2) trends or patterns of non-serious or expected adverse events that occur at a specificity or severity that is inconsistent with prior observations, all in accordance with the obligations set forth in 21 C.F.R. 312.32(c), 21 C.F.R. 312.33(b), 21 C.F.R. 56.108(b) and FDA’s Guidance on Adverse Event Reporting to Institutional Review Boards in Clinical Trials (January 2009).

3.4 [The sponsor] agrees to provide data and safety monitoring plans to the principal investigator prior to IRB review of the study. [The sponsor] will provide the organization’s principal investigator with any findings from its data and safety monitoring that could affect the safety of subjects or their willingness to participate or influence the conduct of the study. Reports of an urgent nature must be provided within ten business days; routine reports must be submitted within 30 business days. (This language is not required in the contract if these provisions are described in the protocol)

3.5 [The sponsor] shall provide notice to the institution of any findings that may (i) affect the safety and welfare of subjects, (ii) affect the willingness of subjects to continue their participation in the clinical trial, (iii) influence the conduct of the clinical trial or (iv) alter the IRB’s approval to continue the clinical trial. The institution will work with its IRB and the principal investigator to disseminate this information to the subjects.

3.5 The [Organization] considers “timely” or “prompt” in general to mean 30 days or less.