AdventHealth Orlando

WORKSHEET: Contracts

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

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1. Requirements (All must be met)

1.1	☐	One of the following is true:	
		○ Research-related injury is not possible	
		○ 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	☐	One of the following is true:	
		○ The sponsor will not conduct monitoring of its site	
		○ 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	☐	One of the following is true:	
		○ The IRB-approved protocol does not include a data and safety monitoring plan	
		○ The contract requires the sponsor to send data and safety monitoring plans and reports to the organization (see Footnotes 4 and 5)	
1.4	☐	One of the following is true:	
		○ The organization does not have policies and procedures regarding the publication of findings from sponsored research	
		○ 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.
3.2	Sample language: • [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. • 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.
3.3	Sample language: • [The sponsor]/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]or CRO shall in a timely manner notify the investigator and, if non-compliance is serious or continuing, the site . • [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 how 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.
3.4	Sample language: • [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. 312.55(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). • [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). • [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.

3.6	Sample language: • [The sponsor] acknowledges and accepts the interest of the [organization] in the noncommercial publication of the results, independent of a positive or negative outcome of the study. With respect to any proposed publication or presentation of the results of the study, the organization and/or investigator agree to submit to [the sponsor] a copy of the proposed publication or presentation at least two months prior to the submission thereof for publication or the date of such presentation in order to allow [the sponsor] to review it. Any manuscript for publication submitted to [the sponsor] shall be reviewed without unreasonable delay and approval shall not be withheld unreasonably. If [the sponsor] does not notify [the organization] within thirty days of [the sponsor's] receipt of the intended publication, [the organization] shall be free to publish. In case a difference of opinion between [the sponsor] and [the organization], the contents of the publication will be discussed in order to find a solution which satisfies both parties. [The organization] acknowledges that in case of multi-center studies the results of the study are to be published only through coordination by [the sponsor] in order to combine the results of all participating centers. [The organization] shall be free to publish the results of their center provided the overall results have not been published with twenty-four months from the completion of the study, subject to the compliance to the remaining terms set forth in the section. [The sponsor] may recommend any changes to the publication it reasonably believes are necessary for scientific purposes. [The organization] agrees that the implementation of such recommended changes shall not be unreasonably refused. If [the sponsor] informs[the organization] that such publication could be expected to have an adverse effect on the confidentiality of any of [the sponsor's] confidential information, [the organization] shall prevent the publication, unless the confidential information can be deleted from the publication without detriment effect on the scientific correctness of the publication. If the publication could in [the sponsor's] view have an adverse effect on the ability to obtain patient protection for any invention, [the sponsor] may request a delay of the publication for a reasonable period of time in order to permit the preparation and filing of any desired patent application by or on behalf of [the sponsor], such period, however, not to exceed three months from the date on which [the sponsor] received the intended publication for review. [The sponsor] may request a further delay of publication only in case that a patent application has been filed and that the priority application is incomplete and subject matter has to be added to the application during the priority year. In this case [the sponsor] may request delay of any publication until the completion of the priority application. [The sponsor] shall not unduly delay such completion. The organization and/or investigator shall comply with all applicable requirements regarding disclosure of industry support (financial or otherwise) in connection with such publications and presentations. [The organization] shall impose the same obligations on publication as set forth in this section on all study team members. The obligation set forth in this section shall survive for a period of ten years upon early termination or expiration of this Agreement. • Publication. [The organization] shall be free to use the results of the research and clinical study for its own teaching, research, education, clinical and publication purposes without the payment of royalties or other fees. [The organization] shall submit to [the sponsor] for its review, a copy of any proposed publication resulting from the research at least thirty (30) days prior to the date of submission for publication, and shall consider in good faith all comments provided by [the sponsor] during that review period. If [the sponsor] determines that the proposed publication contains patentable subject matter which requires protection, [the sponsor] may require the delay of publication for a period of time not to exceed sixty (60) days for the purpose of filing patent applications. {If multicenter study, may insert language agreeing to delay publication until the earlier of the multicenter publication, or one year after end of study, but with firm commitment from Sponsor to encourage publication}.
3.7	Sample language: • Following completion of this study under this contract, if [the sponsor] becomes aware of relevant findings from the study data that would directly affect the safety of the former study subjects, [the sponsor] shall promptly notify the institution of such relevant finding so that the institution may communicate such findings to the former study subjects. [The sponsor] shall determine the relevance of the findings and the institution shall inform former study subject as appropriate. [The sponsor's] reporting obligation shall continue for two years following completion of the study conducted under this contract. • During and for a period of at least two years after the completion of the study, [the sponsor] shall promptly report to the investigator any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol. In each case, the investigator and [the organization] shall be free to communicate these findings to each study subject and the IRB.