McLaren HEALTH CARE

AAHRPP Checklist for Clinical Trial Agreements

AAHRPP Standard I-8 deals with five provisions for contracts and funding agreements that are designed to contribute to the protection of research participants in sponsored research. Accredited organizations must negotiate with sponsors to ensure that contracts and funding agreements include the required provisions when each specific Element is appropriate for the research under negotiation.

Instructions: After completing checklist sign/date page 2 and attach to application in iRIS. Pages 3 and 4 are informational only.

Research Study Title:

PI: **MHC IRB Protocol Number:**

Element 1.8 A	**Yes**	**No**	**Comments**
Medical care for research participants with research-related injury, when appropriate.			
Does the contract or funding agreement define whether there is payment for research related injury?			
Does the contract or funding agreement define what payments are covered for research related injuries to the subject and or the institution?			
*If no to any of the above – provide sponsor with sample language to address this requirement **			
Element 1.8 B	**Yes**	**No**	**Comments**
Prompt reporting to the organization after a research site monitoring visit of findings that could affect the safety of participants or influence the conduct of the study.			
Does the sponsor specify the way research activity would be monitored - as either a site visit or remote monitoring?			
If Yes - Does, the sponsor indicate the frequency of the monitoring?			
Will results of the monitoring visit be provided to the organization promptly?			
*If no to any of the above -provide the sponsor with the sample language to address this requirement **			
Element 1.8 C	**Yes**	**No**	**Comments**
Reporting of the data and safety monitoring plan and annual reporting of the results to the organization.			
Does the contract indicate that the sponsor will provide the data and safety monitoring reports to the organization?			
Is the frequency for reporting indicated?			
Is it at a minimum on an annual basis?			
*If no to any of the above – provide the sponsor with sample language to address this requirement**			

Element 1.8 D (*This section is informational only and not a binding element)*	**Yes**	**No**	**Comments**
Sponsors plans for disseminating findings from the research and the roles that researchers and sponsors will play in the publication or disclosure of results.			
Does the sponsor provide plans for dissemination of findings?			
Does the sponsor allow the organization to publish results from the data collected? – *make researchers aware of answer*			
Element 1.8 E *(if applicable)*	**Yes**	**No**	**Comments**
Notification to the organization of study results (after the study has ended) if they directly affect the safety of the participants. This information to be considered in the decision to inform the participants.			
Does the study continue until disease progression? If yes following question is not applicable			
If the study ends upon completion of active study protocol – is future communication / notification regarding data analysis that results in findings that may be adversely associated with participant safety included in the agreement or contract? *If No- provide the sponsor with sample language to address this requirement* *			

Reviewer Signature _____ Date_____

Title _____

*Sample Language to Address AAHRPP Requirement

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Element 1.8 A ***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.*
Element 1.8 B [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.
Element 1.8 C [The sponsor] agrees to provide data and safety monitoring reports 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).
Element 1.8 D **(*This section is informational only and not a binding element)*** [The sponsor] acknowledges and accepts the interest of the [organization] in the non-commercial 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}.

Element 1.8 E

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.

The following is acceptable language for I.8.B, I.8.C and I.8.E because it is written to cover all (this was implemented after Step 2 Application submission to AAHRPP in 2016):

During and for a period of at [specify a period of time appropriate to the specific study, for example, least two years; or specify a triggering event, for example, completion of data analysis] after the completion of the study, [the sponsor] shall promptly (or in a timely manner appropriate to the level of risk involved) 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.
Data and safety monitoring reports shall be sent to the organization (at a minimum annually) so they can be considered by the IRB at the time of continuing review.