TEXAS A&M UNIVERSITY	WORKSHEET: Contracts		
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The purpose of this worksheet is to provide support for individuals reviewing contracts and other funding agreements and the budgets associated with those contracts. This worksheet is to be used when reviewing contracts and funding agreements. It does not need to be completed or retained. [1]

	1 Requirements (Check if **"Yes"** or **"N/A".** All must be checked)
☐	The contract or funding agreement indicates who will provide care for subject injury and who is responsible to pay for it. [2] **("N/A" if the research involves no more than Minimal Risk to subjects.) N/A:** ☐
☐	The above description of who will provide care for subject injury and who is responsible to pay for it is consistent with the consent document. **("N/A" if the research involves no more than Minimal Risk to subjects.) N/A:** ☐
☐	The contract or funding agreements requires the sponsor to promptly report (within 30 days) to the Institution any findings that could affect the safety of participants or influence the conduct of the study. **("N/A" if the research involves no more than Minimal Risk to subjects.)[3] N/A:** ☐
☐	The contract or funding agreement obligates the sponsor to provide the results of data and safety monitoring reports to the investigator within a specified time-frame. The time frames should cover routine and urgent reports. Alternatively, the time frame may be left open-ended or the requirement can be included or referred to in a survivor clause. **("N/A" if the research involves no more than Minimal Risk of injury, the research does not have a data and safety monitoring plan; or the investigator is responsible for the data and safety monitoring plan.) N/A:** ☐
☐	The contract or funding agreement includes a description of the right of investigators to publish data that is consistent with the institution's policy regarding the publication of findings from sponsored research. [4] **("N/A" if the organization has no policy regarding the publication of research results.) N/A:** ☐
☐	The contract or funding agreement includes a description of the plans to disseminate findings from the research.
☐	The contract or funding agreement obligates the sponsor to communicate to the investigator results uncovered after study closure that directly affect subject safety. This obligation may be limited to a number of years after study closure. **("N/A" if the research does not involve medical procedures.)[5] N/A:** ☐
☐	The contract, funding agreement, or associated budget **does not include** "finder's fees" (Payments to professionals in exchange for referrals of subjects.)
☐	The contract, funding agreement, or associated budget **does not include** "bonus payments" (Payments to investigators or research staff in exchange for referrals of subjects.)
☐	For Independent IRBs, if contracting directly with sponsors or clinical research organizations, contracts or other funding agreements include a requirement that Sponsors communicate findings from a closed research study to the IRB when those findings directly affect participant safety. Specify a time frame or triggering event after closure of the study during which the Sponsor will communicate such findings (e.g., two years or after the close of data analysis), when appropriate.

[1] This document satisfies AAHRPP elements I.8.A, I.8.B, I.8.C, I.8.D, I.8.E, II.3.C-II.3.C.1

[2] For independent IRBs, this should include an attestation or other written statement from the researcher or clinical research organization, for example, master service agreement or work order.

[3] The intent of this element is that if the sponsor is responsible for having an on-site study monitor periodically review the conduct of the research or remote monitoring of study activities and the monitor finds serious problems with the research, such as Serious or Continuing Non-Compliance, lack of supervision of the research, or falsification or fabrication of data, this information will make it back to the institution. Per IRB policy (see "HRP-214 - FORM - Reportable New Information"), investigators are required to promptly provide this information to the IRB.

[4] For independent IRBs, this should include an attestation or other written statement from the researcher or clinical research organization, for example, master service agreement or work order.

[5] The intent of this element is that if a study is closed and the sponsor subsequently learns that the study procedures cause problems that indicate that subjects should undergo medical care to mitigate risks, the sponsor will notify the investigator. The investigator and IRB will determine how to take action on this information. Per IRB policy (see "HRP-214 - FORM - Reportable New Information"), investigators are required to promptly provide this information to the IRB.

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