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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. All of the following questions must be “Yes” or “N/A” as described for the contract to be signed | |
| Yes  No  N/A | The contract or funding agreement indicates who will provide care for subject injury and who is responsible to pay for it. **(“N/A” if the research involves no more than minimal risk**[[1]](#endnote-1) **of injury.)** |
| Yes  No  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 of injury.)** |
| Yes  No  N/A | The contract or funding agreement requires the sponsor to promptly report (within 30 days) to the IRB or the appropriate party any findings of on site study monitors that could affect the safety of subjects, or influence the conduct of the study. **(“N/A” if the sponsor will not be monitoring the research.)[[2]](#endnote-2)** |
| Yes  No  N/A | The contracts or funding agreements state that data and safety monitoring plans will be provided prior to IRB approval of the research. **(“N/A” if the research does not have a data and safety monitoring plan or someone other than the sponsor (e.g., investigator) is responsible for the data and safety monitoring plan.)** |
| Yes  No  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 based on a specific triggering event (such as completion of data analysis), or 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.)** |
| Yes  No  N/A | The contract or funding agreement includes a description of the right of investigators to publish data that is consistent with the organization’s policy regarding the publication of findings from sponsored research. **(“N/A” if the organization has no policy regarding the publication of research results.)** |
| Yes  No  N/A | 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.)[[3]](#endnote-3)** |

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| 1. All of the following questions must be “No” for the contract to be signed | |
| Yes  No | The contract, funding agreement, or associated budget includes “finder’s fees” (Payments to professionals in exchange for referrals of subjects.) |
| Yes  No | The contract, funding agreement, or associated budget includes “bonus payments” (Payments to investigators or research staff in exchange for referrals of subjects.) |

1. *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons. [↑](#endnote-ref-1)
2. 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 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, the study monitor will notify the IRB. [↑](#endnote-ref-2)
3. The intent of this element is that if a study is close and the sponsor subsequently learns that the study procedures cause problems that affect subject safety, the sponsor will notify the IRB who will determine whether and how to provide this information to former subjects. [↑](#endnote-ref-3)