University of Central Florida	CHECKLIST: Clinical Agreement Items Related to Human Subject Protections		
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The purpose of this checklist is to assist contracts and grants staff in reviewing clinical agreements and the budgets associated with those agreements. It does not need to be retained.

1 Requirements (Check if "Yes" or "N/A". All must be checked)

☐ Yes ☐ N/A	The clinical agreement indicates, in case of research related injury, who will provide medical care and who is responsible to pay for it. ("N/A" if the research involves no more than Minimal Risk of injury.)
☐ Yes ☐ N/A	The above description of who will provide care 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 ☐ N/A	The clinical agreement obligates the sponsor to promptly provide study monitor reports to investigators. ("N/A" if the sponsor will not be monitoring the research.)[1]
☐ Yes ☐ N/A	The clinical 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 both routine and urgent reports. ("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 ☐ N/A	The clinical agreement includes a description of the right of investigators to publish data that is consistent with UCF's policy regarding the publication of findings from sponsored research.
☐ Yes ☐ N/A	The clinical 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.)[2]
☐ Yes	The clinical agreement, or associated budget does not include "finder's fees" (Payments to professionals in exchange for referrals of subjects.)
☐ Yes	The clinical agreement, or associated budget does not include "bonus payments" (Payments to investigators or research staff in exchange for referrals of subjects.)

[1] The intent of this element is the following: 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, then this information will make it back to the University. Per IRB policy (see "HRP-218 FORM - Reportable New Information"), investigators are required to promptly provide this information to the IRB.

[2] 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-218 FORM - Reportable New Information"), investigators are required to promptly provide this information to the IRB.