WORKSHEET: Contracts

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]](#endnote-2)

1. Contract Items Related to Human Subjects (Check if “Yes” or “NA”. 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]](#endnote-3) **(“NA” if the research involves no more than Minimal Risk to subjects.) NA:**

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. **(“NA” if the research involves no more than Minimal Risk to subjects.) NA:**

The contract or funding agreement requires the sponsor to promptly report (within 30 days) to the Organization any findings that could affect the safety of participants, influence the conduct of the study or alter the IRB’s approval to continue the study. **(“NA” if the research involves no more than Minimal Risk to subjects)[[3]](#endnote-4) NA:**

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.) NA:**

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. **(“NA” 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.) NA:**

1. Contract Items Related to the Budget (Check if “Yes”. All must be checked.)

The contract, funding agreement, or associated budget includes no “finder’s fees” (Payments to professionals in exchange for referrals of subjects.)

The contract, funding agreement, or associated budget includes no “bonus payments” (Payments to investigators or research staff in exchange for referrals of subjects.)

Delete or move payment language which will conflict with the budget exhibit, including language which mentions specific amounts.

Payment terms, typically negotiated on a per-patient basis, should reflect a 35 percent overhead rate, consistent with Mount Sinai’s policy of indirect cost recovery of industry-sponsored clinical research.

In the case of early termination payment terms should reflect coverage of uncancellable obligations and commitments as well as pro-rated coverage of work performed to date, and/or patients enrolled and screened to date.

Sponsor shall reimburse Institution for IRB fees at prevailing rates within 30 days of receipt of Institution's invoice.

1. Contract Items Related to Publications (Check if “Yes”. All must be checked.)

Must include right to publish. Can accept publications committee to negotiate changes, but the committee must be comprised of independent scientists, not a majority from the sponsor.

Notification should be 30-45 days prior to submission, with an additional 30-45 days required for patent filing. Do not go over 120 days total.

If the Study has been designed as multicenter study, we can agree to delay publication until the multi-site publication has been published or 12 months after the completion at all participation sites which ever comes first. Can accept 18 months.

1. Contract Items Related to Patent/Invention Policy (Check if “Yes”. All must be checked.)

Faculty shall assign all rights and title to the Institution.

Language includes carve out for institutional inventions, unrelated to Confidential Information or Sponsor’s IP (Study Drug or Device).

We can accept to enter either a royalty bearing exclusive license (prefer) or a royalty free non-exclusive license.

1. Contract Items Related Indemnification (Check if “Yes”. All must be checked.)

Should be included within the Agreement. If not, must have separate Letter of Indemnification with sponsor.

We should only indemnify for our own negligence and / or willful malfeasance.

Sponsor should indemnify the administration or use of the Study Drug AND Study mandated procedures (Both)

Deviations from the protocol done for the safety of the patient do not constitute negligence

If drug/device is approved, sponsor should indemnify for manufacturing defects.

1. Contract Items Related Insurance (Check if “Yes”. All must be checked.)

General liability is 1 million per occurrence and 2 million in the aggregate. Can reference self insurance.

Professional liability is $1,300,000 per occurrence and $7,000,000 in the aggregate.

1. Additional Contract Clauses (Check if “Yes”. All must be checked.)

**Governing Law** - should be in accordance with New York State. (May remain silent)

**Publicity** - need each other’s permission to use name/logo, etc.

**HIPAA** - Include standard HIPAA language that sponsor will not use PHI to market to or recruit patients.

**Force Majeure** included

**Indigent Patient** language included or deleted, as applicable.

**Device Cost** language included, if this is a Category B device

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.I [↑](#endnote-ref-2)
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. [↑](#endnote-ref-3)
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 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 organization. Per IRB policy (see “HRP-214 – FORM – Reportable New Information”), investigators are required to promptly provide this information to the IRB. [↑](#endnote-ref-4)