Dear [Sponsor/CRO],

The Association of American Cancer Institutes (AACI) comprises 103 premier academic and freestanding cancer centers in the United States and Canada. AACI is accelerating progress against cancer by empowering North America's leading cancer centers in their shared mission to alleviate suffering. As an AACI member, one of our missions is to help deliver new and promising therapies to cancer patients while building strong relationships with our industry partners. To do this, we strive to streamline the study activation process to help complete studies in a more timely and efficient manner, and we have identified the expectations below for overall responsiveness, turnaround times, standard fees, and contracting language.

If you find that any of these expectations will cause significant impediments to study activation, please let us know. We will work with you to find a mutually acceptable alternative if possible.

Please let us know if you are interested in pursuing a master agreement for future clinical trials.

Timelines

Our goal is to respond to our sponsors within two business days of receipt of an email, phone call, or other means of communication. Expected and unexpected staffing shortfalls will be corrected with temporary reassignment to maintain timelines. To ensure the integrity of the anticipated timelines, you will be expected to respond to {name of university/cancer center} regarding all study activation activities within three business days.

Study activation timelines are an important metric by which we are judged by our institutional leaders and the National Cancer Institute (NCI). NCI expects to have industry studies activated in 90 days from the initiation of scientific review. Meeting activation timelines depends on receipt of all study documents. Because study activation processes are done in parallel, all documents are required before activation activities can start. By agreeing to initiate the activation of a clinical trial at {cancer center], sponsor agrees to make a good faith effort to adhere to the timelines. A sponsor's failure to respond in a timely manner and/or failure to meet the timelines below may result in study abandonment.

Receipt of all study documents: {insert date}

Activation Activity	**Target Deadline**	**Responsible Party**
Budget Negotiation	[insert date]	{Cancer Center} & Sponsor
SRMC Review and Approval	[insert date]	{Cancer Center}

Contract Negotiation	[insert date]	{Cancer Center} & Sponsor
Review and Approval of Informed Consent language	[insert date]	{Cancer Center} & Sponsor
IRB Review, Approval and CTMS Documentation	[insert date]	IRB of Record
SIV; Open to Accrual	[insert date]	{Cancer Center} & Sponsor

[insert date] Open to accrual by: [insert date]

{Cancer Center} Standard Contracting Language: Pages 2-4

* insert signatures for the below titles

Associate Director for Clinical Research | Administrative Director, Clinical Research | Associate Director

Parties	The {name of cancer center} Board of Trustees constitutes the Institution's contracting agent pursuant to {state} statutes. {Cancer center} does not permit its investigators to be a party to the contract, although he/she may sign as "read and acknowledged." {Cancer center} requests that "Study Personnel" be defined as institutional employees who participate in the conduct of the Study at the Institution and should not include agents or contractors.

Confidentiality	{Cancer center} requests the inclusion of mutual confidentiality clauses to cover any receipt or disclosure on both ends. {Cancer center} does not want to receive trade secrets as part of confidential information. {Cancer center} requests that confidential information be marked, or at least be limited to information that a reasonable person familiar with clinical research would consider confidential based on the nature of the information and the circumstances of disclosure. [As a state entity, {Cancer center} requires acknowledgment of Section 1004.22, {state} Statutes ({state's} open records law) in all contracts to state that in the event of a public records request, {Cancer center} will release certain information about the contract without providing advance notice (*title and short description of the Study, the name of the researcher, and the amount and source of funding provided for the Study*).] {Cancer center} requests that a term of disclosure under a Confidential Disclosure Agreement (CDA) to be limited to one (1) year. {Cancer center} requires a term to hold confidential information and prefers five (5) years post completion, expiration, or termination.
Use of Name	{Cancer center} requires that any limitation on the use of names be mutually agreed upon and allow {Cancer center} to post information on its clinical trial directory and website that would be public on www.clinicaltrials.gov.
Data	{Cancer center} requires the right to retain ownership of its original source documents that are collected during the conduct of a clinical trial and requires the right to use study data and results for its internal research, educational, publication, IRB, regulatory, legal, clinical, and non-commercial purposes. {Cancer center} has a general statement in all contracts that Sponsor, and its representatives will not attempt to contact participants unless permitted by the consent document. Minimum requirement of five (5) business days for data entry.
Monitoring and Audit	{Cancer center} will not agree to the industry sponsor having oversight and/or approval of {Cancer center} regulatory responses related to FDA-type audits. The Sponsor should only be present during audits/inspection to the extent required by the FDA or requested by {Cancer center} during mutually agreed upon times and during normal business hours.

Association for the Accreditation of Human Research Protection Programs (AAHRPP)	As a component of the {Cancer center}'s AAHRPP certification, certain language is required in all contracts to maintain the certification. Below is the suggested language from AAHRPP that covers the elements needed for sponsor reporting obligations. "*During and for a period of two (2) years after completion of the Study, Sponsor shall promptly report to the Institution 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 Data and information in monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the Institution shall be free to communicate these findings to each Study subject and the IRB."*
Compensation	{Cancer center} requires its standard payment language in every contract with four options depending on the structure of the study. {Cancer center} requires a statement that {Cancer center} will apply the applicable indirect cost rate on total direct costs, including pass-through costs whether or not they are included in the sponsor's budget. {Cancer center} requires its standard term related to a potential default in payment that is not cured within thirty days after notice to the Sponsor. {Cancer center} prefers payment by paper check. If using a contract research organization (CRO), {Cancer center} requests that Sponsor guarantee payment and provide a letter of indemnification for subject injury and indemnification. {Cancer center} conducts research, not "business" because of its status under {State} law as an institution of higher education and the high priority placed on the {Cancer center}'s right to publish.
Publication	{Cancer center} requires the right to publish data and results to maintain its AAHRPP certification. Also, publication is a valued right of {Cancer center} investigators. If {Cancer center} did not have the right to publish, {Cancer center} could lose its tax-exempt status. {Cancer center} shall not agree for Sponsor to approve the publication or presentation but {Cancer center} will agree to a defined review period of no more than thirty (30) days from submission to sponsor (including submitting a patent application). {Cancer center} will allow a maximum delay for review and patent protection of ninety (90) days.

Indemnification	[{Cancer center} has sovereign immunity as a state of {state} institution and will not agree to indemnify any third party. It is {Cancer center}'s position that industry sponsors of clinical trials should indemnify {Cancer center} for the conduct of the study, use of the investigational product/device, and the use of the delivered study data based on its status as a non-profit institution and the inherent imbalance of reward. {Cancer center} also requires these additional rights: *Sponsor will not settle or compromise any claim, suit, action, demand, or judgment in a manner that imposes any restrictions or obligations on Institution Indemnitees, nor will Sponsor settle any claim or suit with an admission of liability or wrongdoing by the Indemnitees without Institution Indemnitees' written consent. Institution shall have at all times the right to retain counsel at its own expense to protect its interests.*
Liability & Insurance	As a state of {state} institution with qualified sovereign immunity, {Cancer center} requires language approved by {Cancer center} General Counsel which states the levels of coverage equal to the limits to which sovereign immunity is waived. {Cancer center} OCR will not negotiate changes to the approved language. {Cancer center}'s General Counsel-Approved Liability Statement: *The Institution assumes any and all risks of personal injury and property damage attributable to the negligent acts or omissions of the Institution and the officers, employees, servants, and agents thereof while acting in the scope of their employment by the Institution. The Institution warrants and represents that it is self-funded for liability insurance, both public and property, with such protection being applicable to the Institution's officers, employees, servants and agents while acting within the scope of their employment by the Institution. The Institution and Sponsor further agree that nothing contained herein shall be construed or interpreted as (1) denying to either party any remedy or defense available to such party under the laws of the State of {state}; (2) the consent of the Institution, [the State of {state},] or their agents and agencies to be sued; [or (3) a waiver of the sovereign immunity of the Institution, the State of {state}, and their agents and agencies beyond the waiver provided in Section {relevant legislative section} {state} Statutes].* [{Cancer center}'s General Counsel-Approved Insurance Statement: *Institution participates in the State Risk Management Trust Fund administered by the Department of Financial Services, Division of Risk Management of the State of {state}, for worker's compensations, general liability and fleet automobile liability insurance. The program provides financial protection for bodily and personal injury and property damage arising from the operations of the Institution. The combined limits for general liability and fleet*

	automobile liability coverage amount to $200,000 per person per claim and $300,000 per occurrence. Nothing herein shall be construed as a waiver of the sovereign immunity of the Institution, the State of {state}, and their agents and agencies beyond the waiver provided in Section {relevant legislative section} {state} Statutes.]