Accelerated Confidential Disclosure Agreement

[This Accelerated Confidential Disclosure Agreement ("ACDA") is intended as a companion document to the Accelerated Clinical Trial Agreement ("ACTA") template in an effort to ensure an accelerated contracting process between sponsors and CTSA Institutions for company-sponsored clinical trials. Some of the language identified in this template is relatively standard "boilerplate" language. However, for those terms that are usually more focused on during negotiations, comments have been added clarifying the specific language drafted. The terms of the ACDA have been keep as consistent with the equivalent terms of the ACTA as possible.]

This ACCELERATED CONFIDENTIAL DISCLOSURE AGREEMENT (the "Agreement") is made by and between:

{INSTITUTION NAME}, a non-profit, educational, research and healthcare institution ("Institution") with an address of {INSTITUTION ADDRESS}

and

{COMPANY NAME}, a corporation having its principal place of business at {COMPANY ADDRESS} ("Sponsor").

Sponsor and Institution are herein referred to collectively as "Parties." Individually, each of Sponsor and Institution is a "Party."

WHEREAS, Sponsor is seeking to identify potential investigative sites for a study relating to {INSERT NAME OF DISEASE OR DRUG/DEVICE BEING STUDIED} pursuant to Protocol {INSERT PROTOCOL TITLE AND/OR NUMBER} (the "Study"), and Institution desires to obtain the study protocol and to review information about the Study on behalf of {PRINCIPAL INVESTIGATOR NAME} in order to determine whether it would be interested in participating in the Study ("Purpose"); and

WHEREAS, Parties agree to the use of this standard confidentiality agreement to accelerate the process of translating laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers; and

WHEREAS, in consideration for the opportunity to be considered as an investigative site, Institution is willing to receive the Confidential Information subject to the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the benefits set forth herein, the Parties hereby agree as follows:

[Recognizing that this template is intended to cover only discussions related to exploring the Parties' interest in a company sponsored clinical trial, the ACDA language is generally considered more amenable to Sponsors if it protected only Confidential Information disclosed by the Sponsor to the Institution for the purposes of the Study, first and foremost the Sponsor's protocol, and did not provide reciprocal protection for any confidential information that might be disclosed by the Principal Investigator/Institution to the Sponsor.]

1) "**Confidential Information**" refers to information of any kind which is disclosed to the Institution by Sponsor to evaluate the Purpose which:

[Although this language references the need to appropriately identify by marking the Confidential Information, it also broadly protects information that by its nature a reasonable person would consider confidential given its content and circumstance of disclosure. The requirement for verbal communications to be followed up in writing marked "confidential" was added so that Sponsors were not relying on the Institution's judgment regarding what was discussed and/or disclosed.]

a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure; or

b) if disclosed orally, is identified in a marked writing within thirty (30) days as being confidential.

[Please note that the terms of the ACDA do not purport to meet or alter all or any of the requirements of the various state Freedom of Information laws that govern the disclosure and exemption from disclosure of confidential information disclosed to public institutions, particularly including requirements related to identification, labeling, and reduction to writing.]

Sponsor will make reasonable efforts to mark Confidential Information as stated in (a) and (b) above. However, to the extent such marking is not practicable, then in the absence of written markings, information disclosed (written or verbal) that a reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure shall be deemed as such.

[The period of non-disclosure is identified as five years following the termination or expiration of the Agreement, which was felt to be more favorable to Sponsors than the standard three years that many sites require in their negotiations.]

Institution agrees, for a period of five (5) years from the effective date stated below, to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received from Sponsor in accordance with this Section.

Institution agrees to use Sponsor's Confidential Information solely as allowed by this Agreement. Institution agrees to make Sponsor's Confidential Information available only to those personnel who require access to it to evaluate the Purpose and to inform such personnel of the confidential nature of such information and the obligation of confidentiality to which they are bound.

[The following exclusions imply an objective standard and rest upon commonsense principles. However, because of the narrow scope of the internal distribution right (above), subsection d) is primarily necessary in the event that an institution needs to disclose Confidential Information to a third-party IRB.]

2) The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:

a) is or becomes public knowledge through no breach of this Agreement by Institution;

b) is disclosed to Institution by a third party entitled to disclose such information without known obligation of confidentiality;

c) is already known or is independently developed by Institution without use of Sponsor´s Confidential Information as shown by Institution´s contemporaneous written records;

d) is necessary to obtain IRB approval of Study; or

e) is released with the prior written consent the Sponsor.

[Clinical trials and drug development are highly regulated, and public institutions are subject to request for information under "Freedom of Information" acts. As such, this section contemplates various kinds of legally compelled or required disclosures, potentially including but not limited to a FOIA request, an exercise of regulatory authority, or a writ of mandamus.]

3) Institution may disclose Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, IRB, government agency, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Institution, subject to the requirement, order, or subpoena, promptly notifies Sponsor.

[It is not uncommon for a Sponsor to request that recipient institution to be responsible for seeking the protective order or to agree to participate at an unqualified level in any Sponsor efforts. In reality, an Institution's receipt of Confidential Information does not make it an agent of a Sponsor. As may be expected, non-profits cannot bear the costs that such provisions often unqualifiedly imply.]

To the extent allowed under applicable law, Sponsor may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Institution will disclose only the minimum amount of Confidential Information necessary to comply with law, or court order as advised by Institution's legal counsel.

4) No license or other right is created or granted hereby, except the specific right to use the Confidential Information under the terms of this Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.

5) Upon Sponsor's written request, Institution agrees to return all Confidential Information supplied to it by Sponsor pursuant to this Agreement except that Institution may retain such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement.

[Most institutions can agree to a basic no-publicity provision. However, most institutions are subject to various public reporting requirements and processes, some internally and some externally mandated, and this language cannot be construed to limit such public reporting. This is especially true for public institutions.]

6) Neither Institution nor Sponsor may use the name, trademark, logo, symbol, or other image or trade name of the other Party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written consent of an authorized representative of the Party whose name is being used. Such approval will not be unreasonably withheld.

7) This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, and is binding on all Parties notwithstanding that each of the Parties may have signed different counterparts. Scanned copies of signatures or electronic images of signatures shall be considered original signature unless prohibited by applicable law.

8) This Agreement shall expire one (1) year from the effective date of this Agreement.

9) This written Agreement constitutes the entire agreement between the Parties concerning the subject matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter. Any changes made to the terms or conditions cited in this Agreement require the written approval of each Party's authorized representative.

[This agreement does not contain a "governing law" provision. Parties to these agreements often try to negotiate various states based on their location (e.g., the state where the institution or sponsor is located) and the benefits of that state's applicable laws. The CTSA Institutions felt that by remaining silent, sponsors would view this as a more favorable position.]

THE REMAINDER OF THIS PAGE IS LEFT INTENTIONALLY BLANK

The authorized representatives of the Parties have signed this Agreement effective as of the date last signed below:

{SPONSOR}

By: _____
{NAME}
Title: _____

Date: _____

{INSTITUTION}

By: _____
{NAME}
Title: _____

Date: _____

READ AND ACKNOWLEDGED

By: _____
{PRINCIPAL INVESTIGATOR}

Date: _____