Subject Line:  XXXXX

Today, documentation regarding the above-entitled research project was received by our office.  {Contract Manager Name/email address/phone number} will be the contract manager handling the contract on behalf of the University of Rochester.

The University of Rochester is dedicated to providing its patients with access to promising new treatments.  Therefore, in order to expedite the contract process, we would like to propose utilizing the Accelerated Clinical Trial Agreement (ACTA) developed by 25 CTSA institutions for sponsor-initiated multi-site studies. To date, 50 organizations representing over 225 sites, including academic medical centers, have agreed to use the ACTA without the need for further legal negotiations.  The ACTA was developed with input from industry.

I have attached the ACTA agreement, as well as a Fact Sheet, providing some additional background concerning the development of this agreement, for your review and consideration.  If you have further questions regarding the ACTA, or if you are in agreement with using the ACTA for this study, please contact {Contract Manager}.

We look forward to working with you.

Sincerely,

Attachments:  ACTA Agreement (PDF) & ACTA Fact Sheet

Many organizations face challenges in finalizing clinical trial agreements. Data from a 2010 Clinical and Translational Science Awards (CTSA) Contracts Processing Study1 showed that an average contract negotiation of contract terms (exclusive of budget and IRB approval) of 55 days could be reduced to 22 days if a “master agreement” was used. This information prompted CTSA awardees to develop an efficient contract that, if adopted, could help further reduce delays in trial start-up.

With support from the National Institutes of Health’s National Center for Advancing Translational Sciences, grant #5U54TR000123, the [Accelerated Clinical Trial Agreement (ACTA)](https://ara4us.org/acta/) was developed by 25 leading academic institutions and medical centers engaged in clinical research and translational science in collaboration with the University Industry Demonstration Partnership (UIDP) and with input from several pharmaceutical companies. The ACTA is a straightforward and unambiguous document which clearly sets forth the contractual obligations of both parties, and presents language which — while perhaps not ideal for either party — is acceptable to both. Adoption and use of the ACTA will expedite the contract negotiation process and reduce the time it takes to start up industry-sponsored, multi-center clinical trials.

To date, approximately 50 organizations representing more than 225 research sites, including academic medical centers, universities, hospitals and physician practices, have agreed to the terms of the ACTA and accept the ACTA without revision. Those interested in using the ACTA or additional accelerated agreements can learn more at [www.ara4us.org](http://www.ara4us.org).

The initial ACTA was drafted and finalized by participating CTSA institutions and shared with external reviewers — AAHRPP, Shire, Pfizer and Epizyme — for their input. The UIDP joined this initiative in March 2014.

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**Use of the ACTA is voluntary; accepting the terms does not in any way mandate its use by any party.**

1. ***\* Observational study of contracts processing at 29 CTSA sites****.* [*Clin Transl Sci.*](http://www.ncbi.nlm.nih.gov/pubmed/?term=CTSA+contract,+rosenblum) *2013 Aug;6(4):279-85.* [*Kiriakis J*](http://www.ncbi.nlm.nih.gov/pubmed?term=Kiriakis%20J%5bAuthor%5d&cauthor=true&cauthor_uid=23919362)*,* [*Gaich N*](http://www.ncbi.nlm.nih.gov/pubmed?term=Gaich%20N%5bAuthor%5d&cauthor=true&cauthor_uid=23919362)*,* [*Johnston SC*](http://www.ncbi.nlm.nih.gov/pubmed?term=Johnston%20SC%5bAuthor%5d&cauthor=true&cauthor_uid=23919362)*,* [*Kitterman D*](http://www.ncbi.nlm.nih.gov/pubmed?term=Kitterman%20D%5bAuthor%5d&cauthor=true&cauthor_uid=23919362)*,* [*Rosenblum D*](http://www.ncbi.nlm.nih.gov/pubmed?term=Rosenblum%20D%5bAuthor%5d&cauthor=true&cauthor_uid=23919362)*,* [*Salberg L*](http://www.ncbi.nlm.nih.gov/pubmed?term=Salberg%20L%5bAuthor%5d&cauthor=true&cauthor_uid=23919362)*,* [*Rifkind A*](http://www.ncbi.nlm.nih.gov/pubmed?term=Rifkind%20A%5bAuthor%5d&cauthor=true&cauthor_uid=23919362).

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| **Examples of** **Institutions/Organizations that have accepted the ACTA** |
| Albert Einstein College of Medicine | Stanford University | University of Michigan |
| Boston University | Tufts Medical Center | University of Minnesota |
| Children’s National Medical Center | University of Illinois, Chicago | University of New Mexico Health Sciences Center |
| Cincinnati Children’s Hospital Medical Center | University of Alabama at Birmingham | University of North Carolina at Chapel Hill |
| Dartmouth College | University of Arkansas for Medical Sciences | University of Pennsylvania |
| Duke University | University of California, Davis | University of Pittsburgh/University of Pittsburgh Medical Center (UPMC) |
| Georgia Regents University | University of California, Irvine | University of Rochester |
| The Ohio State University | University of California, Los Angeles | University of Southern California |
| Indiana University School of Medicine | University of California, Riverside | University of Texas-Austin |
| Johns Hopkins University | University of California, San Diego | University of Texas-Houston |
| Mayo Clinic | University of California, San Francisco | University of Texas-Medical Branch |
| Medical College of Wisconsin | University of Chicago | University of Texas, San Antonio |
| Mount Sinai School of Medicine | University of Florida | Georgetown University |
| New York University School of Medicine | University of Iowa | University of Texas-Southwestern Dallas |
| Northwestern University | University of Kansas Medical Center | University of Utah |
| Oregon Health & Science University | University of Kentucky Research Foundations | University of Wisconsin – Madison |
| The Pennsylvania State University/The Milton S. Hershey Medical Center | University of Louisville | Vanderbilt University Medical Center |
| Rockefeller University | University of Massachusetts Medical School, Worcester | Washington University, St. Louis |
| Scripps Health | University of Miami | Yale University |
| Case Western University School of Medicine | University Hospitals Case Medical Center | University of Kansas |
| Rush University Medical Center | Healthcare Corporations of America (HCA) **(includes 165 Institutions)** | Sucampo Pharmaceuticals, Inc |
| MedStar Health Research Institute | Medpace | Medical University of South Carolina |
| Michigan State University | Aurora Denver Cardiology Assoc. | PPD |
| Clinical Physiology Associates | Expedite Research, LLC | FibroGen Inc. |
| Future Care Solution, LLC | Pharma Research International, Inc. | Pinnacle Research Group, LLC |
| QUEST Research Institute | Wisconsin Center for Advanced Research | Mercy Research Institute |
| Apellis Pharmaceuticals, Inc. | AZCERT | Wake Forest University Health Services |

**Contact:** Terri Edwards, RN, RAC | Project Manager | 615-322-7342 | acta@ara4us.org