

UT SYSTEM IRB RECIPROCITY AGREEMENT  
APPLICATION FOR ADDITION OF SITE

**Information for Overall Principal Investigator** – In addition to submitting an application to your organization’s IRB (designated as “Reviewing IRB”), an application for addition of site investigator must be submitted for each participating organization. This application may be submitted at the time of initial review or after the initial submission has been approved.

**Information for Site Investigator** – The purpose of this form is to give enough information to the Reviewing IRB to allow them to make a determination about addition of your site. You may not submit this application form to the Overall Principal Investigator unless your institution has agreed to rely on the Reviewing IRB.

**Reminder** – You are not authorized to initiate research at your organization until you have received approval for addition of your site from the Reviewing IRB **as well as** all the other applicable approvals from your institution.

**1.0 GENERAL INFORMATION**

1.1 Study Title:

1.2 Site Principal Investigator:

1.3 Site Name Name of the Relying Organization:

1.4 Address:

1.3 Office Phone:

1.3 Cell Phone or Pager:

1.4 Email Address:

**2.0 STUDY POPULATION**

2.1 How many subjects will you recruit at your site?

2.2 How will you recruit subjects for this research?

Existing patients in investigator / co investigator’s practice

Database of potential subjects (who have agreed to be contacted for future research)

Referrals

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Advertisements (please attach copies of recruitment material to be used)

Other, please specify

2.3 Describe the recruitment process.

2.4 Describe the consent process at your site (who will conduct the consent discussion, when and where it will take place).

2.5 Will vulnerable subjects be recruited at your site?

Children

Pregnant women

Cognitively impaired persons

Prisoners

**3.0 INVESTIGATOR AND RESEARCH TEAM QUALIFICATIONS**

3.1 Do you and your research team members have current human subjects / GCP training at your institution?

CITI Human Subjects Training

CITI GCP Training

Others, please specify

3.2 How long have you been conducting research?

3.3 How many active research studies are you involved in currently?

3.4 Do you and your team have adequate resources to conduct this research?

Yes No, if No please explain

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3.5 Do you or any of the research team members have any significant financial conflict of interest in this research?

Yes      No, if yes please attach the conflict of interest management plan.

**4.0 Acknowledgement by Site Principal Investigator**

- *I am aware of my institutional policies and procedures in the conduct of research at my institution.*
- *I will obtain informed consent from participants before enrolling them into the research unless informed consent has been waived by the Reviewing IRB.*
- *I will follow the protocol and not implement any changes without prior approval from the Reviewing IRB.*
- *I will report unanticipated problems involving risks to subjects or others within the timeframe specified by the Reviewing IRB.*
- *I will cooperate with monitoring oversight visits by the Reviewing IRB and my institutional representatives.*

\_\_\_\_\_  
Signature of Site Principal Investigator

\_\_\_\_\_  
Signature Date

**Instructions for Site PI**

Submit the completed form with the following documents to the Overall PI for onward submission to the Reviewing IRB:

1. Intent to Rely form signed by Relying Organization
2. Site Specific Consent document (consent document with local contact information)
3. Advertisements and other recruitment material (with site specific information)
4. CV of the Site Principal Investigator
5. Conflict of Interest Management plan, if any

When you have received approval from the Reviewing IRB, submit the approval letter to the Relying Organization. The Relying Organization will issue an 'Activation Letter' after which you may initiate the research.