THE UNIVERSITY *of* TEXAS SYSTEM

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Toolkit for Utilizing The University of Texas System Restated and Amended IRB Reciprocity Agreement Memorandum of Understanding

DRAFT

May 2015

Toolkit for Utilizing The University of Texas System Restated and Amended IRB Reciprocity Agreement Memorandum of Understanding

The University of Texas System

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I. PURPOSE

This toolkit was prepared to facilitate Institutional Review Board staff and researchers from across UT System institutions in using the UT System Restated and Amended Institutional Review Board Reciprocity Agreement Memorandum of Understanding (Master Reciprocity Agreement). In 2010, the UT System IRB Reciprocity MOU (MOU) was signed by all 15 UT System institutions. In addition to the MOU, stakeholders also developed Standard Operating Procedures (SOPs) for Initial Review, Continuing Review and Reporting; these SOPs were agreed to by all UT System institutions. The SOPs are included in this toolkit to provide researchers with the necessary steps to effectively use the Master Reciprocity Agreement. Also included are sample templates/forms, as well as contact information for all UT System IRB offices. For institutional specific forms, you are encouraged to contact your local IRB office directly.

In early 2015, the MOU was restated and amended to include the University of Texas Rio Grande Valley (UTGRV) and to more clearly distinguish between Participating Institutions and Affiliated Organizations (entitled "Restated and Amended Institutional Review Board Reciprocity (IRB) Agreement Memorandum of Understanding" (Master Reciprocity Agreement)). This Master Reciprocity Agreement replaces and supersedes the MOU.

II. The UT System Master Reciprocity Agreement Standard Operating Procedure - Initial Review

Policy

A research project may be approved by the Reviewing IRB under the scope of the Master Reciprocity Agreement with permission from the Relying Institution. Both the institutions may decline triggering the reciprocity for any particular protocol.

Key Terms

- **Affiliated Organization -** An entity, for example a business, society, association, hospital or clinical care center who agrees to rely on a Participating Institution's IRB and agrees to formally participate in this Master Reciprocity Agreement. An Affiliated Organization shall not serve as a Reviewing IRB under the Master Reciprocity Agreement.
- **Participating Institution -** Any Texas institution of higher education who, in addition to serving as a Reviewing IRB (as defined below), may also agree to rely on another Participating Institution's IRB (see definition below for Relying Institution). Additional Participating Institutions may be added to this Master Reciprocity Agreement.
- **Relying Institution** - A Participating Institution or Affiliated Organization who agrees to rely on another Participating Institution's IRB for a specific study.
- **Reviewing IRB** - A Participating Institution who agrees to serve as the IRB of record for a specific study for one or more of the other Participating Institution(s) or Affiliated Organization(s).
- **Overall PI** - The principal investigator at the Reviewing IRB's Participating Institution.
- **Site PI** - The principal investigator at the Relying Institution.

Procedure

1. A research project is reviewed and approved at one Participating Institution. The PI at this Participating Institution is called the Overall PI. The IRB that reviewed and approved the research proposal is called the Reviewing IRB.

2. A wide range of research projects are covered under the scope of the reciprocity agreement:
    a. Multi-center clinical trial with lead PI at the institution of the Reviewing IRB;
    b. Multi-center clinical trial sponsored by industry with no lead PI;
    c. Multi-center clinical trial with a lead PI at a non-UT location;
    d. Research project being conducted at one UT System member with certain parts of the research being done at another UT System member;
    e. Research project being conducted at one UT System member but has collaborators from another UT System member; and
    f. Other types of research projects that fall under the oversight of more than UT System member HRPP.

3. When a research project falls under the oversight of more than one UT System member IRB, either the Overall PI or the Site PI may trigger the reciprocity agreement. Both the Overall PI and Site PI must understand and accept the additional responsibilities they would have if the research project is reviewed under the reciprocity agreement.

Triggering the Master Reciprocity Agreement

4. The process is initiated by the Site PI at the Relying Institution. The Site PI must follow the Relying Institution's procedure for seeking permission to rely on an IRB of a Participating Institution. In most Participating Institutions, this process is handled by the Relying Institution's IRB office.

5. The Site PI must submit supporting documentation while seeking permission to rely on another Participating Institution. When the Relying Institution has an electronic IRB system, the institution may require the Site PI to complete an electronic application or registration and attach the supporting documents. At the minimum, this should include:
    a. Completed Permission to Rely form;
    b. Site Specific Consent form (Site PI Contact, local IRB Contact); and
    c. Protocol (if required by the Relying Institution).

Permission to Rely from Relying Institution

6. If any Affiliated Organizations are involved, the Reviewing IRB should be listed on their FWA. The Relying Institution should consider:
    a. Whether the research proposal falls within the scope of the UT System Master Reciprocity Agreement;
    b. Study team members human subjects training verification and COI disclosures;
    c. Any concerns about the research submission;
    d. Any concerns about the qualifications of the Site Investigator / Site research team; and
    e. Any concerns about the resources available at the site.

7. If the relying institution disapproves the request to rely, the Site PI will submit a regular application to the Relying Institution's IRB.

8. If the Relying Institution application for permission to rely on a Participating Institution's IRB is approved, the Relying Institution should send the Site PI a written permission letter or a signed 'Permission to Rely' form.

9. Preferably, all the communication with the Reviewing IRB should be through the Overall PI. The Site PI should submit the following documents to the Overall PI:
    a. Permission to Rely form with Relying Institution's Signature;
    b. Completed 'Addition of Site' form;
    c. CV of the Site PI; and
    d. Site specific Consent Document.

Review by Reviewing IRB

10. If the research project had already been reviewed and approved by the Reviewing IRB at the time of the Site PI's submission, the Overall PI will submit these documents as a protocol amendment / addition of site / change request submission. The Overall PI should clearly indicate that approval is being sought for inclusion of the site at the Relying Institution. If the research project has not yet been approved by the Reviewing IRB, the Overall PI will include the Site PI documents with the initial application to the Reviewing IRB.

11. The Reviewing IRB screens the request to rely and may decide to accept or decline the request to rely. If the Reviewing IRB accepts the request, this may be assigned for expedited or full board review. If the Reviewing IRB declines, the submission is returned to the Overall PI with a letter declining the request to be the Reviewing IRB.

12. If the Reviewing IRB accepts the request to rely, the application may be reviewed through expedited review or full board review. In addition to the regulatory criteria for approval for approval of research at the Reviewing IRB's institution, the Reviewing IRB should consider the following:
    a. Investigator Qualifications - The Site PI should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial;
    b. Study Team - The Site PI should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely. Significant research-related duties may be delegated only to adequately qualified individuals;
    c. Recruitment plan and consent process - If the plan for recruitment and consent process is different from the strategy outlined by the Overall PI, the Reviewing IRB should assess whether the Site PI's plan is appropriate; and
    d. Conflict of interest disclosures and management plans, if any, by the Site PI and study team.

13. If the Reviewing IRB requires more information or local context, the Reviewing IRB may seek help from the Relying Institution's IRB. Local context may be provided by a member or staff of the IRB from the Relying Institution. This individual may provide information as Consultant for the Reviewing IRB and may participate in the Reviewing IRB's meeting via teleconference. The Consultant does not have the right to vote at the Reviewing IRB's meeting.

Post Review Communication

14. If the addition of site is approved, the Reviewing IRB should send the approval letter and stamped consent document to the Overall PI. The approval letter should include information on the reporting requirements of the Reviewing IRB. If the Relying Institution requested for direct communication, the Reviewing IRB must send a copy of the approval letter to the Relying Institution. In all other cases, the Overall PI.

15. Reviewing IRB staff should review the notification arrangement requested by the Relying Institution to make sure they can meet the requirements of the Relying Institution. If there is disagreement, the Reviewing IRB staff should communicate with the Relying Institution staff to come to a mutually acceptable arrangement.

16. The Site PI must submit the approval letter, stamped consent form and any other documents requested by the Relying Institution. The Site PI must also submit relevant documents to any Affiliated Institution involved in the research. Research may not begin until all necessary approvals are in file. Relying Institution IRB may issue an Activation Letter.

Responsibility

This guidance applies to those members of the clinical research team involved in conducting the clinical research. This includes the following:

- Overall Principal Investigator;
- Local Principal Investigator;
- Reviewing IRB and IRB Office;
- HRPP Staff at Relying Institution; and
- Staff at Affiliated Organization.

III. The UT System Master Reciprocity Agreement Standard Operating Procedure - Continuing Review

Policy

The Overall PI is in charge of coordinating the submission of renewal application to the Reviewing IRB. The Site PI must submit necessary information in a timely fashion to the Overall PI.

Key Terms

- **Affiliated Organization** - An entity, for example a business, society, association, hospital or clinical care center who agrees to rely on a Participating Institution's IRB and agrees to formally participate in this Master Reciprocity Agreement. An Affiliated Organization shall not serve as a Reviewing IRB under the Master Reciprocity Agreement.
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- **Relying Institution** - A Participating Institution or Affiliated Organization who agrees to rely on another Participating Institution's IRB for a specific study.
- **Reviewing IRB** - A Participating Institution who agrees to serve as the IRB of record for a specific study for one or more of the other Participating Institution(s) or Affiliated Organization(s).
- **Overall PI** - The principal investigator at the Reviewing IRB's Participating Institution.
- **Site PI** - The principal investigator at the Relying Institution.

Procedure

1. The Overall PI is in charge of submitting a renewal application to the Reviewing IRB in a timely manner. Continuing review will occur at the same time for all the sites even if the sites were added after the original site had received approval earlier.

2. In most institutions, the IRB sends reminders to the Overall PI to turn in a 'Continuing Review Application' form well before the IRB approval expiry date. However, it remains the responsibility of the Overall PI and the Site PIs to ensure that continuing review approval is obtained before study expiry.

Submission of Continuing Review Application

3. The Overall PI must send the Reviewing IRB's continuing review form to the PI's at all sites. The Overall PI must consolidate information from all the sites into a single continuing review application. The Overall PI must submit the consolidated continuing review application to the Reviewing IRB. The Overall PI must indicate the names of the sites whose information is included in the application. The Overall PI may attach the individual forms from the Site PIs to the continuing review application.

Review by the Reviewing IRB

4. The Reviewing IRB is responsible for the review of the continuing application for all the sites. In addition to the criteria for approval and other issues considered at continuing review, the Reviewing IRB should also determine whether all the sites have provided information about the conduct of research at their site.

Post Review Communication

5. If the continuing review application is approved, the Reviewing IRB should send the approval letter and stamped consent document to the Overall PI. (Some institutions may not issue newly stamped consent forms at the time of continuing review). The approval letter should include the list of all the sites for which continuing approval has been granted. If the Relying Institution requested for direct communication, the Reviewing IRB must send a copy of the approval letter to the Relying Institution. The Overall PI must send a copy of the approval letter and stamped consent form to the Site PIs.

Special Consideration - Study Expiry

6. If the continuing approval is not granted by the Reviewing IRB before study expiry, research activity must stop at all the sites. If the investigators believe that stopping the study might be harmful for participants, investigators must submit a justification to the Reviewing IRB to continue research activities. The Reviewing IRB will review such a request according to their policies and procedures.

7. If one or more sites participating in the research study did not submit information to the Overall PI for the continuing review application, the Reviewing IRB should conduct continuing review for the sites that did submit their information. For the sites that did not submit information, the study will expire. The Reviewing IRB should issue a letter asking the sites where approval has expired to stop all research activities.

8. The Reviewing IRB must communicate information to the Relying Institution when a study has expired at the Relying Institution. If any Affiliated Institutions are involved, the Relying Institution must communicate this information to them.

Responsibility

This guidance applies to those members of the research team involved in conducting the research. This includes the following:

- Overall Principal Investigator;
- Local Principal Investigator;
- Reviewing IRB and IRB Office;
- HRPP Staff at Relying Institution; and
- Staff at Affiliated Organization.

IV. The UT System Master Reciprocity Agreement Standard Operating Procedure - Reporting To IRB

Policy

Each of the PIs at the sites must comply with the problem reporting requirements of the Reviewing IRB. The Reviewing IRB must communicate problem reporting requirements at the time of initial approval.

Key Terms

- **Affiliated Organization** - An entity, for example a business, society, association, hospital or clinical care center who agrees to rely on a Participating Institution's IRB and agrees to formally participate in this Master Reciprocity Agreement. An Affiliated Organization shall not serve as a Reviewing IRB under the Master Reciprocity Agreement.
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- **Reviewing IRB** - A Participating Institution who agrees to serve as the IRB of record for a specific study for one or more of the other Participating Institution(s) or Affiliated Organization(s).
- **Overall PI** - The principal investigator at the Reviewing IRB's Participating Institution.
- **Site PI** - The principal investigator at the Relying Institution.
- **Unanticipated Problem** - A problem that is unanticipated or unexpected, related to the research and places the subjects or others at a greater risk of harm than was previously known or recognized.

Procedure

1. The Reviewing IRB is responsible for communicating problem reporting requirements to the PIs at all the approved sites. This includes Unanticipated Problems and noncompliance reports. The Reviewing IRB must also communicate timelines for problem reporting either by listing them in the initial approval letter and the site specific approval letters (when the sites are added on after initial approval of the research) or referencing the problem reporting policy along with the approval letter.

Submission of Continuing Review Application

2. When a site becomes aware of a problem that needs to be reported to the IRB as per the Reviewing IRB's policy, the Site PI must submit the required information to the Overall PI. The Overall PI must submit the information to the Reviewing IRB in the relevant forms. Both the Site PI and Overall PI must ensure that the problem reporting timelines are met.

Review by the Reviewing IRB

3. The Reviewing IRB is responsible for the review of the problem report and determining if the problem meets the definition of:
    a. Unanticipated problem involving risks to subjects or others; and
    b. Serious or continuing noncompliance.

4. The Reviewing IRB must follow its own policy and procedure for making these determinations and an action plan. When a problem is restricted to one site, the Reviewing IRB may decide to stipulate actions from the affected site. When the problem may affect the entire study, the

Reviewing IRB may decide to issue stipulations for all the approved sites. The Reviewing IRB may suspend or terminate its approval for one or more sites without affecting its approval for conduct of the research at the other sites.

Post Review Communication

5. The Reviewing IRB must communicate its findings and stipulations in writing to the Overall PI. The Overall PI must send a copy of the approval letter and stamped consent form to the Site PIs. When the Reviewing IRB makes a determination of Unanticipated Problem involving risks to subjects or others or serious or continuing noncompliance, or issues a suspension or termination, the Reviewing IRB must also communicate this information to the Relying Institution. When Affiliated Institutions are involved, the Relying Institution is responsible for informing them in a timely manner.

6. It is the responsibility of the Reviewing IRB to report Unanticipated Problems, serious or continuing noncompliance and suspensions and terminations of IRB approval to federal agencies. The Reviewing IRB should copy the institutional official at all the Relying Institutions on these letters.

Responsibility

This guidance applies to those members of the clinical research team involved in conducting the research. This includes the following:

- Overall Principal Investigator;
- Local Principal Investigator;
- Reviewing IRB and IRB Office;
- HRPP Staff at Relying Institution; and
- Staff at Affiliated Organization.

Appendix A. CONTACT INFORMATION FOR UT SYSTEM INSTITUTIONAL REVIEW BOARD OFFICES

Note: Contact information needs to be updated for all UT System institutions.

Health-Related Institutions

The University of Texas Health Science Center at Houston
Phone 713.500.7943
Fax: 713.500.7951
Email: cphs@uth.tmc.edu
https://www.uth.edu/CPHS/

The University of Texas Health Science Center at San Antonio
Phone: 210.567.8250
Email: IRBMail@uthscsa.edu
http://research.uthscsa.edu/irb/

The University of Texas Health Science Center at Tyler
Phone: 903.877.7632
Fax: 903.877.5134

The University of Texas MD Anderson Cancer Center
Phone: 713.792.2933
Fax: 713.794.4589
Email: IRB_help@mdanderson.org

The University of Texas Medical Branch at Galveston
Phone: 409.266.9475
Fax: 409.266.9499
http://research.utmb.edu/IRB/Default.aspx

The University of Texas at Southwestern Medical Center
Phone: 214.648.3060
Fax: 214.648.2171
Email: irb@utsouthwestern.edu
http://www.utsouthwestern.edu/research/research-administration/irb/index.html

Academic Institutions

The University of Texas at Arlington
Phone: 817.272.3723
Fax: 817.272.5808
Email: regulatoryservices@uta.edu
http://www.uta.edu/research/administration/departments/rs/human-subjects-irb/

The University of Texas at Austin
Phone: 512.471.8871
Fax: 512.471.8873
Email: orsc@uts.cc.utexas.edu
http://www.utexas.edu/research/rsc/humansubjects/

The University of Texas at Brownsville
Phone: 956.882.5023
Fax: 956.882.7851
Email: irb@utb.edu
http://www.utb.edu/research/ric/Pages/IRB.aspx

The University of Texas at Dallas
Phone: 972.883.4579
Fax: 972.883.4569
http://www.utdallas.edu/research/orc/irb/

The University of Texas at El Paso
Phone: 915.747.7693
Email IRB.ORSP@utep.edu
http://research.utep.edu/Default.aspx?tabid=72130

The University of Texas Pan American
Phone: 956.665.2889
Email: irb@utpa.edu
http://portal.utpa.edu/utpa_main/daa_home/research/research_compliance/research_irb

The University of Texas Permian Basin
Phone: 432.552.2361
http://www.utpb.edu/research-grants/institutional-review-board-(irb)

The University of Texas Rio Grande Valley
Phone Numbers: 956.665.3008 and 956.665.3204
Fax: 956-665-2940
Email: irb@utrgv.edu (effective September 1st, 2015)

- Before September 1st, 2015, please send emails to gcolon@utpa.edu and/or sadiq@utpa.edu

IRB Webpage: Currently Under Construction

- University Webpage: http://www.utrgv.edu/

The University of Texas at San Antonio
Phone: 210.458.6473
Fax: 210.458.6966
Email: irb@utsa.edu
http://research.utsa.edu/oric/irb/

The University of Texas at Tyler
Phone: 903.565.5774
Email: research@uttyler.edu
https://www.uttyler.edu/research/compliance/irb/

Appendix B. UT Centralized IRB Review Notification to Relying Institution and Intent to Submit for Centralized Review

Information for the Overall Principal Investigator (Overall PI)

In addition to submitting an application to your institution's IRB (designated the "Reviewing IRB"), an "Intent to Submit for Centralized Review" form must be submitted to the IRB office at each Participating Institution.

Information for the Site Principal Investigator

The purpose of this form is to request centralized review at your institution (designated the "Relying Institution"). This request will be considered by your institution and a decision made on a case-by-case basis. The IRB office from your institution will forward the final decision to the Reviewing IRB.

If your institution agrees to Centralized IRB Review, you will be required to submit additional materials in accordance with local policy. The review of local issues by your institution is a separate process from the IRB approval being sought by the Overall PI.

Reminder: You are not authorized to initiate research at your institution until both processes are completed: 1) the study is approved by the Reviewing IRB and an *approval* letter is issued, and 2) the local policy issues have been resolved and an *activation* letter has been issued by your Institution.

Form

Study Title:			
1. Name and Address of Site Principal Investigator (PI)?			
Site PI's Name (Last Name, First Name, MI):			
Department:			
PI's Telephone Number:		**PI's Cell or Pager Number:**	
PI's Email Address:		**PI's FAX Number:**	
2. Name of the Overall Principal Investigator (PI)?			
Overall PI's Name (Last Name, First Name, MI):			
Institution:			

3. Which University of Texas Participating Institution will serve as the Reviewing IRB?

Select only one.

☐ UT Arlington (UTA)	☐ UT Pan American	☐ UT HSC - Houston (UTHealth)
☐ UT Austin (UT Austin)	☐ UT Permian Basin	☐ UT HSC - San Antonio (UTHSCSA)
☐ UT Brownsville	☐ UT Rio Grande Valley (UTRGV)	☐ UT HSC - Tyler
☐ UT Dallas (UTD)	☐ UT San Antonio (UTSA)	☐ UT MD Anderson Cancer Center
☐ UT El Paso (UTEP)	☐ UT Tyler	☐ UT Medical Branch (UTMB)
		☐ UT Southwestern Medical Center

4. Which University of Texas Participating Institution will be engaged in this research?	
Column A - Participating Institutions Select the Participating Institution(s) that will be engaged in the research.	**Column B - Affiliated Organizations with Participating Institutions** Insert the Affiliated Organizations with Participating Institution(s) that will be engaged in the research.
☐ UT Arlington (UTA)	
☐ UT Austin (UT Austin)	
☐ UT Brownsville	
☐ UT Dallas (UTD)	
☐ UT El Paso (UTEP)	
☐ UT Pan American	
☐ UT Permian Basin	
☐ UT Rio Grande Valley (UTRGV)	
☐ UT San Antonio (UTSA)	
☐ UT Tyler	
☐ UT HSC - Houston (UTHealth)	
☐ UT HSC - San Antonio (UTHSCSA)	
☐ UT HSC - Tyler	
☐ UT MD Anderson Cancer Center	
☐ UT Medical Branch (UTMB)	
☐ UT Southwestern Medical Center	

FOR IRB OFFICE USE ONLY

1. Select the appropriate Institution.		
☐ UT Arlington (UTA)	☐ UT Pan American	☐ UT HSC - Houston (UTHealth)
☐ UT Austin (UT Austin)	☐ UT Permian Basin	☐ UT HSC - San Antonio (UTHSCSA)
☐ UT Brownsville	☐ UT Rio Grande Valley (UTRGV)	☐ UT HSC - Tyler
☐ UT Dallas (UTD)	☐ UT San Antonio (UTSA)	☐ UT MD Anderson Cancer Center
☐ UT El Paso (UTEP)	☐ UT Tyler	☐ UT Medical Branch (UTMB)
		☐ UT Southwestern Medical Center

2. The investigator's intention to include this organization as part of the Centralized IRB Review by the IRB designated in item 3 is:	
☐ Acceptable	☐ Not Acceptable

3. Notification Preference - the Reviewing IRB must notify this institution of approvals and study closure using the following method(s):	
☐ send a copy of the IRB letter	☐ send a monthly statement of listing the protocols approved in the previous month
☐ send a weekly statement of listing the protocols approved in the previous week	☐ send an copy of the IRB letter to the Site PI at this organization who is then responsible to provide this information to the Institution

4. Federal-wide Assurance Information - select the applicable statement(s):
☐ The box that applies Subpart A to all research is checked.
☐ The box that applies Subparts B, C, and D to all research is checked

5. Verification that Reviewing IRB is listed on FWA:
☐ The IRB designated in Item 3 above is listed on this institution's Federal-wide Assurance.
☐ The IRB designated in Item 3 above is also listed on the Federal-wide Assurance for each affiliated institution listed in Item 4, Column B

6. Signature of the Official Authorized by Institution:	
PRINT NAME ABOVE	**SIGNATURE**
PRINT TITLE ABOVE	**SIGNATURE DATE**

Appendix C. UT System IRB Master Reciprocity Agreement Application For Addition Of Site Investigators

Information for Overall Principal Investigator (Overall PI)

In addition to submitting an application to your institution's IRB (designated as "Reviewing IRB"), an application for addition of site investigator must be submitted for each Participating Institution. 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 institution 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.

Form

1.0 General Information	
1.1 Study Title:	<Text Field>
1.2 Site Principal Investigator:	<Text Field>
1.3 Site Name:	<Text Field>
1.4 Address:	<Text Field>
1.5 Office Phone:	<Text Field>
1.6 Cell Phone or Pager:	<Text Field>
1.7 Email Address:	<Text Field>
2.0 Study Population	
2.1 How many subjects will you recruit at your site?	<Text Field>
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 ☐ Advertisements ☐ Other, please specify: <Text Field>
2.3 Describe the recruitment process.	<Text Field>
2.4 Describe the consent process at your site (who will conduct the consent discussion, when and where it will take place.	<Text Field>
2.5 Will vulnerable subjects be recruited at your site?	☐ Children ☐ Pregnant women ☐ Cognitively impaired persons ☐ Prisoners ☐ Other, please specify: <Text Field>

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 ☐ Other, please specify: <TEXT FIELD>
3.2 How long have you been conducting research?	<TEXT FIELD> YEARS
3.3 How many active research studies are you involved in currently?	<TEXT FIELD>
3.4 Do you and your team have adequate resources to conduct this research?	☐ Yes ☐ No, if yes please describe: <TEXT FIELD>
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 describe: <TEXT FIELD>

4.0 Acknowledgement by Site Principal Investigator	
• *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 am aware of my institutional policies and procedures in the conduct of research at my institution.* • *I will cooperate with monitoring oversight visits by the Reviewing IRB and my institutional representatives.*	
Signature of Site Principal Investigator	**Signature Date**

UTHealth
The University of Texas Health Science Center at Houston

Committee for the Protection of Human Subjects
6410 Fannin Street, Suite 1100
Houston, Texas 77030

NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES June 19, 2014

HSC-MS-13-0322 - "Pre-hospital Versus In-hospital Stroke Treatment: A Multicenter Randomized Prospective Trial"

PI: James Grotta, MD

PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc. The activities of approved BCM study personnel are limited to obtaining consent from subjects and collecting study data. A letter of support is required for the addition of each BCM affiliated location.

REFERENCE NUMBER: 107045

CHANGE APPROVED: The addition of Jose I. Suarez, MD; and agreement with Baylor College of Medicine (BCM) IRB to rely on UT Health IRB (CPHS) for the conduct with the above mentioned study protocol by BCM affiliated personnel and at BCM locations.

APPROVED: At a Convened Meeting

MEETING DATE: 6/06/2014

CHAIRPERSON: Rebecca Lunstroth, JD

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved at this meeting.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that if revisions to the informed consent form were made and approved, then old copies of the ICF MUST be destroyed. Only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any Unanticipated Problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.

UTHealth
The University of Texas Health Science Center at Houston

Committee for the Protection of Human Subjects
6410 Fannin Street, Suite 1100
Houston, Texas 77030

[redacted]

NOTICE OF PERMISSION TO RELY ON CHESAPEAKE IRB

September 04, 2012

[redacted]

CHAIRPERSON: John C. Ribble, MD

PROVISIONS: This permission relates to the research to be conducted under the above referenced title.

CPHS has reviewed the above submission and determined that it meets the criteria for being reviewed by Chesapeake IRB. Please submit an application to Chesapeake IRB via their electronic system and await written approval.

Research participants must sign authorization for release of medical records unless such authorization is waived by Chesapeake IRB or UT Houston CPHS.

The research should not be initiated until all necessary institutional approvals and signatures have been obtained including but not limited to fully executed clinical trial agreement and Memorial Hermann Hospital approval (if the research is being conducted at a MHH facility).