RTRN IRB Harmonization

Standard Operating Procedures

Version 1.7

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[This document describes the policies and procedures for the IRB administrators.]

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1. SCOPE

1.1 The Standard Operating Procedures (SOPs) applies to all human subject research involving multi-institutional collaborations amongst the RTRN institutions who have signed the IRB Authorization Agreement (IAA).

2. PURPOSE

2.1 RCMI Translational Research Network (Appendix I) Ethics and Regulatory Subcommittee established the RTRN IRB Harmonization Working Group to reduce the administrative burden and the delays in research initiation, while protecting the safety, welfare and rights of the volunteering research participants. The Standard Operating Procedure (SOP) contains the steps for engaging in reciprocity of review amongst the RTRN institutions.

2.2 The objectives of the IRB Harmonization Working Group amongst the RTRN institutions are as follows:

2.2.1 Remove redundant IRB reviews in multi-institutional RTRN collaborations

2.2.2 Enhance protection of human subject in multi-institutional RTRN collaboration by sharing research and compliance expertise, IRB reviewers and community opinions

2.2.3 Improve the quality and consistency of IRB reviews

2.2.4 Establish best practices for the review and oversight of multi-institutional human subject research.

3. RELIANCE PROCESS

3.1 Overall Submission and Review Process

3.1.1 **Reviewing IRB** receives Request for Reliance from the Lead PI.

3.1.2 Discussion among the IRB staff to decide which institution will (1) review, (2) rely, or (3) conduct their own independent review.

3.1.3 **Reviewing IRB** notifies their PI to submit the IRB application. As applicable, the submission material also includes,

- institution-specific informed consent and recruitment material from the other relying sites
- Copy of completed and signed Request for Reliance

3.1.4 Lead PI submits the IRB application using their institution's IRB forms or web-based IRB submission system.

3.1.5 **Reviewing IRB** reviews and approves the protocol.

3.1.6 **Reviewing IRB** sends approved documents to the Lead PI and Relying IRB.

- Approval Letter from the Reviewing IRB
- Approved IRB application
- Approved research protocol (i.e. scientific protocol)
- Approved consent forms
- Approved recruitment materials
- Approved study instruments
- Approved scripts
- **Relying IRB** may request additional information

3.1.7 **Relying IRB** makes decision to accept or decline the review.

- Review Accepted. **Relying IRB** sends acknowledgement letter (to accept the review) and approved documents to their PI. Letter also copied to **Reviewing IRB** for documentation.

- Review Declined. **Relying IRB** sends notification to their PI to submit IRB application using their institution's procedures. Notification also sent to **Reviewing IRB** (and any other **Relying IRB**) for documentation.

  *Alternatively, Lead PI may send in an amendment to their IRB (Reviewing IRB) to address issues raised by the Relying IRB.

3.2 Considerations by the **Relying IRB** to Accept or Decline the Review

3.2.1 Adequate resources and funding to support the study

3.2.2 Research capacity

3.2.3 Experience, qualifications, training of the investigators and staff at their site

3.2.4 High risk studies or studies involving vulnerable population

- Studies involving vulnerable populations, such as prisoners or children, which may be subject to different state laws
- Stem cell research, gene transfer studies, clinical studies of xeno-transplantation, clinical studies involving Risk 3 or 4 biological agents
- Controversial behavioral studies
- Bioterrorism research
- High-risk clinical procedures

3.3 Consent Form

3.3.1 Lead PI includes the informed consent of other sites at the time of IRB submission.

3.3.2 **Reviewing IRB** sends the approved informed consent to the **Relying IRB** along with the other approved documents.

3.3.3 **Relying IRB** reviews the informed consent. **Relying IRB** can only make pre-arranged changes that affect the institutional language or local site requirements. **Relying IRB** sends the revised informed consent to their PI for enrollment and to the **Reviewing IRB** for documentation. Acceptable pre-arranged changes include,

- Institution's contact information for subject's rights (IRB/HRPP)
- Research-related subject injury language
- Emergency and research contact information
- Local site investigator on the first page
- Institution logo
- IRB number

3.3.4 **Reviewing IRB** reviews and approves any other changes made by the **Relying IRB**.

- Relying IRB notifies and attaches the revised informed consent to the Lead PI, Relying PI and the Reviewing IRB.
- Lead PI submits amendment to the Reviewing IRB.
- Reviewing IRB reviews and approves the revised informed consent.
- Reviewing IRB sends the approved informed consent back to the Relying IRB.
- Relying IRB releases the approved informed consent to their PI.

3.5 Procedures for Adding New Sites to Existing Approved Studies

3.5.1 Common examples include addition of new sites to increase participant enrollment. Investigators are using RTRN IAA reliance mechanism for the first time.

3.5.2 In these cases, the **Reviewing IRB** is the IRB that initially approved the study.

3.5.3 Lead PI submits amendment to include other sites to the **Reviewing IRB**. Request for Reliance is included in the amendment.

3.5.4 **Reviewing IRB** reviews and approves amendment as described above.

3.6 Amendments and Continuing Reviews

3.6.1 The Lead PI submits an amendment or continuing review to the **Reviewing IRB**.

3.6.2 The Lead PI submits the **Request for Reliance Form** only if there are any changes to the collaborating site(s), including changes to personnel, research activities, funding status, etc.

3.7 Other Issues

3.7.1 Each institution is responsible for HIPAA, ancillary approvals (e.g., Institutional Biosafety Committee, Radiation Safety Committee, Conflict of Interest Committee), investigator qualifications and training, monitoring, and others relevant approvals.

3.7.2 The institution that receives the grant ensures that the research protocol is consistent with the funded grant.

4. CHANGES TO THE RTRN IRB COLLABORATION POLICIES AND PROCEDURES

4.1 RTRN IRB Harmonization Working Group continuously seeks to improve the implementation of the reciprocal review process. As such, the SOP is a living document. The members will discuss any pertinent changes and vote by a simple majority.

4.2 The Chair of the RTRN Ethics and Regulatory Subcommittee will report and submit revised SOP to the Principal Investigator of RTRN.

5. ABBREVIATIONS

RCMI – Research Center for Minority Institutions
RTRN – RCMI Translational Research Network
CFR – Code of Federal Regulations
FWA – Federal Wide Assurance
IO – Institutional Official
PI – Principal Investigator
IAA – IRB Authorization Agreement
IBC – Institutional Biosafety Committee
RSC – Radiation Safety Committee
DSMB – Data Safety Monitoring Board

6. APPENDICES

Appendix 1 – Definitions

Human Subject Research – The definition of human subject research is set forth in 45CFR §46.102(f) and 21CFR §50.3(g), §103(e), §312.3(b) and §812.3(p).

Institutional Official – The Institutional Official (IO) is the Signatory Official on the Federal Wide Assurance (FWA) filed with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) to assure compliance with regulations governing protection of human subjects.

Lead Principal Investigator (PI) – In this SOP, the Lead PI is the investigator who is responsible for submitting all applicable IRB documents and reports to the Reviewing IRB.

Relying Principal Investigator (PI) – In this SOP, the Relying PI is the investigator who is collaborating with investigators from other RTRN institutions and is requesting that their institution's IRB rely on the review and approval of the Reviewing IRB.

Reviewing IRB (IRB of Record) – Reviewing IRB has oversight of research conducted at all collaborating sites.

Relying IRB – IRB has ceded review to another IRB for joint studies.

Full reliance – The model in which the Reviewing IRB will take full responsibility for the review and oversight of the research conducted at all collaborating institutions. The Reviewing IRB will be the IRB of Record and the Relying IRB agrees to accept all terms of the Reviewing IRB.

No reliance – Circumstances in which the IRB may not want to rely on another IRB for review due to institutional policies or other reasons. A single review can still be conducted amongst the remaining IRBs.

Appendix 2 – RCMI Institutions

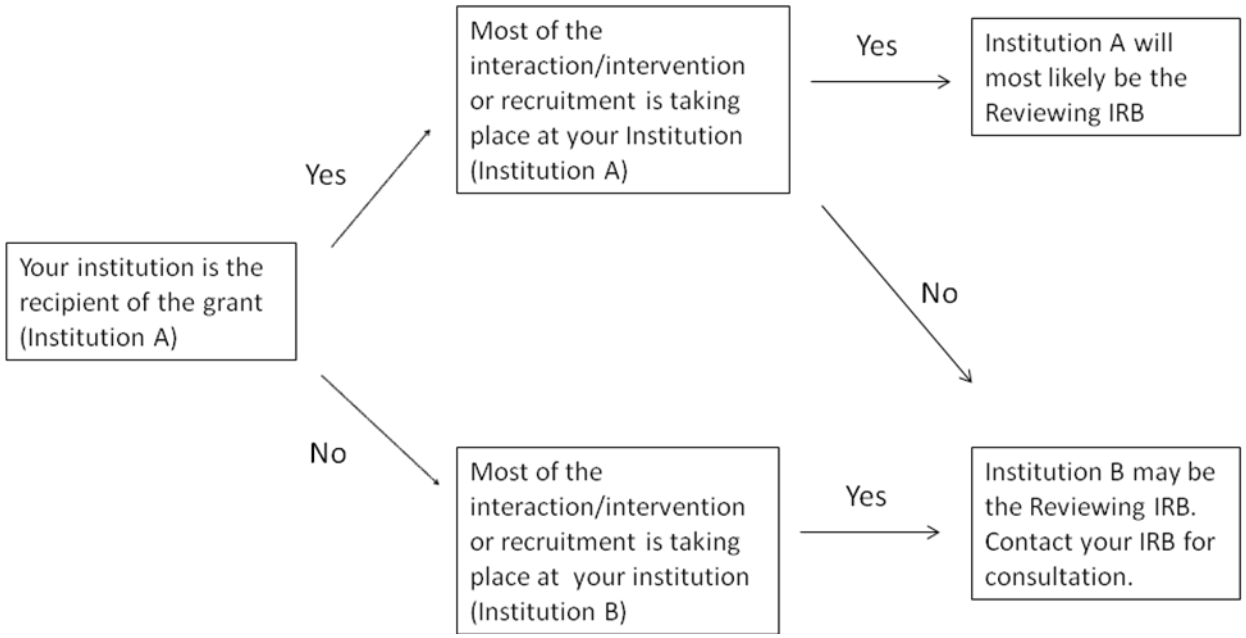
Institution	City	State	Time Zones
Charles R. Drew University of Medicine and Science	Los Angeles	California	Pacific
City College of New York, CUNY	New York	New York	Eastern
Clark Atlanta University	Atlanta	Georgia	Eastern
Florida A & M University	Tallahassee	Florida	Eastern
Howard University College of Medicine	Washington	District of Columbia	Eastern
Hunter College, CUNY	New York	New York	Eastern
Jackson State University	Jackson	Mississippi	Central
Meharry Medical College	Nashville	Tennessee	Central
Morehouse School of Medicine	Atlanta	Georgia	Eastern
Ponce School of Medicine & Health Sciences	Ponce	Puerto Rico	Atlantic
Texas Southern University	Houston	Texas	Central
Tuskegee University	Tuskegee	Georgia	Eastern
Universidad Central del Caribe	Bayamón	Puerto Rico	Atlantic
University of Hawai'i	Honolulu	Hawaii	Hawaii
University of Puerto Rico Medical Sciences Campus	San Juan	Puerto Rico	Atlantic
University of Texas at El Paso	El Paso	Texas	Central

University of Texas at San Antonio	San Antonio	Texas	Central
Xavier University	New Orleans	Louisiana	Central

Appendix 3

Decision Tree to Determine Which Institution Will be the Reviewing IRB

Scenario: Collaboration between Institutions A and B



Appendix 4. Designated IRB Contact Person for Multi-institutional RTRN Collaboration

Institution	IRB Contact	Phone	E-mail
Charles R. Drew University of Medicine and Science	Junko Nishitani	323-563-4966	Junkonishitani@cdrewu.edu
City College of New York, CUNY			
Clark Atlanta University			
Florida A & M University			
Howard University College of Medicine			
Hunter College, CUNY			
Jackson State University			
Meharry Medical College			
Morehouse School of Medicine	John Smith	404-752-1973	josmith@msm.edu
Ponce School of Medicine & Health Sciences			
Texas Southern University			
Tuskegee University	Stephen O. Sodeke	334-727-8210	sodeke@mytu.tuskegee.edu
Universidad Central del Caribe			
University of Hawai'i			
University of Puerto Rico Medical Sciences Campus			
University of Texas at El Paso			
University of Texas at San Antonio			
Xavier University			

7. REFERENCES

1. RTRN IRB Authorization Agreement

2. Standard Operating Procedure, UCLA CTSI IRB Harmonization

3. Harvard Catalyst. Powerpoint presentation on "IRB Administrator and Staff Training for Request for Single IRB Review of Multisite Research: Cede Review Form" by Sabune J. Winkler, Elizabeth Witte, Maria Cervone

4. HMO Research Network, IRB Review of Multi-Site Research

RCMI IRB Directors Contact List
August 14, 2014

State	***Institution***	**IRB Director**	**Phone**	**Email**
Alabama	*Tuskegee University*	Stephen Sodeke, PhD	334-727-8210	sodeke@mytu.tuskegee.edu
California	*Charles Drew University*	Junko Nishitani, PhD	323-563-4966	junkonishitani@cdrewu.edu
Florida	*Florida A & M University*		850-412-5246	irb@famu.edu
Georgia	*Clark Atlanta University*	Paul I. Musey, PhD	404-880-6829	pmusey@cau.edu
Georgia	*Morehouse School of Medicine*	John Smith	404-752-1973	jsmith@msm.edu
Hawaii	*University of Hawaii at Manoa*	Denise Lin-DeShetler	808-956-8287	lindesh@hawaii.edu
Louisiana	*Xavier University of Louisiana*	Charles Gramlich, PhD	504-520-7397	cgramlic@xula.edu
Mississippi	*Jackson State University*	Sophia Leggett, PhD	601-979-4917 (IRB Office) 601-979-8846 (Dr. Leggett)	irb@jsums.edu; sophia.s.leggett@jsums.edu
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New York	*City College of New York*	Arita Winter	646-664-8919	arita.winter@cuny.edu
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Puerto Rico	*Universidad Central del Caribe*	Frances García		frances.garcia@uccaribe.edu
Puerto Rico	*UPR Medical Sciences Campus*	Georgamaly Estronza Serrano	787-758-2525 x2510	georgamaly.estronza@upr.edu
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