Version 1.2

08-14-2018

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OF NEW JERSEY

LATIN AMERICAN
LAIRC
INDICATOR RESEARCH
COLLABORATORY

Table of Contents

Version 1.2

08-14-2018

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Dear Prospective Partner,

On behalf of Rutgers Biomedical Health Sciences Program in Global Surgery, Harvard Medical School Program in Global Surgery and Social Change (PGSSC), and Virginia Commonwealth University Department of Surgery, we present the Latin American Indicator Research Collaboratory (LAIRC). Your interest in improving access to surgical care globally complements the LAIRC's fundamental commitment to development of data collection, analysis and interpretation of the six surgical World Development Indicators (WDI). Together we will assess and inform surgical system strengthening with respect to National Surgical, Obstetric and Anesthesia Planning (NSOAP) dissemination and implementation in Latin American and Caribbean countries.

The purpose of this collaboratory is to guide low-to-middle income countries' (LMIC) and high-income countries' (HIC) partnerships that expand global surgery science in WDI data collection and NSOAP. These efforts are fundamental to surgical public health education, training, and research sustainability in Latin American and Caribbean countries. The LAIRC, and its partners in the LMIC and HIC, are committed to collaboration that generates timely, safe and affordable surgical care through adherence to global surgery policy and advocacy items set forth by the World Health Organization, United Nations and World Bank (i.e. WHA Resolutions 68.15 and 70.35).

The enclosed introductory content includes:

- Brief introduction to the LAIRC
- Memorandum of Understanding detailing a process for LAIRC membership

Upon execution of the MOU and joining the collaboratory, the LAIRC will formally recognize you as a Global Surgery Research Unit (GSRU). As a GSRU, you join a multinational team with whom the LAIRC has committed to sharing a research toolkit and team science that stewards LMIC and HIC unification and implementation of WDI data collection, analysis and interpretation.

Sincerely,

Gregory Peck, DO, FACS and Joseph Hanna, MD, PhD, FACS
LAIRC Co-Chairs, Rutgers University

Version 1.2

08-14-2018

BRIEF INTRODUCTION TO THE LATIN AMERICAN INDICATOR RESEARCH COLLABORATORY

The Latin American Indicator Research Collaboratory (LAIRC) was established in 2016 as a result of partnership between Rutgers Biomedical Health Sciences Global Surgery Program, the Harvard Medical School Program in Global Surgery and Social Change (PGSSC), and Virginia Commonwealth University (VCU) Department of Surgery to address the call to action established by the Lancet Commission on Global Surgery (LCoGS).[1] Specifically, high quality data collection, analysis, and interpretation of the six LCoGS core surgical indicators [now accepted as six surgical World Development Indicators (WDI)] are needed to assess, inform, and implement National Surgical, Obstetrics and Anesthesia Planning (NSOAP) in Latin American and Caribbean countries in a transparent manner. The LAIRC's mission is to facilitate cross-sectoral coordination and collaboration between Latin American, Caribbean, and North American partners in global surgery, public health, policy, and ministries of health to activate this data collection and surgical systems strengthening through health systems research (HSR).

Logistical details are based on a longitudinal process initiated in 2014 that focused on improving regional access to surgical care in Colombia. Lessons learned from individual efforts in Colombia, combined with the LCoGS's indicators measurement initiatives in Africa and Brazil, and the Panamerican Trauma Society's (PTS) commitment in Latin America, helped to inform a WDI measurement protocol developed at Rutgers University. Looking to the future, this protocol was iteratively improved upon with collaborators from PGSSC and VCU, ultimately resulting in a framework that can be employed by future partners at Latin American, Caribbean, and North American institutions dedicated to informing NSOAP. These partnerships when formed are referred to as Global Surgery Research Units (GSRUs) and function within the LAIRC framework to coordinate large-scale WDI data aggregation for quantitative and qualitative analysis.

AIMS

- Stimulate research team (GSRU) initiation of Specific, Sustainable, Measurable, Attainable, Relevant, Time-bound protocol-based collection of the six surgical WDI in Latin American and Caribbean countries (See Protocol)
- Leverage the six surgical WDI data collection plans A-D championed by GSRUs to inform an iterative mixed methodology for improved data collection, NSOAP, and HSR in Latin American and Caribbean countries

BENEFITS

- **Capacity building:** Expands global surgery academic and research capacity in Latin American and Caribbean institutions
- **Partnership:** Enables closer relationships between Latin American, Caribbean and North American institutions for collection of surgical WDI data to inform NSOAP
- **Efficiency:** By adopting a universal protocol, institutions will be able to immediately engage in this effort more efficiently, saving precious time and resources that would otherwise be spent independently developing protocols and relationships
- **Scalability:** Expands collaboration and consistent data collection regionally, which in turn provides a more accurate assessment of current progress in national surgical preparedness, delivery, and affordability (reflection of Indicators 1-2, 3-4, and 5-6, respectively)
- **Applicability**: Data collected can be sent directly to ministries of health to meet recommendations set by the World Health Organization, the United Nations Data Statistics Commission, and the World Bank for the WDI dataset

LOGISTICS

Global Surgery Research Units (GSRUs)

- Formalized partnerships among Latin American, Caribbean and North American institutions
- Research team led by two Primary Investigators (PIs), one from each partner institution
- Daily tasks/activities guided by two research fellows, one from each partner institution
- Research fellows will facilitate coordination and action of the local GSRU
- LAIRC protocol will guide on-the-ground data collection by GSRU (see appendix entitled ABBREVIATED PROCEDURES for Rutgers IRB Approved LAIRC Protocol)

Latin American Indicator Research Collaboratory (LAIRC)

- The LAIRC is a steward and promoter of GSRU formation, relationships with peer GSRUs, and the GSRUs' cumulative progress in WDI data collection, analysis and interpretation
- We encourage GSRUs to utilize the LAIRC for mentorship in all stages of development

Data capture and sharing

- Data will be captured in real-time by each GSRU in the standardized REDCap[2] database to enable efficient data collection, security, and integrity
- A REDCap database template, developed by the LAIRC, will be provided to each GSRU to ensure data collection consistency and accuracy
- Regional and national level data analysis will be accomplished by aggregating individual GSRU datasets through quarterly LAIRC reports
- All data collection, analysis, and interpretation will be shared among the GSRUs in real-time via the LAIRC to ensure timely, collaborative dissemination of scientific approaches, findings, and research implementation that informs NSOAP

- We encourage individual GSRUs to perform an independent data analysis for publication of the collected data as regional variation in surgical capacity will be important to disseminate

Outputs

- High quality data for the six surgical WDI across Latin America and Caribbean to inform NSOAP across the region
- International benchmarks for surgical system capacity across Latin America and Caribbean (preparedness, delivery, and affordability)
- Each GSRU and the LAIRC will be quantitatively and qualitatively assessed iteratively via dissemination and/or a team science framework to facilitate NSOAP implementation outcomes (e.g. acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration, and sustainability)

APPLICATION REQUIREMENTS

To apply, a prospective GSRU requires two partner organizations (one Latin American or Caribbean, one North American) with a PI and lead research fellow from each respective organization. If an applicant does not have a partner PI, we encourage a formal request to the LAIRC for partnership assistance to begin a process for match.

Application to the LAIRC requires that interested parties complete the following to become a GSRU and acquire the freely shareable LAIRC protocol:

1. A prospective GSRU may initiate the process of application to the LAIRC by submitting the Memorandum of Understanding (MOU) between the Rutgers Latin American Indicator Research Collaboratory and Global Surgery Research Unit members declaring an understanding of the terms of data transparency, data quality, data sharing and broader implementation of NSOAP
2. Upon execution of the MOU, each partner of the respective GSRU will receive the IRB protocol and REDCap Database templates
3. Prior to initiation of data collection, notification of official IRB and/or ethics committee approval (by both GSRU partners) of the LAIRC protocol must be submitted to the LAIRC at Rutgers Biomedical Health Sciences

All documentation may be addressed to:

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References

1. Meara, J. G. *et al.* Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. *Lancet Lond. Engl.* **386,** 569–624 (2015).
2. Harris, P. A. *et al.* Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J. Biomed. Inform.* **42,** 377–381 (2009).

Founding Member Acknowledgements

Latin America and Caribbean	North America
FUNDACIÓN VALLE DEL LILI Dr. Carlos Ordoñez	RUTGERS Drs. Gregory L. Peck, Javier Escobar, Richard Marlink, Vicente H. Gracias
Universidad del Valle Dr. Luis Fernando Pino	HARVARD MEDICAL SCHOOL Drs. John G. Meara, Mark Shrime, Isabelle Citron, Saurabh Saluja, Lina Roa
SANVICENTE fundación Drs. Carlos Morales, Maria Clara Mendoza Arango, San Vicente Hospital Foundation	VCU VIRGINIA COMMONWEALTH UNIVERSITY Dr. Edgar Rodas

Appendix to LAIRC Brief Introduction: ABBREVIATED PROCEDURES from Rutgers IRB Approved LAIRC Protocol

PLAN A

Method: In-person interviews with institutional leaders to obtain facility-specific data, using LCoGS Hospital Assessment Tool (HAT) for measurement of:

- **Indicator 1:** Percentage of the population that is geographically 2 hours from a facility that can perform definitive surgical intervention – i.e. cesarean section, management of open fracture, laparotomy, and timely surgical care assessment and resuscitation
    - Target: 80% coverage of essential surgical/anesthesia services within 2 hours per country by 2030
- **Indicator 2:** Number of surgeons, anesthesiologists and obstetricians (SAOs) per 100,000 population
    - Target: 100% of countries with at least 20 SAO per 100,000 by 2030

PLAN B

Method: Retrospective examination of operative logs and patient charts to collect aggregate data; additionally prospective data collection over 30-day period for measurement of:

- **Indicator 3**: Number of surgical procedures performed per 100,000 population
    - Target: 80% of countries by 2020 and 100% of countries by 2030 are tracking surgical volume; and 5000 procedures conducted per 100,000 population by 2030
- **Indicator 4**: Unadjusted, in-hospital 30-day post-operative mortality rate
    - Target: 80% of countries by 2020 and 100% of countries by 2030 are tracking perioperative mortality; in 2020, assess global data and set national targets for 2030

PLAN C

Method: Pre-hospital and hospital data aggregation to improve data collection processes, using Emergency Medical Services (EMS) “run sheets” and trauma registry databases for measurement of:

- **Indicator 1:** see above for definition

PLAN D

Method: In-person patient interviews upon discharge using adapted PGSSC Financial Risk Questionnaire, for all patients having undergone surgical procedure and/or trauma admission for measurement of:

- **Indicator 5**: Percentage of the population at risk for the development of an impoverishing expenditure should they need to undergo a surgical procedure
    - Target: 100% protection against impoverishment* from out-of-pocket payments for surgical and anesthesia care by 2030

    - **Impoverishing: pushes an individual or family below the poverty line in that country (or further into poverty if already living below the poverty line)*
- **Indicator 6**: Percentage of the population at risk for the development of a catastrophic expenditure should they need to undergo a surgical procedure
    - Target: 100% protection against catastrophic** expenditure from out-of-pocket payments for surgical and anesthesia care by 2030
    - ***Catastrophic: Exceeds 40% of the household's subsistence income after paying for basic subsistence needs*

Memorandum of Understanding between the Rutgers Latin American Indicator Research Collaboratory and Global Surgery Research Unit Members

This MEMORANDUM OF UNDERSTANDING (this "MOU") is entered into and made effective as of the ___ day of _____, 20__ (the "Effective Date"), by and between Rutgers University Latin American Indicator Research Collaboratory (the "LAIRC") at Rutgers Biomedical and Health Science and _____ ("_____", being the Latin American/Caribbean institution or "LMIC") and _____ ("_____", being the North American institution "HIC"). LMIC and HIC, together, comprise a Global Surgery Research Unit ("GSRU").

1. Purpose. The purpose of this MOU is to establish an agreement between the Latin American Indicator Research Collaboratory (LAIRC) and each Latin American/Caribbean institution and North American institution, who together form a Global Surgery Research Unit (GSRU). This MOU memorializes the rights and responsibilities of the parties with regard to their participation in the protocolized Study, as members of a GSRU, and as participants in the LAIRC.

2. Background and Definitions.

2.1 "Latin American Indicator Research Collaboratory" or **"LAIRC"** was formed by the Rutgers Global Surgery program of Rutgers Biomedical and Health Sciences, a unit of Rutgers, The State University of New Jersey, to address the call to action established by the Lancet Commission on Global Surgery ("LCoGS"). The LAIRC's goal is to undertake high quality data collection, analysis, and interpretation of the LCoGS's six core surgical indicators which are needed to assess, inform, and implement National Surgical, Anesthesia, and Obstetrics Planning ("NSOAP") in Latin American and Caribbean countries in a transparent manner. The LAIRC's mission is to facilitate cross-sectoral coordination and collaboration between Latin American/Caribbean and North American institutions engaged in global surgery, public health or health policy, as well as ministries of health, who will undertake data collection and help introduce improvements to surgical systems through fundamental health systems research ("HSR"). The LAIRC was created in cooperation with the Harvard Medical School Program in Global Surgery and Social Change and the Virginia Commonwealth University School of Medicine Department of Surgery.

2.2. Lancet Commission on Global Surgery ("LCoGS") six core surgical indicators means:

2.2.1. Indicator One: Percentage of the population that is geographically within 2 hours from a facility that can perform definitive surgical intervention bellwether procedures (i.e. cesarean section, management of open fracture and laparotomy).

- Indicator 1 target: 80% coverage of essential surgical/anesthesia services within 2 hours per country by 2030.

2.2.2. Indicator Two: Number of surgeons, anesthesiologists and obstetricians (SAOs) per 100,000 population.

- Indicator 2 target: 100% of countries with at least 20 SAO per 100,000 population by 2030.

2.2.3. Indicator Three: Number of surgical procedures performed per 100,000 population.

- Indicator 3 target: 80% of countries by 2020 and 100% of countries by 2030 are tracking surgical volume; and 5000 procedures conducted per 100,000 population by 2030.

2.2.4. Indicator Four: Unadjusted, in-hospital 30-day post-operative mortality rate.

- Indicator 4 target: 80% of countries by 2020 and 100% of countries by 2030 are tracking perioperative mortality, in 2020, assess global data and set national targets for 2030.

2.2.5. Indicator Five: Percentage of the population at risk for the development of an impoverishing* expenditure should they undergo a surgical procedure

- Indicator 5 target: 100% protection against impoverishment from out-of-pocket payments for surgical and anesthesia care by 2030

  *Impoverishing expenditure is defined as an out-of-pocket payment for a surgical procedure (direct and indirect costs) that pushes an individual or family below the poverty line in that country (or further into poverty if already living below the poverty line).

2.2.6. Indicator Six: Percentage of the population at risk for the development of a catastrophic** expenditure should they undergo a surgical procedure.

- Indicator 6 target: 100% protection against catastrophic expenditure from out-of-pocket payments for surgical and anesthesia care by 2030.

  **Catastrophic expenditure is defined as an out-of-pocket payment for a surgical procedure (direct and indirect costs) that exceeds 40% of the household's subsistence income after paying for basic subsistence needs.

2.3. "Data" or **"Dataset"** means the information collected pursuant to LCoGS's six core surgical indicators.

2.4. "Global Surgery Research Unit" or **"GSRU"** is a dyad formed by Latin American/Caribbean and North American institution and personnel. Each GSRU is led, at a minimum, by two Primary Investigators ("PI"); contains two research fellows, and maintains a Latin American/Caribbean:North American ratio of 1:1 of PIs and research fellows from each partner institution. Establishment and function of the GSRU is guided by the LAIRC Toolkit and ongoing stewardship of the LAIRC.

2.5. "HIC" means high-income country; used in reference to the North American institution partner in the GSRU.

2.6. "LMIC" means low-to-middle income country; used in reference to Latin American/Caribbean institution partner in the GSRU.

2.7. "Protocol" means the Latin America Core Surgical Indicators Measurement and Implementation study, Protocol No. 20170000334 (Gregory Peck, DO, Principal Investigator).

2.8. "LAIRC Toolkit" is a LAIRC-developed comprehensive research protocol designed to facilitate high quality data collection, analysis, and interpretation of the Lancet Commission on Global Surgery's (LCoGS) six core surgical indicators, which are needed to assess, inform, and implement National Surgical, Anesthesia, and Obstetrics Planning ("NSOAP") and fulfill the World Bank's six surgical World Development Indicator dataset. The LAIRC Toolkit consists of:

2.8.1. An IRB-approved protocol for the collection of LCoGS indicators 1-6.

2.8.2. REDCap database templates for the collection and storage of LCoGS indicators 1-6.

2.8.3. GSRU Checklist to guide GSRU development and deployment of resources.

A. Reference literature to disseminate for the education and training of GSRU research staff.

2.8.4. "Pocket Cards" to guide on-the-ground research tasks and activities.

2.8.5. A template Affiliation Agreement (the "Affiliation Agreement") which may be used as the basis for each GSRU to create institution-specific documents for establishing inter-institutional relationships as specified in the LAIRC Toolkit.

2.9. "Study" means the research activities described in the Protocol.

3. Rights and Responsibilities of GSRU Members.

3.1. By signing this MOU, the LMIC and the HIC are together expressing their individual and mutual intention to: (a) form a GSRU; (b) formally participate in the LAIRC; and, (c) work collaboratively towards informing National Surgical, Anesthesia, and Obstetrics Planning (NSOAP) in Latin America and/or the Caribbean by capturing the Data.

3.1.1. Creation of a GSRU is accomplished through the execution of an Affiliation Agreement between the LMIC and the HIC. The responsibilities of the LMIC and HIC to each other are set forth in the Affiliation Agreement.

3.1.2. Once this MOU is fully executed, research-specific portions of the LAIRC Toolkit will be provided to GSRU members.

3.2. Each GSRU member will seek approval from its respective IRB and/or Ethics Committee for the Protocol and each GRSU member shall be responsible to modify the Protocol according to requests made by their respective institutional IRB or Ethics Committee (with subsequent notification to the LAIRC of any required changes).

3.2.1. IRB/Ethics Committee approval shall be submitted to LAIRC for documentation of readiness to participate in the LAIRC.

3.3. The LMIC and HIC shall each conduct the Study and obtain the Data in full compliance with the requirements of their respective IRBs and/or Ethics Committee.

3.3.1. As a GSRU member and participant in the LAIRC, you commit to the data quality requirements. Assurance of data quality is accomplished by having each GSRU member obtain IRB and/or Ethics Committee approval of the Protocol at specific sites of research, reflecting each respective institution's discretion and validation of data collection and integrity.

3.4. Within thirty (30) days following the close of each calendar quarter, each GSRU will share by forwarding to the LAIRC all Data collected by the GSRU during such previous calendar quarter.

3.5. The LMIC and HIC agree to assist the LAIRC in undertaking Study and LAIRC Toolkit assessment and development activities to iteratively improve research culture.

3.6. No GSRU member may redistribute or publish the LAIRC Toolkit in any fashion, whether modified or unmodified.

4. Rights and Responsibilities of LAIRC.

4.1. The LAIRC will assist each LMIC and HIC in identifying a partner.

4.2. The LAIRC will assist each GSRU with publication of its own Data in its own Publication.

4.3. Once finalized, GSRU status will be highlighted on the LAIRC's "Global Collaborators Map". Each GSRU member will have access to the LAIRC website.

4.4. The LAIRC reserves the right to engage in qualitative data collection and analysis designed to improve Study and LAIRC Toolkit improvements. In any Publications resulting from such qualitative data analysis, the LAIRC agrees to acknowledge the GSRU institutions and GSRU principal investigators.

5. Data Confidentiality.

5.1. The parties agree to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of the Data; to prevent the use or disclosure of the Data other than is permitted in this MOU; and, to the extent applicable, the parties agree to protect the confidentiality of all Study subjects.

6. Ownership and Use of Data.

6.1. The Data is the sole property of the LMIC and the LMIC hereby grants to the HIC and the LAIRC an unlimited, fully paid-up, royalty-free, non-exclusive, worldwide, non-transferable, perpetual right and license to use and fully exploit the Data.

6.1.1. For the avoidance of doubt, the foregoing license includes the use of the Data by any party (as well as anyone else who may be granted use of the Data by the LAIRC) in creating manuscripts that will be submitted for peer-review and if accepted will be made publicly available in clinical journals ("Publications"). All Publications shall comply with LAIRC publication citations and shall make reference to LAIRC-developed protocols.

6.2. Each GSRU Publication shall acknowledge LAIRC membership and use of the LAIRC Toolkit shall be reported in the methods section of each Publication.

6.3. The parties agree that the Data is "as is" and the LAIRC and Rutgers make no representations or warranties as to the quality or accuracy of the Data.

6.4. The LAIRC reserves the right to facilitate submission of, or to submit, the Data to the World Development Indicator Dataset.

6.5. The LAIRC reserves the right to aggregate the GSRU Data with the other data submitted to the LAIRC. All such Publications will include in each Publication an appropriate acknowledgement and/or strongly encourage co-authorship of the publication by the respective GSRU principal investigators.

6.6. The LAIRC reserves the right to permit others to use the Data for Publications, and to submit the Data to the World Development Indicator Dataset, subject to LAIRC publication citations.

7. Term and Termination.

7.1. Term. The initial term of this MOU is 10 years from the Effective Date (the "Initial Term"), subject to Section 7.3 below.

7.2. Automatic Extension. Subject to Section 7.3 below, this MOU will automatically extend for 10-year terms ("Subsequent Terms") unless one of the parties provides to the other parties a written notice of termination.

7.3. Withdrawal. Either the LMIC or the HIC may withdraw from this MOU upon ninety (90) days' notice (the "Notice Period") to the other parties. The LAIRC reserves the right to reduce the Notice Period. In the event of a withdrawal which is the result of a dispute between the LMIC and the HIC, the LAIRC will encourage the parties to make a timely resolution of the cause of such dispute in order to maintain the GSRU.

7.4. Termination. In the event of a breach of this MOU by either the LMIC or the HIC, the LAIRC may terminate this MOU upon a date set forth in a notice to the parties. The LAIRC reserves the right, in its sole discretion, to grant a party time to cure the breach to the sole satisfaction of the LAIRC.

8. Rights and Responsibilities of the Parties following Termination.

8.1. Following the termination of this MOU for any reason, the LMIC and the HIC (as the case may be) agree to provide transition assistance for the benefit of the LAIRC, including the delivery of current Data and the provision of assistance to a replacement LMIC or HIC to help such replacement continue the Study.

8.2. A party withdrawing from this MOU continues to have the ownership and license rights set forth in Section 4.1 above, subject to obligations of Section 22 below.

9. Logos/Trademarks. Nothing in this MOU grants or permits a party the right to use the logos and trademarks of any other party without the express advance written approval of such party. Notwithstanding the foregoing, a party may use the LAIRC logo in its internal and external promotional materials and may use the marks of any party in internal publications and presentations, as well promotional materials addressed to employees, students, parents, alumni and supporters of the party. Notwithstanding the foregoing, LAIRC hereby grants (without fee) to each party the right to: (i) publicize the Study (including a link to or copy of the Study) internally and externally to its faculty, staff, students, employees, alumni and prospective students through various media and publications (including, but not limited to, magazines, newsletters and internet/email publications); (ii) post a link to or a copy of the Study on one or more of party's websites; and, (iii) permit a party to use the materials in its educational and other programs which support the mission of the party. The foregoing right shall include a perpetual, world-wide license (without fee) for use of the Study. In all uses of the Study, a party will appropriately attribute LAIRC.

10. Choice of Law and Venue. This MOU, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this MOU, or the negotiation, execution or performance of this MOU (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this MOU or as an inducement to enter into this MOU) shall be governed by and enforced in accordance with the internal laws of the State of New Jersey, including its statutes of limitations and without reference to its conflicts of laws principles. Each of the parties irrevocably submits to the exclusive jurisdiction of the state and federal courts situated in the State of New Jersey for purposes of any suit, action or other proceeding arising out of this MOU or any transaction contemplated hereby and agrees not to commence any action, suit or proceeding relating hereto except in such courts.

11. Dispute Resolution. In the event of a dispute between the LMIC and the HIC, the LAIRC will use its best efforts to informally mediate between the parties. In the event of a dispute between the LMIC or the HIC and the LAIRC, the parties will use their best efforts to

informally reconcile their differences.

12. No Third Party Beneficiaries. This MOU is made solely for the benefit of the parties, their successors and assigns, and no other person or entity shall have any right, benefit or interest under or because of, or any right to enforce, this MOU.

13. No Other Relationship Created. The relationship created among the parties through the execution and performance of this MOU shall be limited to participation in the LAIRC and the parties have no other rights or privileges as to each other, unless otherwise agreed in writing.

14. Limitation on Damages. This is a non-monetary agreement. No cause of action or right to damages shall accrue in the event that any party to this MOU is not able to fully or partially perform hereunder. To the extent that either of the LMIC or HIC withdraws from the GSRU, the LAIRC will use its best efforts to replace that party within the GSRU. If the LMIC withdraws, it agrees to transfer its data and cooperate with its replacement participant.

15. Assumption of the Risk. The parties acknowledge that collecting Study Data in certain locations potentially presents a heightened personal risk (such as an increased risk of suffering an injury or loss) to those individuals directly engaged in such activities. Each party agrees to exercise due caution and responsible judgment in conducting the Study and especially when directing individuals to places of potentially heightened personal risk. Each party is responsible for any injuries, losses or damages incurred by such party, or its employees, staff, volunteers, agents or students. No party shall make a claim or seek indemnification, contribution or payment from any other party for an obligation incurred due to injuries, losses or damages suffered by a party's employees, staff, volunteers, agents or students by virtue of their involvement in the GSRU, the LAIRC or the Study. Notwithstanding the foregoing, in the event that a party suffers losses due to the misrepresentation (made to either to a party or to an IRB) of another party, or due to the failure of another party to conduct the Study in a responsible manner, then the party suffering the loss may seek indemnification (and/or to be held harmless) from the party making the misrepresentation.

16. Entire Agreement. This MOU, including all attachments or appendices, represents the entire agreement of the parties with respect to the subject matter thereof and supersedes any previous agreements relating to the same subject matter.

17. Strict Compliance. No failure by any party to insist upon the strict performance of any obligation under this MOU will constitute a waiver of any breach thereof. No waiver of any

breach will affect or alter this MOU and every term of this MOU will continue in full force and effect.

18. Severability. If any provision of this MOU will for any reason be held to be invalid or unenforceable, such invalidity or unenforceability will not affect any other provision of this MOU, and this MOU will be construed as if such invalid or unenforceable provision were omitted.

19. Independent Contractor Relationship. The relationship between the each of the parties (and their personnel) will at all times be that of independent contracting parties. Each party, and each party's respective personnel, will therefore be liable for their own respective debts, obligations, acts, and omissions, including the payment of all required withholding, social security and other taxes. All salaries, wages, benefits, taxes, and other expenses of any kind relating to each party's personnel will remain the sole responsibility of that party.

20. Amendments. This MOU may be modified or amended only by the express written consent of all parties.

21. Counterparts. This MOU and any amendments hereto may be executed in any number of counterparts, each of which will be deemed an original, and all of which will together constitute one and the same instrument. Any counterpart signature page delivered by fax transmission or email transmission shall be deemed to be and have the same force and effect as an originally executed signature page.

22. Notices. All notices, requests, approvals, demands, and other communications ("Notice") required or permitted to be given under this MOU shall be in writing and shall be sent to the Principal Investigator and to the Institution Representative of the receiving party, along with a copy to the LAIRC and to Rutgers, via email with a request for delivery confirmation. Each recipient agrees to acknowledge receipt of any Notice sent by email either through a delivery receipt pop-up or via reply email. In the event a receiving party does not acknowledge receipt of a Notice, the sender may choose to forward the Notice via facsimile or a delivery service which provides tracking and/or delivery confirmation.

23. Survival. The respective rights and obligations of the parties under Sections 3.6, 5, 6, 8-15, 22 and 23 survive the termination or expiration of this MOU or such party's withdrawal from this MOU.

IN WITNESS WHEREOF, the parties have caused this MOU to be executed as of the Effective Date.

_____ **GSRU Principal Investigator - LMIC** _____ **Print Name**	_____ **Date** _____ **Email**
_____ **GSRU Institution Representative - LMIC** _____ **Print Name**	_____ **Date** _____ **Email**
_____ **GSRU Principal Investigator - HIC** _____ **Print Name**	_____ **Date** _____ **Email**
_____ **GSRU Institution Representative - HIC** _____ **Print Name**	_____ **Date** _____ **Email**
_____ **LAIRC Co-chair** _____ **Print Name**	_____ **Date** _____ **Email**
_____ **Rutgers Representative** _____ **Print Name**	_____ **Date** _____ **Email**

Signature Page to Memorandum of Understanding