



LUNG REPAIR AND REGENERATION CONSORTIUM POLICIES AND GUIDELINES

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A. DEFINITIONS

1. **LRRC** – The Lung Repair and Regeneration Consortium.
2. **ACC** – The Lung Repair and Regeneration Consortium Administrative Coordinating Center.
3. **Affiliate** – A non-investigator member of the LRRC who is directly employed by a Sponsoring Institution and under the direction of a LRRC Investigator. Affiliates can be research professors, postdoctoral fellows, graduate students, research assistants and other essential support staff. They may not be independently funded Principal Investigators.
4. **Co-Investigator** – An independently-funded investigator who (i) receives funding from a multi-investigator U01 grant awarded in response to RFA-HL-12-006 and is listed as a Co-investigator on that grant. Co-Investigator status may also be awarded via a Collaborative Research Study or Collaborative Resource Validation Study or a LRRC special funding program.



5. **Contact Principal Investigator (Contact PI)** - Each Research Center may be comprised of several collaborating Principal Investigators and Institutions. Therefore, each Research Center will designate a Contact Principal Investigator whose responsibilities will include ensuring that information and decisions flow to and from their center.
6. **EAC** – The LRRRC External Advisory Committee. Comprised of five external scientists, the EAC oversees the LRRRC research activities, conducts review of the LRRC’s progress, and provides peer review for proposed and funded studies.
7. **Member** – A LRRRC Investigator, LRRRC Co-Investigator or LRRRC Affiliate.
8. **NHLBI** – The National Heart, Lung, and Blood Institute. NHLBI is the sponsor of the LRRRC.
9. **Principal Investigator (PI)** – This is a designation that is conferred by NHLBI Program Staff and that carries special privileges within the LRRRC. LRRRC Principal Investigator status is granted to investigators who are designated as such in a LRRRC grant awarded in response to RFA-HL-12-006. Principal Investigator status may be granted to an investigator listed on a Collaborative Research Study or Collaborative Resource Validation Study award or a LRRRC special funding program.
10. **RC** – A LRRRC Research Center. Six RCs, chosen by NHLBI, will conduct collaborative research studies and resource validation studies and will participate in the Skills Development Core.
11. **Resource** – A reagent, model, imaging, data analysis tool, technology, method, or dataset that is generated using funding obtained directly from the NHLBI, or indirectly through the LRRRC Administrative Coordinating Center.
12. **SC** – The LRRRC Steering Committee. Consisting of a representative from each Research Center, a chairperson chosen by NHLBI, the NHLBI Program Officer and the ACC Principal Investigator, the Steering Committee will be responsible for the overall scientific direction, coordination and oversight of the LRRRC.
13. **SDC** – The LRRRC Skills Development Core. The SDC will develop and coordinate activities among the RCs to enhance skills development for graduate students, postdoctoral fellows, and young faculty in the areas of lung science and research fundamentals, laboratory training, career skills development, and mentoring.
14. **SDCC** - The Skills Development Core Committee. The Skills Development Core is headed by a SDC Committee, composed of a representative from each RC, the Principal Investigator of the ACC, and a subject matter expert from the ACC.
15. **Sponsoring Institution** – The institution with which a LRRRC Investigator, external speaker or Consultant is affiliated.

The following matrix provides a summary of what access is granted to the above roles, or definitions:



Role	Signed Policies and Guidelines?	Responsible Party?	Access to Secure Website?	Annual Grantee Meeting Attendee?	Steering Committee Member?	Semi-Annual Steering Committee Meeting Attendee?	Can Have Affiliates?
LRRC Principal Investigator ¹	Yes	N/A	Yes	Yes	Yes	Yes	Yes
LRRC Co-Investigator	Yes	LRRC Investigator	Yes	Yes	No	No	Yes
LRRC Affiliate	Yes	LRRC (Co-) Investigator	Yes	Yes	No	No	No
LRRC ACC	N/A	N/A	Yes	Yes	Yes ²	Yes	No
NHLBI	N/A	N/A	Yes	Yes	Yes ²	Yes	No

1. Only U01 Principal Investigators.
2. The ACC Principal Investigator and the NHLBI Medical Officer(s) will serve as members of the Steering Committee.
3. N/A – not applicable

B. PURPOSE

Integral to the success of the Consortium is the timely and unencumbered sharing of LRRRC resources and related information among LRRRC Members and the dissemination of results to the research community and public at-large. All parties within the LRRRC must establish a deep sense of trust within the consortium in order to enable meaningful collaborations and sharing. To avoid confusion among the group of participating LRRC Principal Investigators, LRRC Co-Investigators, and their Affiliates clearly defined policies and guidelines, and clarification of the penalties for noncompliance, are necessary. Thus, this document has been developed for this cycle of the LRRC beginning on December 31, 2011.

As a condition of participation in the LRRRC, as evidenced by their signatures at the bottom of this document, all LRRC Principal Investigators (and future special funding program investigators) and their sponsoring Institutions acknowledge and agree that they have read and understand, and formally agree to adhere to these policies, guidelines and principles. Likewise, all LRRC Co-Investigators (U01 and other non-LRRC subcontract awards) and Affiliates acknowledge and agree that they have read and understood, and formally agree to adhere to these policies, guidelines and principles. All aforementioned parties agree that this document is a Statement of the LRRC's Policies and Guidelines effective as of December 31, 2011, regarding the conduct of all LRRC Principal Investigators, Co-Investigators and Affiliates; however, these Policies and Guidelines may be revised from time-to-time by mutual consent with such revisions being available at <http://www.lungrepair.org>.



C. OVERVIEW

Mission and Objectives

The mission of the Lung Repair and Regeneration Consortium (LRRC) is to foster research by highly integrated multidisciplinary scientific teams to address knowledge gaps in fundamental mechanisms underlying lung repair and regeneration and to translate this newly gained knowledge to new regenerative medicine strategies for reversing debilitating and life-limiting pulmonary disorders.

The objectives of the consortium are:

1. To test innovative hypotheses of mechanisms that control lung repair/regeneration.
2. To develop small molecule and bioengineering approaches to lung cell therapy and regeneration.
3. Through collaborative research activities, to develop novel resources that will accelerate research progress in lung repair/regeneration.
4. To validate resources developed by the other RCs.
5. To develop and build upon a Skills Development Core for the purpose of training a future generation of researchers in lung regeneration and repair.

Introduction

The Lung Repair and Regeneration Consortium (LRRC) is a team science initiative and consortium of cooperative agreements that was established by the National Heart, Lung, and Blood Institute (NHLBI) in 2011 ([RFA-HL-12-006](#) and [RFA-HL-12-010](#)). As a collaborative effort, the LRRC requires frequent interactions among the awardees and with the NHLBI.

The Consortium consists of six Research Centers and an Administrative Coordinating Center:

Research Centers (RCs) – The RCs are comprised of multidisciplinary teams that will work collaboratively with the other RCs in the LRRC. Each RC has an appointed Contact Principal Investigator (Contact PI). The Contact PI is responsible for ensuring that information flows between their RC and the LRRC. The Contact PI's responsibilities also include ensuring that progress reporting to NHLBI and the LRRC is done accurately and on time, overseeing the budgets for their RC and for any awarded studies, responding to administrative changes within the LRRC and those handed down from NHLBI, and filtering research proposals from their RC before they are submitted in response to a LRRC RFA.

The ACC will initiate solicitations for Collaborative Research Studies across two or more Consortium RCs beginning in Year 1. Beginning in Year 2, solicitations for Collaborative Resource Validation Studies will be issued by the ACC. The resources and protocols generated by these studies will rapidly be shared with members of the Consortium, and eventually advertised and made available on the public portion of the Consortium website. Additionally, funding may be awarded to the RCs to



support development of local Skills Development Core (SDC) infrastructure that will vary by RC depending on the nature and duration of the trainee experience. Collaboration and interaction among LRRC members is a requirement of the program and will be facilitated by the website, teleconferences, and biannual meetings of the investigators organized by the ACC.

In their applications to participate, all LRRC Principal Investigators were required to explicitly indicate their willingness to 1) cooperate with other awardees in the development and design of research priorities, especially regarding resources 2) share the data and resources developed with LRRC funding in accordance with the award 3) participate in Steering Committee Meetings, Annual Grantee Meetings, and regular teleconference calls, 4) participate in the Skills Development Core Committee including attending meetings and teleconferences or assign a designee LRRC-affiliated investigator to fulfill this obligation and 5) agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI.2 of RFA-HL-12-006.

LRRC Co-Investigators are required to 1) cooperate with other awardees in the development and design of research priorities, especially regarding resources, 2) share the data and resources developed with LRRC funding in accordance with the award and 3) agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI.2 of RFA-HL-12-006.

Administrative Coordinating Center (ACC) – The ACC, located at Duke University, serves a range of functions including arranging and organizing teleconferences and in-person meetings, and designing and maintaining written materials and the website to support the Consortium. The ACC is also responsible for solicitation of applications for collaborative research studies and studies to validate resources that are developed by the LRRC. The ACC will oversee the processes of review and award of collaborative study funds for the Consortium, assist in the Skills Development Core, and coordinate the submission of LRRC progress reports by the awardees for review by the External Advisory Committee and NHLBI staff.

The ACC consists of the Leadership Team, the Core Resources Team, and the Operational Team.

The Leadership Team, headed by the ACC Principal Investigator, assumes responsibility for ensuring that the ACC meets its aims.

The Core Resources Team is made up of a team of subject matter experts who will advise the ACC Leadership Team on specific components of the consortium and provide support directly to the RCs in the areas of Regulatory Affairs, Biostatistics and Bioinformatics, and Bioethics.

The Operational Team includes an experienced team of project leaders as well as experts in web development and administration and communications. The Operational Team works closely with the ACC Leadership Team to implement all ACC aims.

The RCs and ACC collaborate on a Skills Development Core:

Skills Development Core (SDC) – The SDC, coordinated by the ACC, will help young investigators develop the skills and experience to progress to more senior status in the field of lung regenerative medicine. The SDC will fund travel and costs for supplies and equipment to support developmental



activities, courses, seminars, workshops, and other activities directly related to the development plan for junior investigators across the Consortium. A SDC Committee (SDCC), composed of an investigator from each RC, and the Principal Investigator as well as a subject matter expert from and from the ACC, will develop and coordinate activities among the RCs to enhance skills development for graduate students, postdoctoral fellows, and young faculty. Each RC will appoint a Skills Development Coordinator, with relevant experience, who will assist with SDC activities at their center.

Oversight

Activities within the LRRRC are overseen by both NHLBI staff members and participating scientists. Oversight committees are as follows:

ACC Leadership Team (LT) – The LT consists of the ACC PI and Co-Investigators. The LT is responsible for the overall progress and management of the LRRRC ACC and for meeting the aims of the LRRRC.

Steering Committee (SC) – The SC consists of a representative from each RC, the ACC PI, and the NHLBI Medical Officer(s). The SC chair is selected by the NHLBI. The SC is the main governing body and decision-making committee for the LRRRC and assumes overall responsibility for scientific direction, coordination, and oversight. The SC reserves the right to request that a LRRRC Member deposit resources or information resulting from LRRRC funds to facilitate their distribution to the scientific community at-large. This request may occur prior to the initial publication of the resource or information.

External Advisory Committee (EAC) – The EAC will be comprised of five non-Consortium-affiliated scientists, appointed by NHLBI with input from all the relevant components of the LRRRC, to provide reviews of the LRRRC progress and peer reviews for the proposed and funded Collaborative Research and Validation Studies. The EAC will meet annually in-person in Bethesda, MD, and on quarterly teleconferences.

Skills Development Core Committee (SDCC) – The SDCC will be composed of a representative from each RC, the PI of the ACC, and a subject matter expert from the ACC. This committee will develop and coordinate activities among the RCs to enhance skills development for graduate students, postdoctoral fellows, and young faculty from each RC. Each RC also has an appointed Skills Development Coordinator, who assists with SDC activities at their center.

D. REPORTING

Each RC is required to report biannually to the EAC and NHLBI on the progress of their Collaborative Research Studies or Collaborative Resource Validation Studies. The reporting process is facilitated by the ACC. The purpose of the LRRRC progress reports are to update the EAC and NHLBI on the research/validation being conducted by the RC and to help ensure that the goals set for each award are being met. Detailed information on the reporting process and requirements is available on the website at <http://www.lungrepair.org>.



E. MEETINGS

The LRRRC generally holds two annual face-to-face meetings. In general, it is expected that all LRRRC Investigators attend the annual meetings. Since attendance at these meetings is essential for the success of the collaborative efforts of the consortium, investigators who fail to attend may lose their good standing and some or all of the associated privileges.

Commencement Meeting

One LRRRC Principal Investigator from each RC was required to participate in the one-time face-to-face meeting in Durham, North Carolina. Co-Investigators and Affiliates were not invited to this meeting. The ACC Leadership and Operational teams as well as the NHLBI Program Officer(s) were also present at the meeting.

Annual Grantee Meeting

The Annual LRRRC Grantee meeting will occur in Bethesda, MD, and will include LRRRC Members, key collaborators, and trainees. This meeting will serve as a forum to share ideas and develop synergies across the LRRRC research landscape. A major goal of these meetings will be to facilitate the sharing of skills, ideas, data and resources. At the meetings, discussions will include the topics of quality assurance, bioinformatics, coordination, sharing, and a means of informing the community about progress made by the Consortium.

Steering Committee

The LRRRC Principal Investigators serving on the SC are required to participate in (1) face-to-face SC meetings two times per year in Bethesda, MD, (2) and monthly teleconferences. The timing of one of the SC meetings will coincide with the Annual Grantee Meeting. Co-Investigators and Affiliates are not invited to the SC meetings and teleconferences. The SC teleconferences are open to all LRRRC Principal Investigators, however only the SC members are allowed to vote. This ensures that there is only one vote per RC regardless of the number of Principal Investigators from that Center. In the event that a SC member is unable to attend a teleconference or meeting, she/he may designate another Principal Investigator from her/his RC to attend the call on vote on their Center's behalf.

Skills Development Core Committee

The appointed SDC representative (LRRRC Principal Investigator or designee) from each RC is required to participate in (1) face-to-face SDCC meetings two times per year in Bethesda, MD, (2) and quarterly via teleconference. The timing of one of the SDCC meetings will coincide with the Annual Grantee Meeting. Co-Investigators and Affiliates are not invited to the SDCC meetings and teleconferences.

F. THE LRRRC WEBSITE AND ITS USAGE

To support the operations of the LRRRC a website (<http://www.lungrepair.org>) has been built and will continue to be updated throughout the duration of the grant. The website serves as the central



repository of information for the LRRRC and provides a means by which the LRRRC Members can gain new knowledge and fulfill their sharing obligations. The primary functions of the website include:

- Facilitating the confidential exchange of information, resources, and protocols between LRRRC Members
- Facilitating the sharing of information and resources with non-LRRRC investigators and the public at large
- Registration for LRRRC meetings and events
- Submission of proposals for Collaborative Research and Resource Validation Studies
- Management of the funded Collaborative Research and Resource Validation Studies
- Progress reporting

Accordingly, the LRRRC website has a central role in the operations of the LRRRC. LRRRC Members are expected to learn its features and visit the site frequently, and are encouraged to recommend enhancements.

Usage of the website by LRRRC Members includes the following expectations:

1. **Member Profiles** – To maintain good standing with the LRRRC, all LRRRC Principal Investigators, LRRRC Co-Investigators and LRRRC Affiliates are required to update their member profiles within the LRRRC website on at least an annual basis. LRRRC Members will be prompted to review and update their member profiles at the beginning of each calendar year. LRRRC Members who fail to update their profiles on an annual basis may have their access to information within the website restricted in addition to the restrictions in Section L.
2. **Entry of Scientific Deliverables and Progress Reporting**– LRRRC Principal and Co-Investigators are required to enter into the website a brief description of scientific deliverables and time estimate for availability for each new resource or dataset described in all Collaborative Research Studies, Collaborative Validation Studies, and/or other yet-to-be-defined LRRRC special funding programs, prior to the distribution of funds for these awards. This information will be viewable only by the NHLBI staff, the ACC and LRRRC Principal and Co-Investigators within that project.

Since the generation of new resources may not always happen according to schedule, LRRRC Principal and Co-Investigators will be provided with the opportunity at the time of the progress report to modify timeframes, to add new resources, or to remove resources resulting from changes in scientific direction or other circumstances. All changes in scientific deliverables will be visible to the ACC, EAC, and to the Medical Officer(s) at NHLBI who may ask for additional information.

3. **Entry of Protocols** – LRRRC Principal and Co-Investigators are required to provide a copy of all study protocols for uploading to the website for all Collaborative Research Studies, Collaborative Resource Validation Studies, and/or other yet-to-be-defined LRRRC special funding programs. Access to information describing these unpublished resources will automatically be granted to LRRRC Principal Investigators, Co-Investigators, and Affiliates. LRRRC Principal and Co-Investigators



may petition the LRRRC Steering Committee to restrict access to the protocol to LRRRC Principal Investigators only.

4. **Entry and Documentation of Resources** – New resources that have been conceived of, or that are in the process of being generated, as a part of a funded study must be documented on the LRRRC website. Access to information describing these unpublished resources will automatically be granted to LRRRC Principal Investigators and Co-Investigators. LRRRC Investigators may petition the LRRRC Steering Committee to restrict access to the information to “LRRRC Principal Investigators Only”. Information about resources from completed studies must be made accessible to the LRRRC Members prior to publication as outlined in Section H. LRRRC-developed resources will not be shipped to and/or shared with collaborating centers until the information describing the resource has been entered into the appropriate data resource on the LRRRC website and made viewable to other LRRRC Members. While it is the responsibility of the LRRRC Principal and Co-Investigators to make necessary website entries and status updates, LRRRC Principal and Co-Investigators may always request assistance from the ACC with this task. The ACC, acting on behalf of the NHLBI, may implement features in the LRRRC website such as restricting access to other protocols and resources in order to encourage compliance in regard to the entry and documentation of resources.
5. **Experimental Datasets** – Like other LRRRC resources, all high throughput datasets must be shared with other LRRRC Members prior to publication as outlined in Section H. This requirement can be satisfied by uploading the dataset onto the website where access to this data, like other LRRRC resources and information, can be securely managed. While it is the responsibility of the LRRRC Principal and Co-Investigators to ensure that the dataset is uploaded, LRRRC Principal and Co-Investigators may always request assistance from the ACC in the uploading process. The ACC, acting on behalf of the NHLBI, may implement features in the LRRRC website in order to encourage compliance with dataset uploading.
6. **Annual Meetings** – Registration for face-to-face meetings of the LRRRC will be managed through the website. Registration is required.
7. **Presentations from Meetings** – PowerPoint and/or Adobe PDF files of all presentations made at the meetings of the LRRRC will be posted on the LRRRC website where they can be viewed by other LRRRC Principal and Co-Investigators. This information should be kept in strict confidence and only shared with LRRRC Affiliates – by way of LRRRC Principal and Co-Investigators – after reminding them of their obligations to also maintain confidentiality.

G. CONFIDENTIALITY OF INFORMATION

LRRRC Members are obliged to maintain the confidentiality of unpublished information that is disclosed to them, either directly or indirectly, during the course of LRRRC meetings and events. The main sources of unpublished information include the data and resource descriptions posted on the LRRRC website and unpublished data presented at LRRRC meetings. However, unpublished information may also be gained by direct disclosure of one LRRRC Member to another LRRRC Member. Such information should not be shared with any third party without the consent of the original contributor(s) of such information, or until the original contributor(s) publishes or otherwise publicly releases such information.



H. SHARING AMONG LRRRC INVESTIGATORS

All LRRRC Principal and Co-Investigators are expected to share information and resources with other members of the LRRRC prior to the initial peer-reviewed publication that describes the development of the resource or the research results. Since the willingness of LRRRC Principal and Co-Investigators to share information and resources depends upon the responsible use of these resources and information, and appropriate scientific attribution, the following sections describe the general expectations for such exchanges in detail.

Sharing of information about research in progress is intended to minimize duplication and stimulate collaboration between LRRRC Principal and Co-Investigators. However, at the same time LRRRC Members must recognize that unpublished information may be incomplete, and sometimes even erroneous. Thus, LRRRC Members are encouraged to directly discuss such data if experiments are being planned that are based on it.

1. **Authorship** – Authorship and other matters relating to publications shall be determined in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/>). The use of an unpublished resource or other key information that leads to a publication necessitates a discussion of authorship with the donating Principal Investigator(s). In general, the prepublication sharing of LRRRC resources should be dealt with through scientific collaborations in which the terms for the specific use of the LRRRC resource are agreed upon in advance. The forms and processes for documenting collaborative agreements involving the use of newly developed resources are available on the website (<http://www.lungrepair.org>). In general it is expected that LRRRC Principal and Co-Investigators maintain good scientific relationships with other LRRRC Members. The failure of a LRRRC Principal Investigator or Co-Investigator to maintain good scientific relationships due to non-compliance with the terms of a scientific collaboration may result both in a loss of good standing within the Consortium and a restriction of their privileges to access information on the LRRRC Website (Section L).
2. **Publications** – All publications arising from collaborations that utilize unpublished resources or information from other Principal or Co-Investigators should include the donating investigator(s) and key RC personnel as co-authors, unless explicitly agreed to and documented otherwise. In general, the provider of the resource or information has the right to publish the description and use of the resource or information first. However, at the same time LRRRC Principal and Co-Investigators must be willing to commit to a reasonable timeframe for submission for publication that does not hinder other users of key resources the ability to publish their own results in a timely manner.
3. **Third Parties** – Unpublished resources obtained from one LRRRC Principal and Co-Investigator by another should not be transferred to a third party without the prior written consent of the originating contributor. LRRRC Affiliates should always consult with their Research Center's Principal and Co-Investigators before transferring reagents to other individuals including other individuals within their own institution.
4. **Documentation of Collaboration** – To facilitate collaboration between LRRRC Principal and Co-Investigators, the terms of use for unpublished reagents and datasets between collaborating



Research Centers and Principal and Co-Investigators will be documented and posted to the website. The agreements can be updated by the collaborating parties as needed, with facilitation from the ACC.

5. **Material Transfer Agreement** – It is the responsibility of both parties to ensure that all MTAs or other institutional documents associated with this collaborative effort are submitted in a timely manner through their appropriate institutional offices. In most cases, the Simple Letter Agreement found at <http://www.lungrepair.org> should be used.

I. SHARING BETWEEN LRRRC AND NON-LRRRC MEMBERS

All published resources that were made using LRRRC funds, either in total or in part, must be freely distributed to investigators at academic institutions who request use of these resources for non-commercial research. “Freely distributed” is defined as the unencumbered distribution patterned after practices of NIH-sponsored repositories, where distribution is carried out without regard to the requestor’s identity or experimental designs. Individuals found to be in breach of this policy may be subject to sanctions, including possible termination of their award.

1. **Distribution** – LRRRC Principal and Co-Investigators who have generated a LRRRC resource will be responsible for distributing it to all requesting investigators. LRRRC Research Centers may ask the requesting investigator to reimburse the reasonable costs for preparing and distributing the resource. If the expense of distributing a resource becomes burdensome, the LRRRC Research Center may petition the LRRRC ACC for subsidization of distribution costs. A resource request mechanism will be available on the LRRRC website to assist in tracking and managing such requests. Guidelines for how requests for resources should be routed and managed through the LRRRC website will also be made available at <http://www.lungrepair.org>.
2. **Intellectual Property** – LRRRC Principal and Co-Investigators are expected to adhere to the NIH Grants Policy on Sharing of Unique Research Resources including the “Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Grants and Contracts” issued in December, 1999 (http://www.ott.nih.gov/policy/rt_guide_final.html). Specifically, all material transfers should be set forth in an agreement and reviewed through the appropriate institutional offices. In most cases, a Simple Letter Agreement should be utilized but must not have any reach-through requirements (<http://www.lungrepair.org>). Moreover, should any intellectual property be patented the technology must remain widely available to the research community in accordance with the NIH Principles and Guidelines document.

J. LRRRC AFFILIATE RESPONSIBILITIES

LRRRC Affiliates contribute to the atmosphere of collaboration and sharing by adhering to the operational procedures and guidelines outlined here. Not only does this facilitate the mission of the LRRRC in accelerating the discovery process for lung repair and regeneration, it also promotes the LRRRC Affiliate’s scientific aspirations and goals by providing access to key information and resources.



LRRC Principal and Co-Investigators are responsible for determining their LRRC Affiliates, and are responsible for ensuring that these individuals both understand and comply with the Policies and Guidelines of the LRRC as described within this document.

LRRC Affiliates are encouraged to assist their LRRC Principal and Co-Investigators in entering relevant resources, experimental datasets, and protocols into the appropriate locations on the LRRC website.

1. **Addition of LRRC Affiliates** - All LRRC Affiliates must first sign the Policies and Guidelines document and submit it to the ACC prior to conducting any Consortium-related activities. LRRC Principal and Co-Investigators are responsible for ensuring that their LRRC Affiliates are added to the website and that they create a Member Profile.
2. **Removal of LRRC Affiliates** - Once the LRRC Affiliate is no longer associated with the LRRC the affiliation should be terminated by the LRRC Principal or Co-Investigator who oversees the Affiliate. The LRRC Principal or Co-Investigator must also notify the ACC of the needed change. The ACC can then remove the Affiliate from the website. Both LRRC Affiliates and LRRC Principal and Co-Investigators are required to ensure the removal of affiliation status once the association is no longer deemed appropriate. Nonetheless, the former Affiliate will be able to continue access the LRRC website as a non-LRRC member (public status).
3. **Responsibilities of LRRC Affiliates** - LRRC Affiliates are required to have a member account for the LRRC website and to manage and maintain their own Member Profile which includes ensuring that recent publications, contact information and a portrait-style photograph are present on the site. Furthermore, LRRC Affiliates who attend LRRC meetings must have a completed Member Profile for meeting registration.

K. EXTERNAL SPEAKERS AND CONSULTANTS

External speakers and consultants may be periodically invited to participate in LRRC meetings. These individuals are given privileged access to a breadth of information that is normally disclosed and discussed at these meetings. They will be expected to maintain confidentiality of this information, and to comply with the all Policies and Guidelines pertaining the Sharing of information (Sections H and I). External speakers and consultants and their sponsoring institution will be required to sign this document prior to their attendance at any LRRC event. External speakers and consultants will not be provided with LRRC Member-level website access.

L. FAILURE TO MAINTAIN GOOD STANDING

In its oversight capacity, the SC can in its sole discretion take appropriate actions to ensure proper operation and implementation of the LRRC, including but not limited to the following: LRRC Principal Investigators, LRRC Co-Investigators and LRRC Affiliates who fail to maintain good standing within the Consortium, particularly regarding the sharing of information and reagents, or who inappropriately disclose confidential information, may be subject to sanctions including having further NHLBI funding of the LRRC Principal or Co-Investigator's grant restricted, as well as the following:



1. In general, the first restriction for failing to register for a meeting (Section E) or updating your list of sharable information or resources (Section F) will be a restriction in access to the website.
2. A failure to update a Member Profile or to enter other required information into the LRRRC website (Sections F and J) will lead to an inability to register for the required LRRRC meetings.
3. A failure to document new resources, information or protocols (Section F), the inappropriate disclosure of unpublished data (Section H), maintain confidentiality (Section G) or the failure to comply with the terms of a scientific collaboration (Section H), may lead to the inability to view and/or obtain other unpublished resources, information and protocols.
4. A failure to complete progress reports about resources and information being generated using LRRRC funds (Section D) may lead to the inability to apply to future study solicitations or other yet-to-be-defined special funding programs of the LRRRC.
5. A failure to contribute to or collaborate with the Skills Development Core may lead to the inability for members of that institution to participate in traineeships and special programs of the SDC.

BY SIGNING BELOW, I ACKNOWLEDGE AND AGREE, FOR MYSELF OR FOR THE SPONSORING INSTITUTION OF WHICH I AM A DULY AUTHORIZED OFFICIAL, THAT I HAVE READ, UNDERSTOOD, AND I/THE INSTITUTION SHALL ABIDE BY THE POLICIES, PROCEDURES, AND GUIDELINES OF THE LRRRC.

LRRRC Principal Investigator, Co-Investigator, Affiliate,
External Speaker or Consultant Signature

Date

Printed Name

Institution Name

Contracts Office Official
(Required For Principal Investigator Only)

Date