

(Re)Building A Kidney (RBK) Consortium

Standards of Conduct, Version 3 (V3), Updated Sept. 1, 2017

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Acronyms and Terms Used Throughout Document

1. **RBK.** (Re)Building a Kidney Consortium.
2. **NIDDK.** The National Institute of Diabetes and Digestive and Kidney Diseases.
3. **RBK Hub.** The RBK Hub is supported by the NIDDK via a cooperative agreement; applications were originally submitted in response to RFA-DK-14-009.
4. **RBK Research Project.** *Phased Research Projects* supported by the NIDDK via cooperative agreements (applications were originally submitted in response to RFA-DK-14-010) and projects funded by the RBK *Partnership Project Program (PPP)*.
5. **RBK Collaborating Projects.** Relevant funded projects brought into RBK administratively by the NIDDK.
6. **RBK SC.** The RBK Steering Committee is composed of the following: named PIs of RBK Research Projects and Collaborating Projects, external SC Chair, and NIDDK representatives. All RBK PIs are allowed to attend RBK SC meetings.
7. **RBK PI.** The Principal Investigator(s) of a RBK Research Project or RBK Hub or a RBK Collaborating Project.
8. **Voting member.** The PI(s) of each single-PI RBK Research Projects and Collaborating Projects are voting members. For multi-PI RBK Research Projects and Collaborating Projects a single PI will be designated as the voting member. The NIDDK will have one voting member.
9. **Co-Investigator.** An investigator named in a RBK Research Project application or Collaborating Project application as a Co-Investigator or Co-PI may attend the RBK SC meetings but does not have voting privileges.
10. **RBK Staff Member.** Personnel, including students, involved in a RBK Research Project, Collaborating Project, or Hub that are not members of the RBK SC. RBK PIs are responsible for informing and ensuring Staff Members abide by Standards of Conduct and the RBK Confidentiality and Nondisclosure Policy regarding confidentiality of information and use of shared information and resources generated within RBK.
11. **RBK Member.** The term “RBK Member” is an all-encompassing term which reflects personnel that are members of the consortium (PIs, NIDDK Representatives, Co-Investigators, and Staff Members).
12. **External Experts.** The RBK External Experts attend at least one in-person SC meeting per year to provide input and guidance to the RBK SC and recommendations to NIDDK. The RBK External Experts comprise the External Expert Panel (EEP).
13. **Resource.** A chemical, antibody, genetically modified mouse, cell line, technology, method, or dataset that is generated using funding obtained directly from the NIDDK, or indirectly through the RBK Hub.

14. **RBK Website.** Online data and documentation of Resources for RBK and other online collaboration tools. Content in the website is organized in tiers such that some content is publically accessible or limited to specific RBK Members.



<https://www.rebuildingakidney.org/projects/>

A. Mission and Objectives

(Re)Building a Kidney is a National Institute of Diabetes and Digestive and Kidney Diseases-led consortium to optimize approaches for the isolation, expansion, and differentiation of appropriate kidney cell types and the integration of these cells into complex structures that replicate human kidney function. The ultimate goals of the consortium are two-fold: to develop and implement strategies for in vitro engineering of replacement kidney tissue, and to devise strategies to stimulate regeneration of nephrons in situ to restore failing kidney function. Projects within the consortium will answer fundamental questions regarding human gene expression in the developing kidney, essential signaling crosstalk between distinct cell types of the developing kidney, how to derive the many cell types of the kidney through directed differentiation of human pluripotent stem cells, which bioengineering or scaffolding strategies have the most potential for kidney tissue formation, and basic parameters of the regenerative response to injury. As these projects progress, the consortium will incorporate systematic investigations in physiologic function of in vitro and in vivo differentiated kidney tissue, strategies for engraftment in experimental animals, and development of therapeutic approaches to activate innate reparative responses.

RBK is an international team-science initiative established by the NIDDK in 2015. RBK is governed by a Steering Committee (SC) to coordinate and facilitate research activities for the overall program and to ensure synergy and efficiency. The RBK Hub (U01 cooperative agreement mechanism) is housed at the University of Southern California, and the RBK Research Projects are housed in research at institutions across the US and in Australia (UH2/UH3 cooperative agreement mechanisms and Partnership Project Program). In addition, the consortium will be augmented by Collaborating Projects, which include projects identified directly by the NIDDK

and approved by the SC. The PIs of the Collaborating Projects will be closely engaged with the activities of the consortium and will have the same responsibilities and access to data and results as other RBK PIs.

Activities within RBK are overseen by both NIDDK staff members and participating scientists. Consortium activities are directed by a Steering Committee (SC), which consists of RBK PIs (of Research Projects and the Hub), NIDDK representatives, and an external SC Chair, who is appointed by the NIDDK. PIs of the Partner Projects will also participate in SC activities. The SC meets monthly via teleconference and face-to-face on a semi-annual basis. External Experts serve to provide objective scientific input and guidance to RBK. The RBK Hub provides the organizational infrastructure for RBK and manages the projects funded by the PPP.

The timely and unencumbered sharing of RBK Resources and related information, with RBK Members and the general research community will contribute to the success of the consortium. To maintain these values, defined policies and guidelines, and clarification of the penalties for noncompliance, are necessary to avoid confusion among participating RBK Members.

As a condition of participation in RBK, all RBK Members acknowledge and agree that they have read and understood, and agree to adhere to these policies, guidelines and principles. It is understood that this document is a statement of the RBK's Standards of Conduct as of **September 1, 2017** regarding the conduct of all RBK Members; however, these Standards may be revised from time-to-time with such revisions being available at the RBK Website (rebuildingakidney.org).

B. Failure to Maintain Good Standing

In its oversight capacity, the RBK SC can in its sole discretion recommend to the NIDDK appropriate actions to ensure proper operation and implementation of RBK, including but not limited to the following: RBK Members who fail to maintain good standing within RBK, particularly regarding the sharing of information and other Resources, or inappropriate disclosure of confidential information, may be subject to sanctions, including the following:

1. A failure to document new Resources, the inappropriate disclosure of unpublished data or confidential information, or the failure to comply with the terms of a scientific collaboration, may lead to the inability to view and/or obtain other unpublished Resources and information.
2. A failure to maintain information about Resources being generated may lead to the inability to apply to special programs of RBK (e.g., PPP).
3. A failure to comply with the agreed upon publication policies, may lead to the inability to view and/or obtain other unpublished Resources and information.

NOTE: In addition to the above, noncompliance with the terms and conditions of any award may lead to programmatic actions related to the award.

C. Confidentiality of Information

RBK Members are obligated to maintain the confidentiality of confidential information that is disclosed to them, either directly or indirectly, during the course of RBK meetings and communications. All information provided within the context of the RBK consortium shall be assumed to be confidential unless explicitly stated otherwise. Sources of confidential information can include data, Resource descriptions, manuscripts and abstracts distributed for review, and unpublished data presented at RBK meetings, amongst others. However, unpublished information may also be gained by direct disclosure of one RBK Member to another. Such information should not be shared with any non-RBK 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.

The *Confidentiality and Nondisclosure Policy* will be signed by appropriate officials at the institutions of all RBK Members. A *Conflict of Interest and Intellectual Property Disclosure Form* will be signed annually by RBK PIs.

All in attendance at semi-annual RBK SC meetings must submit updated *Conflict of Interest and Intellectual Property Disclosure Forms* prior to each in-person RBK SC meeting. Visitors will be required to sign meeting *Confidentiality and Nondisclosure Agreements (CDA)* to participate. The Hub will compile results for the RBK SC to review cases in need of clarification and make recommendations to the RBK SC on addressing, disclosing and managing conflicts of interest, as applicable. The RBK SC will also consider any conflict of interest issue of which it becomes aware through other sources. The Hub will compile a list of all disclosures and make this information available as a handout to be distributed at the start of each in-person SC meeting. SC meeting presentations, signed *Confidentiality and Nondisclosure Policy* documents, and completed *Conflict of Interest and Intellectual Property Disclosure Forms* will be posted on the secure portion of the RBK Website.

D. Project Intellectual Property.

“Project Intellectual Property” shall mean all data, research results, patentable inventions, and copyrightable materials conceived and reduced to practice or made in the performance of an RBK Research Project, RBK Collaborating Project, or the RBK Hub. Unless a different agreement is made between individual members of the Consortium for a specific research project and approved by the RBK SC, the following shall apply to all Project Intellectual Property: (1) each party shall own its solely created Project Intellectual Property; (2) Project Intellectual Property that has been conceived and reduced to practice or made jointly by the parties (“Jointly Owned Project IP”) will be owned by the parties equally with each party having a full and undivided share in such Jointly Owned Project IP. Should Jointly Owned Project IP occur under this Agreement, the Parties will negotiate, in good faith, for an Inter-Institutional Agreement for the management of the Jointly Owned Project IP. Note, *RBK Standards of Conduct* is not a legally-binding document, and RBK Members are encouraged to review policies at their institutions and seek guidance from appropriate authorities at their institutions.

E. Sharing

As stated in the funding opportunity announcements for RBK, “prior to publication but upon validation (1) all tools, reagents and data will be shared with consortium members, and (2) all tools and reagents will be made available to the general research community.” All RBK Members are expected to share information, tools, reagents and data prior to the initial peer-reviewed publication that describes the development of the resource or reagent, or research results. Since the willingness of RBK Members to share Resources depends on the responsible use of these Resources and appropriate scientific attribution, the following sections describe the general expectations for such exchanges in detail.

Semi-Annual SC Meetings. The RBK holds semi-annual SC meetings: one in the Spring and one in the Fall. In general, it is expected that all RBK SC Members attend both the Spring and Fall meetings. Since attendance at these meetings is essential for the success of the collaborative efforts of the consortium, Members who fail to attend may lose their Good Standing, and some or all of the associated privileges. As defined in the *Confidentiality and Nondisclosure Policy*, presentations and discussions at these meetings are assumed confidential unless stated otherwise.

Presentations at Meetings. All presentations given at the in-person or web-based SC meetings must be provided to the RBK Hub prior to the completion of the meeting for posting to the RBK Website (Internal pages, see below). As defined in the *Confidentiality and Nondisclosure Policy*, the content of these presentations is assumed confidential unless stated otherwise. Although not mandatory, outside speakers will be encouraged to share their presentations for posting on the RBK Website (Internal pages).

E.1. Sharing within the (Re)Building a Kidney (RBK) Consortium

Sharing of information about experiments in progress is intended to minimize duplication and stimulate collaboration between RBK Members, and the general research community. However, at the same time RBK

Members must recognize that unpublished information may be incomplete, and sometimes even erroneous. Thus, RBK Members are encouraged to directly discuss such data if experiments are being planned that are based on unpublished information. **Furthermore, all information and Resources shared within the RBK, typically accessible only through personal correspondence, presentations at RBK meetings and calls, or on the Internal pages of the RBK Website is considered confidential and requires prior written permission from the originator of that information before use for one's own purposes or transfer to a third party.** For example, a unique Resource generated by an RBK Member and shared on the Internal pages of the RBK Website requires prior written permission of the originator to be used in any publication until that Resource is migrated to the publically accessible pages of the RBK Website. The RBK does not have a publication approval process, but non-compliance with these terms by RBK Members may result in a loss of Good Standing within the Consortium and a restriction of their privileges to access information on the RBK Website.

The RBK Website and RBK SC email list are the recommended media for initial exchange of information. The RBK Website includes sections accessible only to authorized RBK Members (details below).

The degree to which PIs disclose their research that is supported outside of RBK is at the judgment of the PI. Sharing of information and Resources generated outside of RBK is encouraged if the project(s) intersect with key RBK interest areas.

E.2. Sharing Between RBK and Non-RBK Members

All Resources such as mice, genetically-modified cell lines, antibodies, and data that are generated using RBK funds, either in total or in part, must be freely distributed to investigators at academic institutions who request use of these reagents 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. RBK Members are expected to adhere to NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources (<https://grants.nih.gov/policy/sharing.htm>).

F. The RBK Website and Its Usage

The RBK Hub will maintain a variety of tools to enable communication between RBK Members, and between RBK and the general research community. These include the RBK Website (rebuildingakidney.org) and a variety of mailing lists.

The RBK Website provides an easy way for RBK Members to both gain new knowledge and to fulfill their sharing obligations. This platform facilitates the confidential exchange of information and data between RBK Members via access restrictions. Accordingly, the RBK Website has a central role in the operations of the RBK, and RBK Members are strongly encouraged to learn its features, visit the site frequently, and recommend enhancements.

The RBK Hub will maintain 2 tiers of access to the RBK Website. (1) Public access will be provided to top level web pages; (2) Authorized RBK Members (RBK PIs and approved RBK Staff Members), NIDDK, and External Experts will have access to the Internal pages.

The Internal pages will include the Research Plans, Progress Updates, other operational materials, and the biocuration Dashboard. **All information found in the Internal pages is considered confidential and requires permission from the originator of that information before use for one's own purposes.**

As described in the *Sharing* sections above, data and metadata (e.g., pertaining to a new dataset or other Resource) are expected to be made available to RBK via the Dashboard immediately upon generation. The

NIDDK may request additional information regarding a dataset or other Resource be added to the Internal pages. Upon validation and biocuration, this information will be made available to the public via the publically-accessible top level web pages of the RBK Website. Research Plans, Progress Updates, other operational materials will remain only on the Internal pages.

Improper use of the RBK Website or failure to adhere any of the standards above may result of loss of Good Standing within the RBK.