



Kyowa Kirin Co., Ltd. & Harvard University REQUEST FOR PROPOSALS

Proposal Submission Deadline: February 10, 2021

Harvard's Office of Technology Development (<http://otd.harvard.edu>) is pleased to announce the **2021 Request for Proposals (RFP)** under the strategic research alliance recently established between **Harvard University** and **Kyowa Kirin Co., Ltd. ("KKC")**. This five-year strategic research alliance will support multi-year research projects initiated by Harvard faculty, focused on research and development of mutual interest.

Kyowa Kirin Co., Ltd. is a Japanese-based global specialty pharmaceutical company, contributing to human health and well-being worldwide through innovative drug discovery and global commercialization, driven by state-of-the-art antibody technologies, in the core therapeutic areas of nephrology, oncology, central nervous system and immunology. **KKC welcomes Harvard scientists to join them in developing innovative therapies to treat people suffering from kidney-related diseases through unique expertise on specific target molecules, pathophysiology of kidney diseases, and research technologies.** In kidney-related areas, including mineral disorders and anemia, KKC has multiple approved drugs in addition to several ongoing clinical trials. For more information, please visit <https://www.kyowakirin.com>.

FRAMEWORK AND FUNDING

This 2021 RFP is seeking novel research project proposals, **within the scope of the Scientific Challenge proposed by KKC in Appendix A**. Proposals should be based on strong, innovative science and clinical rationale with the goal to develop first-in-class, innovative drugs that can transform the lives of patients of kidney-related diseases with high unmet medical needs.

KKC will provide meaningful funding, **anticipated to be \$750,000 per year for up to 3 years (including direct and indirect costs)**, to support research projects.

APPLICATION PROCESS, REVIEW PROCESS AND SELECTION OF FINAL AWARD RECIPIENTS

Applicants are to develop a 250-word non-confidential executive summary and a 2-page Short Proposal that describes the research objectives, relevant preliminary results and an overview of the planned implementation of the proposed project, **as outlined in Appendix B**. Applicants may submit more than one proposal. The deadline for submission of Short Proposals is **February 10, 2021**. We **require** that you contact us at otdalliances@harvard.edu or reach out to your OTD contact to discuss your idea for a proposal **before** preparing a proposal and to request the Microsoft Word version of the 2021 KKC – Harvard RFP short proposal template.

KKC will review Short Proposals and determine further interest in the development of 4-page Detailed Proposals, which will include a more refined and detailed research plan and budget. Detailed Proposals will be prepared by the applicants in collaboration with KKC’s R&D leadership, which may involve meetings between the selected proposal finalists and KKC. KKC will select the final project award recipients after submission and review of the Detailed Proposals.

APPLICATION TIMELINES

Date	Action
Wednesday, February 10, 2021	Deadline for the submission of Short Proposals
Thursday, April 22, 2021	Announcement of Short Proposals advanced to submission of Detailed Proposals
April 22, 2021 – May 27, 2021	Development of Detailed Proposals in collaboration with KKC
Thursday, May 27, 2021	Deadline for the submission of Detailed Proposals
Friday, July 16, 2021	Announcement of Final Project Award Recipients
Monday, August 16, 2021	Latest start date of projects

ELIGIBILITY AND RESTRICTIONS

Anyone with rights as a Principal Investigator, **whose employer is Harvard University and who has an obligation to assign intellectual property rights to Harvard**, is eligible to apply. Investigators with Harvard academic appointments but who are not employed by Harvard University are not eligible. Post-docs and research scientists who are interested in applying should discuss with their PI and apply jointly. Collaborations within Harvard University are highly encouraged, however, please reach out to your contact within OTD or to

otdalliances@harvard.edu to discuss projects that may involve external collaborators, which includes Harvard-affiliated hospitals.

AWARD TERMS AND CONDITIONS

Project Team: A scientific Project Team will be established for each project, which will include representatives from KKC and Harvard. The KKC Alliance Manager and Harvard Alliance Manager will be the primary points of contact for the Project Teams. Project Teams will meet quarterly to discuss project progress and results.

Publications: Publication of the research project results is permitted, although Principal Investigators will need to comply with a short pre-disclosure period for all research publications and presentations resulting from the funded work, to determine if any publications contain company confidential information or if the publications contain patentable subject matter.

Reporting Requirements: A progress report will be required each calendar year during the funding period, and a final report will be due no later than 60 days after the end of the funding period. Each report should summarize research activities and results relevant to the specific aims of the project.

CONTACT INFORMATION

For additional information on the program and the application process, please contact the Director of Business Development at OTD that supports you or contact us at otdalliances@harvard.edu.

Appendix A: KKC Scientific Challenge /// Short Proposal Submission Deadline: February 10, 2021

The primary goal of the project should be the discovery or development of a novel compound, target molecule, or drug concept for the treatment of kidney-related diseases and/or novel technology to drive such research.

Target diseases are:

- **Chronic Kidney Disease (CKD)** caused by a genetic component or various primary diseases including, but not limited to, Diabetes, Hypertension, Nephrotic Syndrome and Nephritis.
- **Acute Kidney Injury (AKI)** including septic, post-cardiac surgery and drug induced acute injury.
- **End-Stage Kidney Disease (ESKD)** including its complications.
- **Kidney disease-related multi-organ failure.**

Kidney cancer is excluded from the focus of this RFP.

Primary research focus:

1. Novel compounds, target molecules and drug concepts applicable to therapeutics for the target diseases.
 - Areas of high interest include:
 - Kidney dysfunction evaluated by markers such as creatinine and blood urea nitrogen
 - Decrease in glomerular filtration rate
 - Proteinuria/Hematuria
 - Kidney injury induced by a specific gene mutation
 - Damage, dysfunction or loss of podocytes
 - Damage, dysfunction or necrosis of tubular epithelial cells
 - Fibrosis of tubulointerstitium
 - Oxidative stress
 - Injury on vascular endothelial cells
 - Inflammation and/or invasion of inflammatory cells
 - Multi-organ injury related to kidney dysfunction
 - Modalities of interest: small molecule, antibody, peptide, protein, nucleic acid, or cell therapy.
 - Strong consideration will be made for proposals that include *in vivo* proof-of-concept data from animal models for kidney disease or use clinical findings to develop a drug concept.
2. Novel technologies that can drive innovative research and therapies in kidney-related areas.
 - Technologies of interest include:
 - *In vitro* or *ex vivo* assays to replace *in vivo* evaluation enabling a bridge from pre-clinical to clinical studies, or to use for high-throughput compound screening.
 - Methods for segmentation of patients with potential genetic causes of disease identified from clinical samples.
 - Methods for finding promising target molecules or pathways in the target diseases
 - Drug delivery systems targeting kidney, and more preferably specific cell types within kidney, such as podocytes and epithelial cells of tubule or collecting duct.
 - Novel drug modalities or therapeutic technologies, and their application to a target kidney disease. For example, the development of gene therapy enabling more effective gene induction and/or modulation.
3. Proposals in areas other than those described above, yet related to the mission of KKC, may also be welcomed.

Appendix B: Short Proposal Outline /// **Short Proposal Submission Deadline: February 10, 2021**

Applicants are advised to work with OTD to develop their proposal. Please contact us at otdalliances@harvard.edu for a Microsoft Word version of the proposal template.

Cover Page:

- Project title
- Affiliation details of lead PI
- Names and affiliation details of any collaborators
- Total budget request (including indirect costs)
- Project term
- Keywords
- Final deliverable

Non-Confidential Executive Summary (250 words maximum)

Confidential Short Proposal

The Short Proposal research plan should not exceed 2 pages (this limit does include figures but does not include references). Please do not include any structures of chemical matter in your proposal.

1. Background and significance
2. Research objectives, including rationale and preliminary results for each aim
3. Experimental plan
4. Anticipated milestones and timelines
5. KKC contribution
6. Intellectual Property
7. References
8. Publications

Proposal submission: Proposals should be submitted as a single Microsoft Word file, with the exception of supporting publications, which should be provided as PDF files. Please submit proposals via e-mail to otdalliances@harvard.edu. Please include in the subject line the words “KKC RFP” and the PI’s last name.