

**Investigator-Initiated Research on Genetic Counseling Processes and Practices RFAs**  
**Applicant Webinar Summary**  
September 25, 2020

**Purpose:** The National Human Genome Research Institute hosted a webinar to provide an overview of the Investigator-Initiated Research on Genetic Counseling Processes and Practices Request for Applications (RFAs), and to answer questions from prospective applicants.

**RFAs:** [RFA-HG-20-048](#) and [RFA-HG-20-049](#)

**Frequently Asked Questions:** [FAQs](#)

### **Overview of RFAs**

The purpose of the Investigator-Initiated Research on Genetic Counseling Processes and Practices initiative is to assess, innovate, scale, and/or research the implementation of novel genetic counseling practices for genomic medicine. The funding opportunity will support investigator-initiated research on how to optimize the genetic counseling processes including, but not limited to, the communication or genomic results in the context of limited resources. Responsive applications would include research personnel with experience identifying and overcoming challenges in genetic counseling. Additionally, projects should be broadly applicable to genomic medicine; projects studying a specific disease area would have to yield generalizable findings.

While the National Human Genome Research Institute (NHGRI) will primarily fund this initiative, the National Cancer Institute (NCI) will fund up to one R01 application. NCI is interested in applications that address managing germline findings in the context of tumor testing.

This RFA will utilize two funding mechanisms (R01 & R21). R01 applications have a project period of up to 4 years, a budget of up to \$500K direct costs per year and require preliminary data. R21 applications have a project period of up to 3 years, a budget of up to \$200K direct costs per year with a maximum of \$400K direct costs for the total project period, and do not require preliminary data.

### **Deadlines**

Letter of intent: September 28, 2020 (not required)

Applications due: October 28, 2020

Earliest start date: August 2021

Second receipt for new and/or revised applications: July 8, 2021

### **Q&A Session**

*How many applications does NHGRI intend to fund for each receipt date?*

NHGRI anticipates funding 5-7 total R01 and R21 awards across two receipt dates. While the balance will depend on the number of fundable applications in each receipt date and available funding, NHGRI anticipates funding 3-5 applications per receipt date.

*If a research proposal involves cancer genetics but is not entirely oncology focused, will NIH staff determine if the application falls under NCI or NHGRI, or can the investigator request assignment to a particular Institute?*

NIH staff will discuss whether applications involving cancer genetics fall under NCI or NHGRI based on the research proposed. NCI is currently planning to fund only one R01 application. As NHGRI is interested in research that is broadly applicable, applications focused on cancer genetics are encouraged to describe how findings could be applicable to other disease areas and genomic medicine more broadly.

*Is the Letter of Intent (LOI) binding?*

**No-** the LOI is not binding. Information in the LOI including the title of proposed research and key personnel can be changed before submitting an application. The LOI allows NIH staff to estimate the number of applications that will be submitted and helps with planning the review.

*Are foreign institutions eligible to apply?*

**Yes-** applications from foreign institutions are eligible under both the R01 and R21 funding opportunity. Applications from foreign institutions should demonstrate that the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and are not readily available in the U.S. As with all applications, applicants from foreign institutions are encouraged to contact NIH Program Officers before submission.

*Are foreign components of U.S. Organizations eligible to apply?*

**Yes-** applications with foreign components of U.S. Organizations are eligible under both the R01 and R21 funding opportunity. Applications from U.S. Organizations with foreign components are **not** required to demonstrate that the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and are not readily available in the U.S.

*Does NHGRI anticipate a third receipt date that would allow for resubmission of applications that were originally submitted in July 2021?*

NHGRI is not currently planning for a third receipt date. Applicants that submit in July 2021 and are interested in revising their application are encouraged to talk to the NIH Program Officers to determine if their application would be responsive to a different funding opportunity.

*Who should I contact to discuss my application prior to submission?*

For R21 inquiries, contact Nicole Lockhart ([lockhani@mail.nih.gov](mailto:lockhani@mail.nih.gov)). For R01 inquiries, contact Ebony Madden ([ebony.madden@nih.gov](mailto:ebony.madden@nih.gov)). For R01 cancer related inquiries, contact Leah Mechanic ([mechanil@nci.nih.gov](mailto:mechanil@nci.nih.gov)) and/or Ebony Madden ([ebony.madden@nih.gov](mailto:ebony.madden@nih.gov)).

*What are the main differences between the R01 and R21 RFAs?*

The main differences are the budget limits, project period, and preliminary data requirements. The R01 RFA has a larger budget, a longer project period, and requires preliminary data. Applicants should consider how much funding and time their proposed project requires, and whether they have preliminary data when deciding which RFA to apply to.

*When are Letters of Intent for the July 2021 receipt date due?*

Letters of Intent are typically due 30 days before the application deadline, so they will be due on June 8, 2021.

*Is there a Small Business Innovation Research (SBIR) equivalent of this funding opportunity?*

**No-** there is not currently a SBIR equivalent but small businesses are eligible to apply to both the R01 and R21 RFAs. Applicants interested in small business opportunities are encouraged to contact the NHGRI Program Officers.

*Are costs for genetic testing allowable?*

**Yes-** applications can request funds to cover the cost of genetic testing.

*Since NCI is only planning to fund one R01, should applicants interested in cancer genetics submit/resubmit in the July 2021 receipt date?*

If an application is funded by NCI from the October 2020 group of applications, applicants interested in submitting and/or resubmitting a cancer genetics application in July 2021 are encouraged to contact the Program Officers to determine whether the study design and findings could be generalizable, and whether there is another relevant funding opportunity for the application.

*Does early stage investigator (ESI) status apply to these RFAs?*

NIH is always interested in funding early stage investigators, and ESI status would be a consideration when making a funding plan and balancing program priorities.