

Investigator-Initiated Research on Genetic Counseling Processes and Practices

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Logistical Notes

- ▶ **This webinar is being recorded.** We will post the recording at <https://www.genome.gov/> as a resource for potential applicants who are unable to attend
- ▶ All participants are muted
- ▶ Please type your questions into the Q&A box
- ▶ NHGRI staff may enter links or information into the chat box
- ▶ FAQs will be updated following the webinar

Classic Reasons for Genetic Counseling

Family planning



Risk assessment



Understanding phenotype



Health management



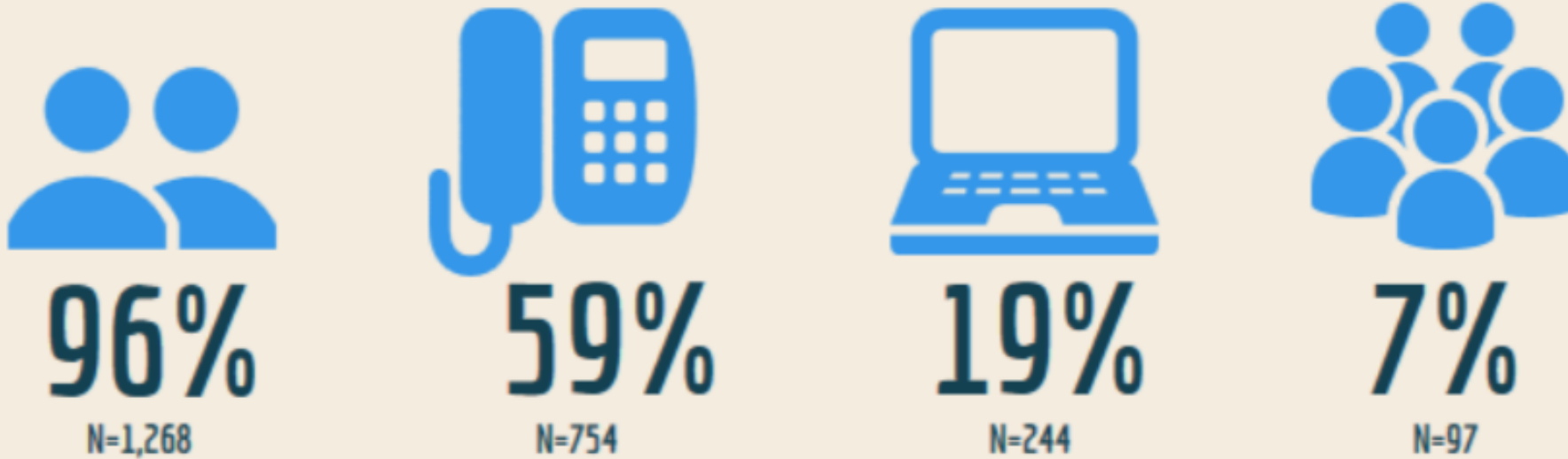
Era of Genomic Counseling

- ▶ Genetic test results have moved from single gene tests to include small risk changes for common diseases and pharmacogenetics
- ▶ American College of Medical Genetics and Genomics (ACMG) recommends that genetics experts be made available for patient test result consultations
- ▶ Only ~4,200 genetic counselors and ~1,300 clinical geneticists currently employed in the US
- ▶ Insufficient to meet current and potential future demand

McGrath, S.P., Walton, N., Williams, M.S. *et al.* Are providers prepared for genomic medicine: interpretation of Direct-to-Consumer genetic testing (DTC-GT) results and genetic self-efficacy by medical professionals. *BMC Health Serv Res* **19**, 844 (2019).

Service Delivery Models Used for Direct Patient Care

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Taken from 2018 NSGC professional status survey

- ▶ **Need more efficient strategies for genetic counseling to provide genomic tests results**
- ▶ **Predicted growth in telemedicine post-COVID**
- ▶ **Continue to provide emotional support as genetic information is translated into healthcare decisions**

RFA: Investigator-Initiated Research on Genetic Counseling Processes and Practices

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Purpose:

- ▶ **Assess, innovate, scale, and/or research the implementation of novel genetic counseling practices for genomic medicine**
- ▶ **Support investigator-initiated research (R01 & R21) on how to optimize the genetic counseling processes including, but not limited to, the communication of genomic results in the context of limited resources**

Research topics on various approaches to genetic counseling in genomic medicine could include:

- ▶ Developing and evaluating processes to triage communication of clinical genomes
- ▶ Assessing alternatives to in-person genetic counseling, including IT solutions
- ▶ Developing and assessing methods to increase capacity for genetic counseling in underserved areas
- ▶ Evaluating and improving strategies to communicate genomic findings and update variant reclassifications
- ▶ Understanding needs of patients and stakeholders and the impact of genetic counseling processes on patient outcomes
- ▶ Evaluating strategies for including genetic counseling processes in clinical and research workflows

Responsive applications would include:



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- ▶ **Research personnel with experience identifying and overcoming challenges in genetic counseling**
- ▶ **Projects broadly applicable to genomic medicine; projects studying a specific disease area would have to yield generalizable findings.**



NCI Areas of Interest (funding up to 1 R01 application)

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- ▶ Interested in applications that address managing germline findings in the context of tumor testing.
- ▶ In addition, NCI is interested in cancer focused applications that consider:
 - ▶ utilization of remote or mobile-ready genetic counseling approaches;
 - ▶ methods to assess the behavioral and psychosocial impact of genetic counseling and testing on the individual and/or family to optimize clinical decision making;
 - ▶ strategies for training and supporting a workforce capable of improving case ascertainment, cascade screening, and follow-up care in healthcare systems

Two Funding Mechanisms

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	R01	R21
Budget Limit	<\$500k direct costs/year	<\$200k direct costs/year, max of \$400K direct for the grant
Project Period	Up to 4 years	Up to 3 years
Preliminary Data Required?	Yes	No

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**



FAQs

Can a genetic counselor consultant fulfill the need to have a person with genetic counseling experience on the team?

No, a person or persons with genetic counseling experience need(s) to be an integral part of the research team including being involved in research design, implementation, and analyses, not just providing advice and guidance.

If submitting to the R21 Funding Opportunity Announcement, can budgets be \$200,000 direct costs in each year for 3 years?

No, budget requests can be up to \$200,000 direct costs in any given year but cannot exceed \$400,000 direct costs for the entire study.

FAQs cont.

What does the RFA requirement that project findings be broadly applicable to genomic medicine as a field and/or yield generalizable findings mean?

It is important that applicants describe how the project findings can be applicable across different genomic medicine disciplines and not only specific to given disease or discipline. Projects proposing to apply a genetic counseling strategy(ies) to a specific disease/discipline should demonstrate how the strategy(ies) and/or finding(s) is broadly applicable to genomic medicine.

FAQs cont.

How many applications do you intend to fund?

NHGRI anticipates funding 5-7 R01 and R21 awards across two receipt dates (balance will depend on number of fundable applications in each receipt date and available funding) and NCI will fund up to 1 R01 award. NHGRI is interested in applications that are broadly applicable to genomic medicine as a field; projects studying a specific disease or disease area should demonstrate how the strategy(ies) and/or finding(s) is broadly applicable to genomic medicine. NCI is interested in cancer focused applications addressing the interest areas as specified in the RFA. **Applicants are strongly encouraged to contact the listed program officers prior to submission in order to allow feedback on the responsiveness of the proposed research.**

FAQs cont.

Can a master's level genetic counselor serve as the PI for these FOAs?

Yes—any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. Principal investigators should have appropriate experience and training to lead the project. For these FOAs, investigator(s) with substantial experience in genetic counseling including identifying and overcoming challenges in the genetic counseling process should be an integral part of the project.

Additional Resources

- ▶ Frequently Asked Questions (FAQs):
<https://www.genome.gov/research-funding/Funding-Opportunities/research/FAQ-investigator-initiated-research-on-genetic-counseling-processes-and-practices-FOAs>
- ▶ Webinar recording will be posted on <https://www.genome.gov/>

Thank You!

Questions? – Enter into Q&A box

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