

CSER2 Pre-application Informational Webinar

The background of the slide features a light blue and white illustration. It depicts a doctor in a white coat examining a patient's arm. A large DNA double helix is shown in the upper right and lower left corners. A stethoscope is visible in the lower right corner.

National Human Genome Research Institute
National Cancer Institute
National Institute on Minority Health and Health Disparities

June 15, 2016

For today

- <https://www.genome.gov/27565226/>

Frequently Asked Questions for Clinical Sequencing Evidence-Generating Research (CSER2) RFAs

- 🔗 [Questions about the Goals of the RFAs](#)
- 🔗 [Questions about Eligibility and Funding](#)
- 🔗 [Questions about PAR-16-209](#)

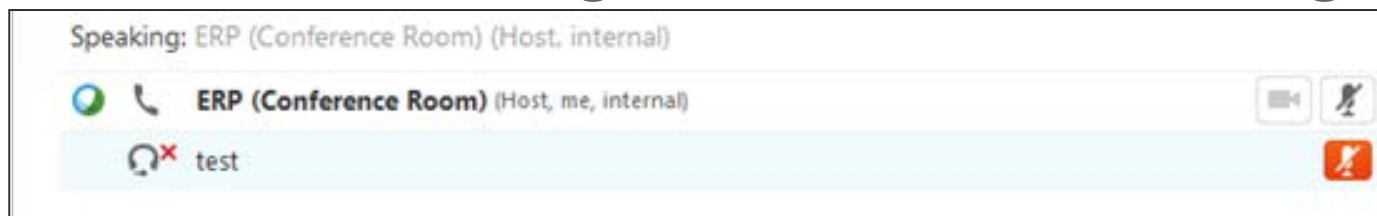
CSER2 Webinar Information

Date: Wednesday, June 15, 2016

Time: 3:00 p.m. - 4:00 p.m. Eastern

The intent of the pre-application webinar is to provide an overview of the CSER2 FOAs and to address questions pertinent to preparing applications. The webinar is optional and not required for application submission.

- WebEx etiquette
 - Please “mute” unless asking a question
 - To “unmute” during the Q/A, click the orange mic



Funding Opportunity Title
Clinical Sequencing Evidence-Generating Research (CSER2) - Clinical Sites (U01)
Activity Code
U01 Research Project – Cooperative Agreements
Announcement Type
Reissue of RFA-HG-12-009
Related Notices
<ul style="list-style-type: none"> June 2, 2016 - Notice Announcing Pre-application Information Webinar for Clinical Sequencing Evidence-generating Research (CSER2) Requests For Applications (RFAs) and Frequently Asked Questions (FAQ) regarding Clinical Sequencing Funding Opportunities. See Notice NOT-HG-16-021. NOT-HG-16-013
Funding Opportunity Announcement (FOA) Number
RFA-HG-16-010

Funding Opportunity Title
Clinical Sequencing Evidence-Generating Research (CSER2) - Clinical Sites with Enhanced Diversity (U01)
Activity Code
U01 Research Project – Cooperative Agreements
Announcement Type
Reissue of RFA-HG-12-009
Related Notices
<ul style="list-style-type: none"> June 2, 2016 - Notice Announcing Pre-application Information Webinar for Clinical Sequencing Evidence-generating Research (CSER2) Requests For Applications (RFAs) and Frequently Asked Questions (FAQ) regarding Clinical Sequencing Funding Opportunities. See Notice NOT-HG-16-021.
Funding Opportunity Announcement (FOA) Number
RFA-HG-16-011

Funding Opportunity Title
Clinical Sequencing Evidence-Generating Research (CSER2) - Coordinating Center (U24)
Activity Code
U24 Resource-Related Research Projects – Cooperative Agreements
Announcement Type
Reissue of RFA-HG-12-008
Related Notices
<ul style="list-style-type: none"> June 2, 2016 - Notice Announcing Pre-application Information Webinar for Clinical Sequencing Evidence-generating Research (CSER2) Requests For Applications (RFAs) and Frequently Asked Questions (FAQ) regarding Clinical Sequencing Funding Opportunities. See Notice NOT-HG-16-021.
Funding Opportunity Announcement (FOA) Number
RFA-HG-16-012

- <http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-16-010.html>
- <http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-16-011.html>
- <http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-16-012.html>

Requests For Application (RFA)

- RFAs serve multiple goals
 - Instructions to applicants
 - Information for reviewers
 - Expectations for funded grantees
 - NIH strategic vision
 - CSER history
- Distinction between responsiveness to the RFA and scientific merit





- Each CSER2 site
 - Part of a whole
 - Unique strengths, approaches
- CSER2 consortium
 - Critical mass of investigators, stakeholders
 - More than the sum of its parts

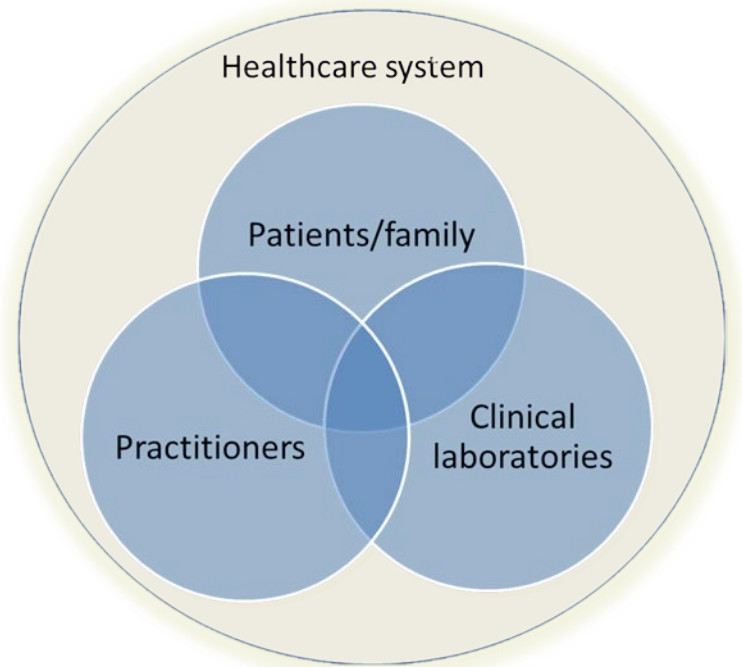
Clinical utility

- Does genomic intervention lead to an improved health outcome (PMID 25764213)?
- Define, generate and analyze evidence regarding the clinical utility of genome sequencing
- Site-specific + consensus measures
- Each site: $\geq 1,100$ participants
- Comparison of sequencing to alternate modalities



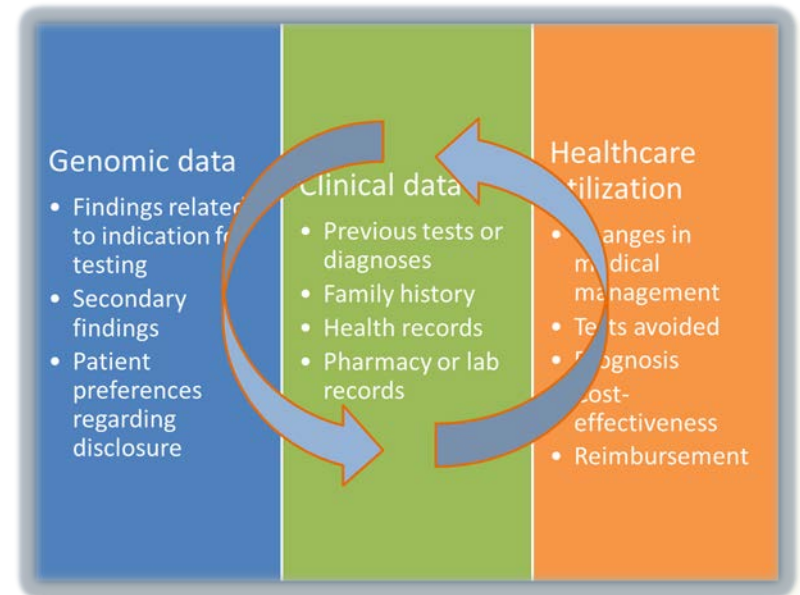
Research at intersections

- Critical interactions that influence implementation of clinical genome sequencing
- How proposed research might generalize to other sites/settings
- Going beyond 2-way interactions
- Relevance to diversity goals/health disparities



Data integration

- Real-world barriers to integrating genomic, clinical, and healthcare utilization data within a healthcare system for clinical decision-making
- Pilot the meaningful integration of data sources within a healthcare system
- Encourage interoperability of processes, standards, best practices, and data across sites and with external healthcare systems as feasible



ELSI




- Must address some ELSI research question(s)
- Research opportunities in all three Aims
- However, flexibility
- CSER1 Structure is possible but not required
- Go beyond consent, return of results and psychosocial outcomes
- Particular interest: ensuring utility of genomics in
 - Diverse populations
 - Healthcare settings beyond academic medicine
 - Ways that address, not exacerbate, health disparities


Stakeholder input





- Professional societies, payers, regulatory agencies, patient groups
- Site-specific stakeholder engagement plan and potential contributions to CSER2-wide engagement
- Value throughout the research process, from study design to implementation of findings



For updates: check
<https://www.genome.gov/27565226/>

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Frequently Asked Questions for Clinical Sequencing Evidence-Generating Research (CSER2) RFAs

- [❶ Questions about the Goals of the RFAs](#)
- [❷ Questions about Application Format](#)
- [❸ Questions about Eligibility and Funding](#)
- [❹ Questions about PAR-16-209 \(Investigator-Initiated Clinical Sequencing Research \(R01\)\)](#)

CSER2 Webinar Information

Date: Wednesday, June 15, 2016
Time: 3:00 p.m. - 4:00 p.m. Eastern

The intent of the pre-application webinar is to provide an overview of the CSER2 FOAs and to address questions pertinent to preparing applications. The webinar is optional and not required for application submission.

Prospective applicants are encouraged to submit their questions or comments regarding the RFA to CSER2rfa@mail.nih.gov before Monday, June 13. Afterwards, slides of the Webinar will be posted on the same website.

Prospective applicants with inquiries concerning the FOAs who are unable to participate in the Webinar are encouraged to view the summary of questions and answers after the webinar. For any additional questions, contact the Scientific/Research contacts listed in [RFA-HG-16-010](#), [RFA-HG-16-011](#), and [RFA-HG-16-012](#).

[Join WebEx meeting](#)
Meeting number: 627-735-927
Meeting password: CSER2

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