Strategic Plan 2020 Implementation: NICHD's Vision for Multisite Clinical Trials Infrastructure
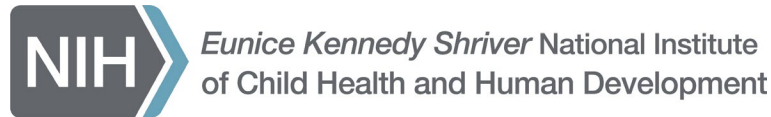
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NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Outline

- Immediate assurances
- Overview of NICHD Strategic Plan 2020
- Four guiding principles driving change
- Examples of multisite clinical trial infrastructure models
- Questions

Immediate Assurances

NICHD is committed to providing critical infrastructure support for multisite clinical trials that involve populations of key relevance to our research mission.

NICHD Currently Supports:

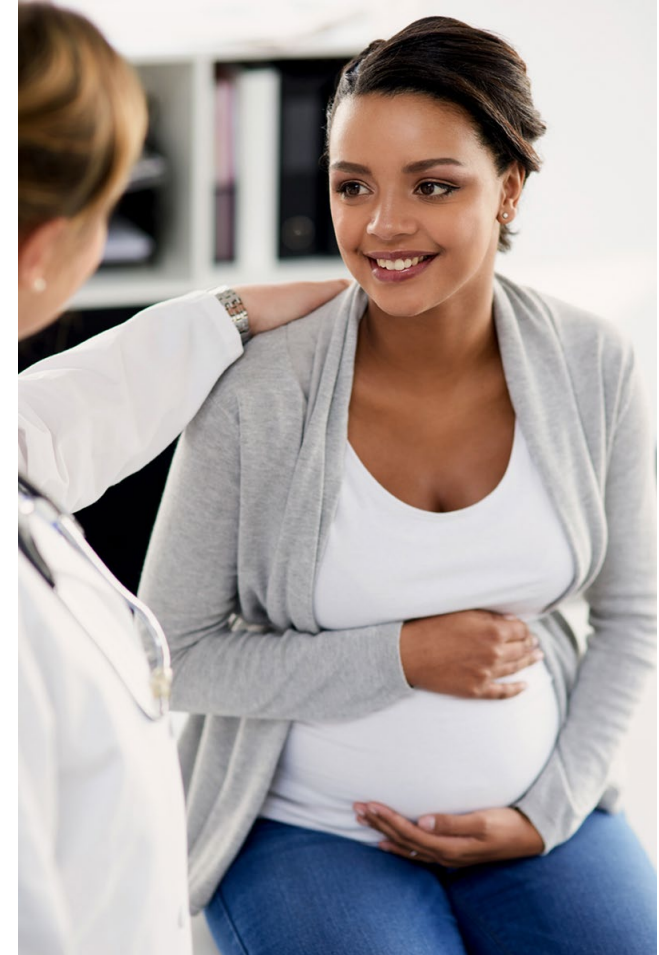| Extramural	Intramural	Division of Intramural Population Health Research
NICHD Networks	NIH Clinical Center NICHD Perinatology Research Branch	Contraceptive Clinical Trials Network

NICHD is committed to completing currently active protocols in existing NICHD-funded networks.

Currently active protocols in existing NICHD-funded networks will receive support **until their completion**.

- Networks will be able to finish protocols in the way they were designed.

- Completion of existing protocols may happen in parallel with the initiation of new approaches to supporting multisite clinical trial infrastructure.

Overview of NICHD Strategic Plan 2020

NICHD Strategic Plan 2020: Scientific Research Themes

1. Understanding the Molecular, Cellular, and Structural Basis of Development

⭐ 2. Promoting Gynecologic, Andrologic, and Reproductive Health

⭐ 3. Setting the Foundation for Healthy Pregnancies and Lifelong Wellness

⭐ 4. Improving Child and Adolescent Health and the Transition to Adulthood

⭐ 5. Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities

NICHD Strategic Plan 2020:
Ten Aspirational Goals identified, including:

⭐ Involves clinical trials

⭐ • Enhancing survival and healthy development of **preterm infants**

⭐ • Catalyzing research on **immune factors in pregnancy** to understand pregnancy loss and mechanisms for other complications

⭐ • Accelerating efforts to diagnose, prevent, and treat **endometriosis**

• And more…

21st Century Cures Act

SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN

Section 402(m) of the PHS Act: Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

NICHD Strategic Plan 2020: Scientific Stewardship

- Facilitating **transparency and communication**

- Improving clinical trial **oversight and management**

- Facilitating **data sharing** and access to **biospecimens**

- Promoting an **inclusive** scientific workforce that fosters research training

- Setting research **priorities**

- **Monitoring and evaluating** programs

- **Partnering** and **aligning resources** to enhance science

NICHD Strategic Plan 2020: Management and Accountability

- Ensuring **infrastructure** innovation

- Improving administrative **efficiency**

- Minimizing **risk** through proper management

- Promoting **workforce** development and balance

Four Guiding Principles Driving Change

Four Guiding Principles Shaping the 21st Century Landscape of NIH-Supported Research

From NOT-HD-19-034 (October 10, 2019)
https://grants.nih.gov/grants/guide/notice-files/NOT-HD-19-034.html

1. Enhancing **rigor and reproducibility**

2. Promoting greater **availability of infrastructure**

3. Facilitating **data sharing** and access to **biospecimens**

4. Facilitating greater involvement of **diverse populations** in multisite clinical trials

Guiding Principle 1: Enhancing the rigor and reproducibility of clinical trial protocols

- All multisite clinical trial protocols will be submitted through the **NIH peer-review process**, promoting fairness and objectivity.

- Scientific stewardship: improving clinical trial **oversight and management**, according to new NIH-wide policies.

- Minimizing NICHD staff exposure to real or perceived **conflicts of interest**.

Guiding Principle 2: Promoting greater availability of multisite clinical trial infrastructure to support trials from a wider range of investigators

- Benefits the science by introducing **new ideas and perspectives**

- Facilitates **open access and fair competition**: All qualified investigators will have the opportunity to participate in the conduct of NICHD-funded clinical trials

- Supports **innovation** and stimulates the field, growing areas of interest to NICHD

- **Expands opportunities** for investigators at different career stages

Guiding Principle 3: Facilitating data sharing and access to biospecimens

- **Maximizes NICHD's infrastructure investments** by promoting reuse of scientific data

- Incorporates **FAIR data principles**, an NIH standard for data management and stewardship

  - **F**indability

  - **A**ccessibility

  - **I**nteroperability

  - **R**eusability

- Enhances data **harmonization**, use of common data elements

- Capitalizes on **artificial intelligence** and other enhanced analytic techniques

Guiding Principle 4: Facilitating greater involvement of diverse populations in multisite clinical trials

- Addresses health disparities, which are significant concerns for NICHD's research populations

- Helps NICHD researchers to include racially and geographically diverse populations

Adhering to these principles ensures proper stewardship of public funds, increases accountability, and helps NICHD maintain the public's trust.

Examples of Multisite Clinical Trial Infrastructure Models

There is no "one size fits all" approach.

- Clinical trials infrastructure can be supported in several ways

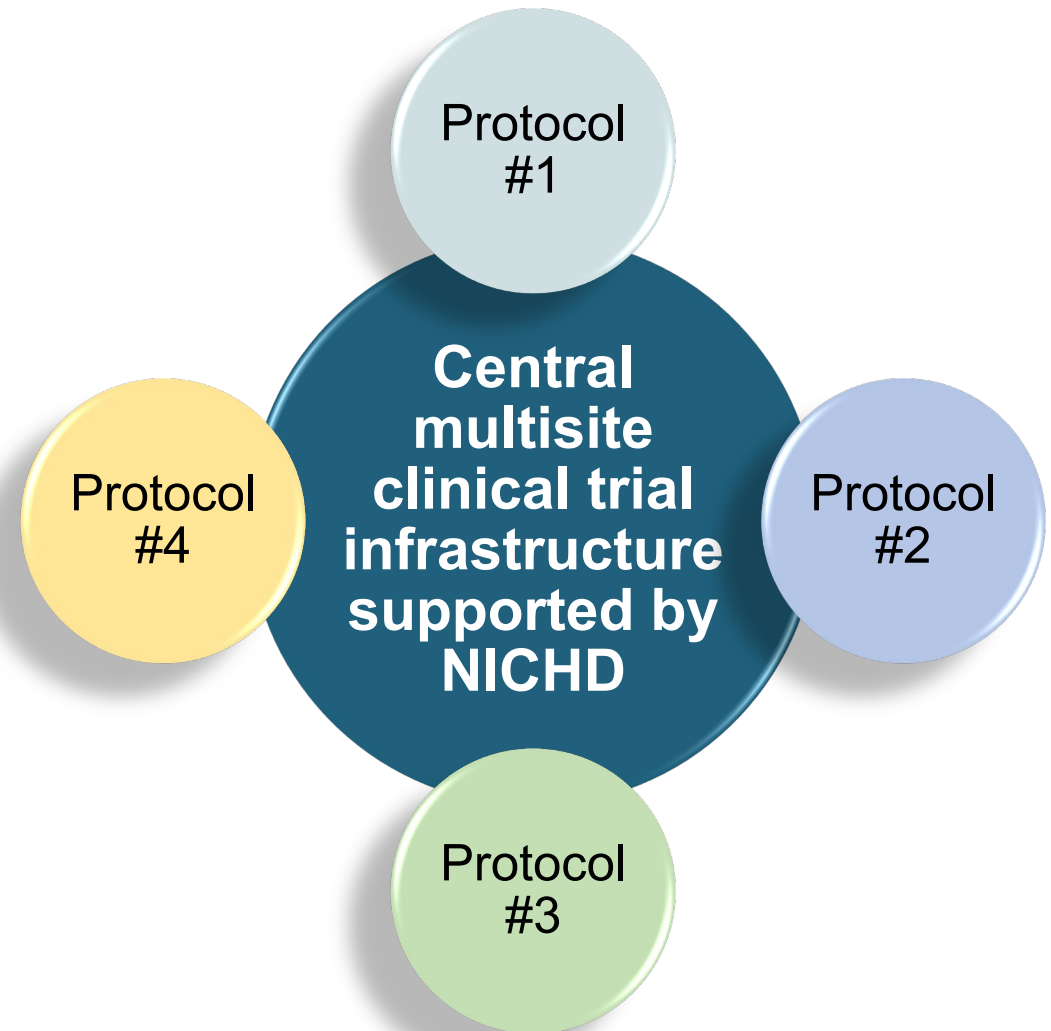# Example 1: NICHD supports infrastructure as a central resource

Central multisite clinical trial infrastructure supported by NICHD

- NICHD solicits applications for **clinical trial infrastructure**.

- Applications undergo **NIH peer review** to evaluate the scientific merits of the infrastructure.

- NICHD **selects and supports** these resources.

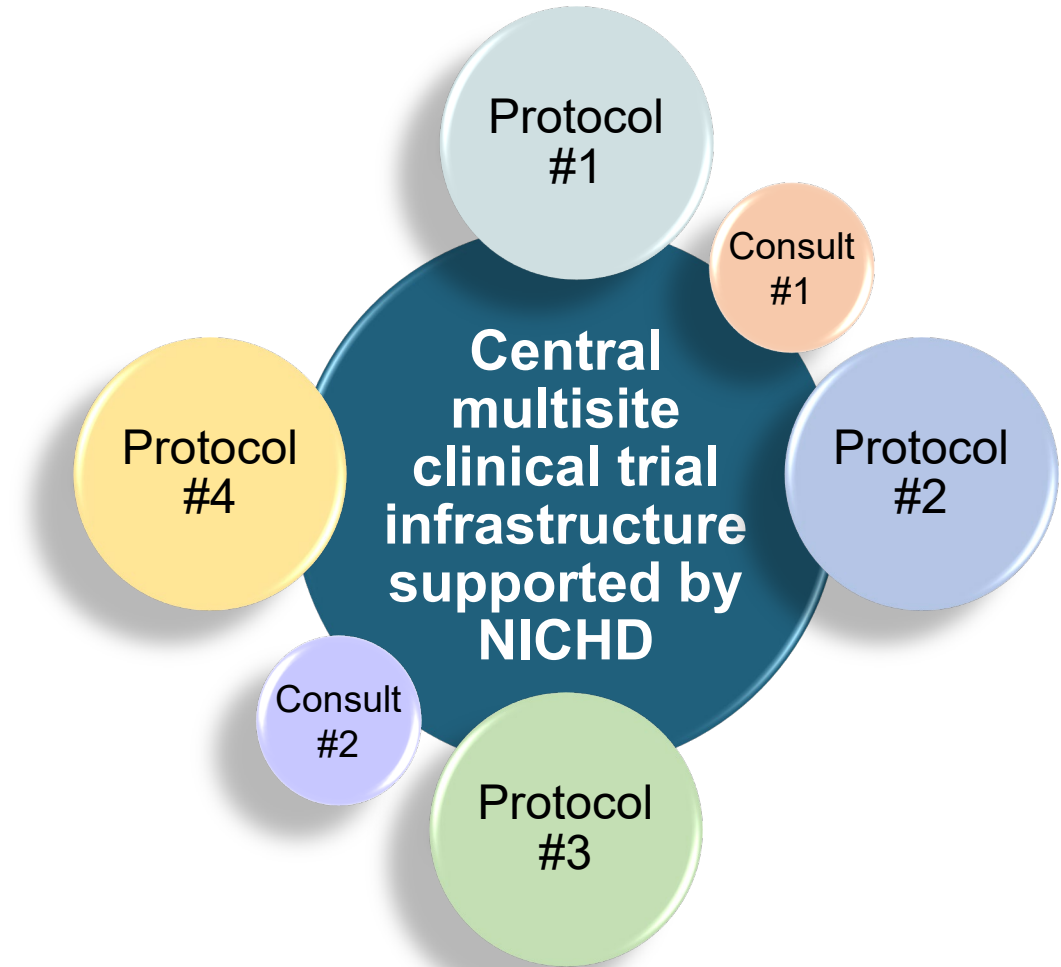- Infrastructure is **made available** to the entire research community.

Example 1: NICHD supports infrastructure as a central resource (cont.)

- **Open competition:** Any qualified investigator(s) can apply to use the infrastructure for a clinical trial protocol.

- All applications/protocols undergo **NIH peer review**.

- Over time, NICHD supports multiple trials conducted by multiple groups sharing the central infrastructure.
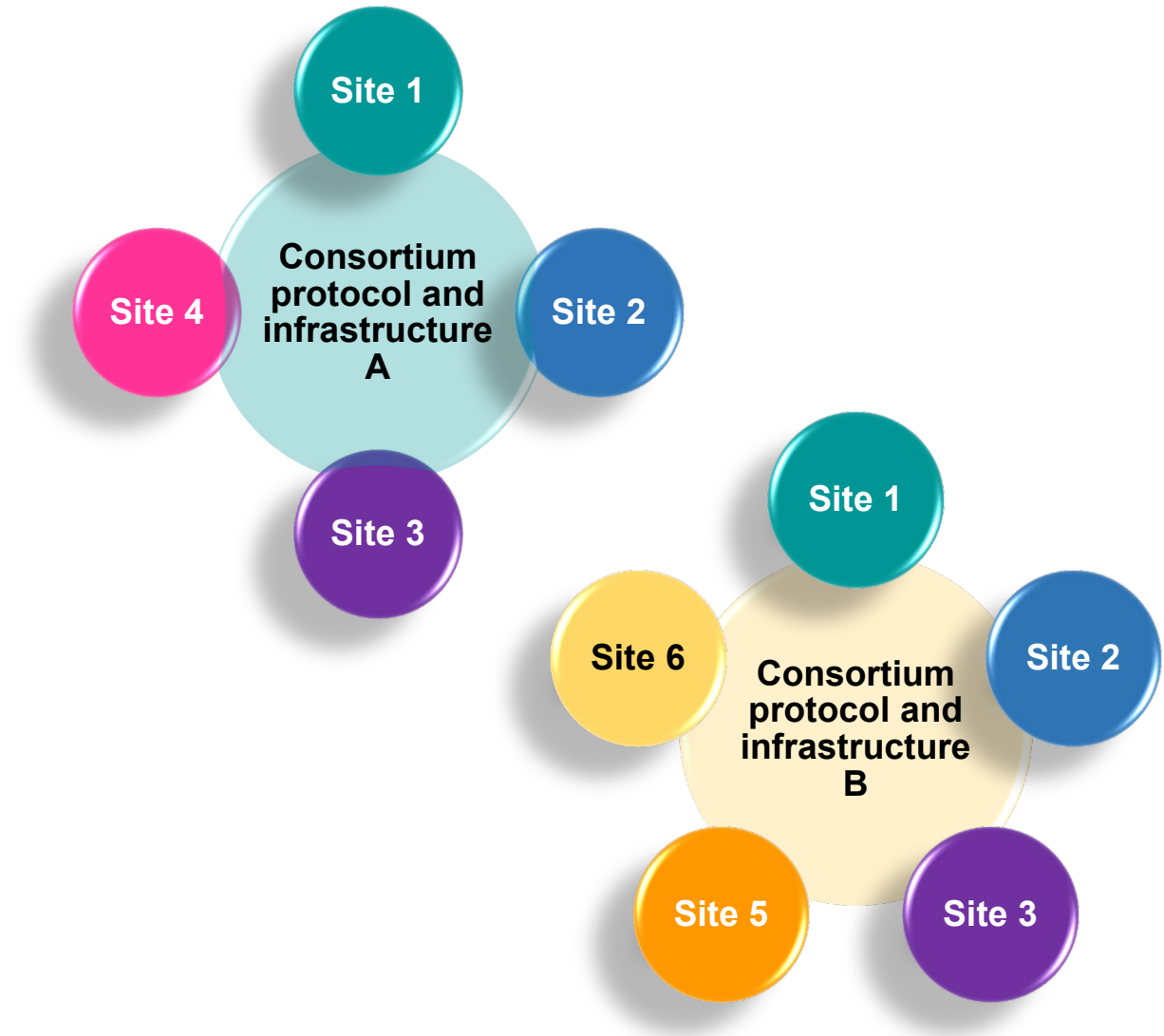
Protocol #1

Protocol #2

Protocol #3

Protocol #4

Central multisite clinical trial infrastructure supported by NICHD

Example 1: NICHD supports infrastructure as a central resource – for the broader scientific community

- The "Consultation Feature"

- Any qualified investigator(s) can apply to **consult the experts** who are part of the infrastructure.

- Allows NICHD to **open the infrastructure** to improve clinical trial design and implementation anywhere.

Protocol #1

Consult #1

Protocol #2

Protocol #4

Central multisite clinical trial infrastructure supported by NICHD

Consult #2

Protocol #3

Example 2: Consortia Model

- **Open competition:** Investigators **self-select** to form a clinical trial **consortium** that includes clinical sites and data center capabilities.

- Application from the consortium undergoes **NIH peer review** of both the infrastructure and protocol.

- NICHD makes decisions based on available funding and supports consortia for protocol implementation.

- This allows for **flexibility** across investigator teams, sites, and protocols.

In Summary

- NICHD is committed to providing critical infrastructure support for multisite clinical trials that involve populations of key relevance to our research mission.

- NICHD is committed to completing all currently active protocols as they were designed.

- NICHD is committed to implementing the four guiding principles, as described.

- There is no "one size fits all" approach to supporting multisite clinical trial infrastructure.

Request for Information (RFI)

- An RFI will soon be published in the NIH Guide to solicit your input on NICHD's vision for supporting multisite clinical trial infrastructure.

- All stakeholders are invited to respond.

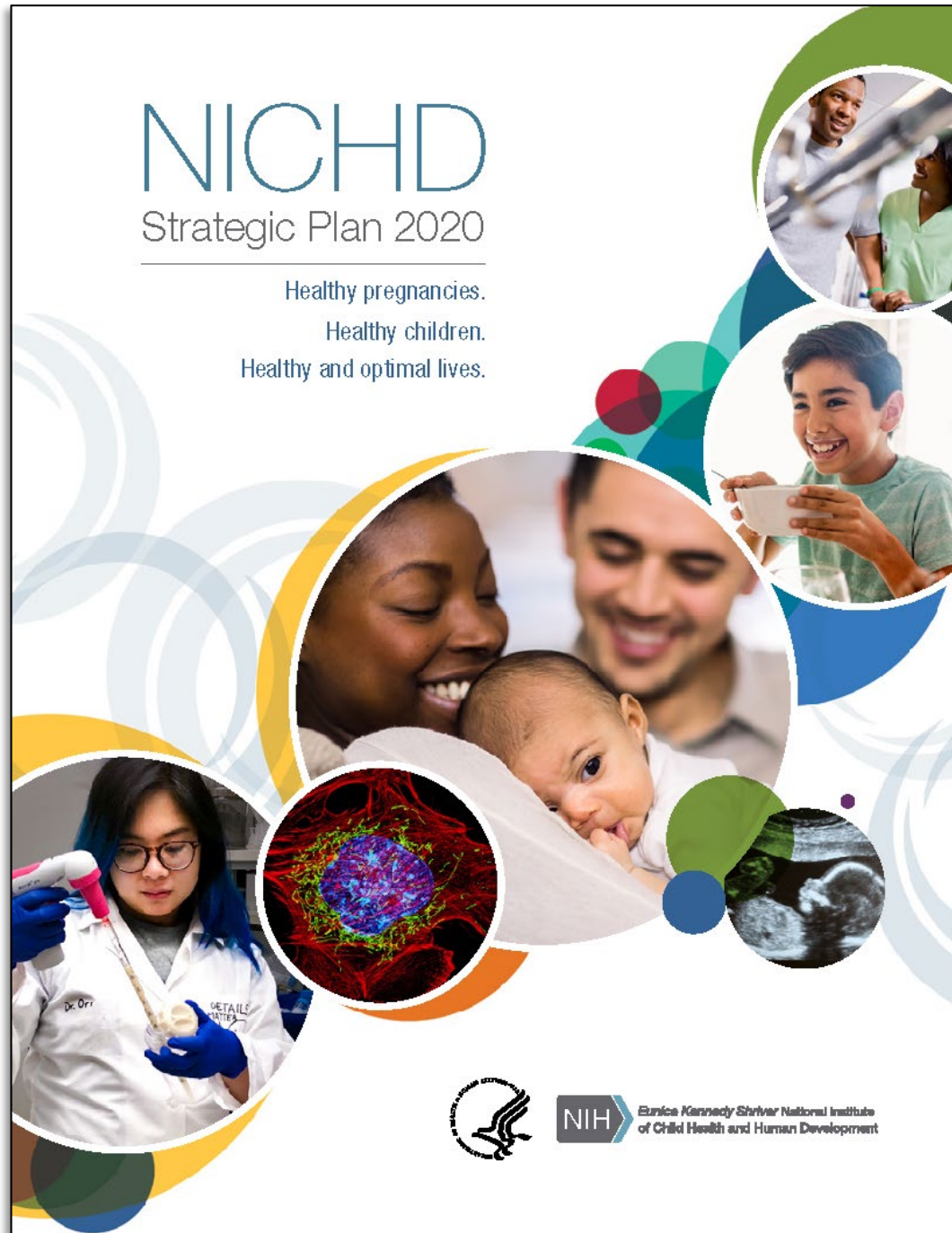- Information about the RFI and how to submit responses will be posted on the NICHD website.
  https://www.nichd.nih.gov/about/meetings/2019/110119

Questions?