Women First Research Coalition

October 26, 2026

Lyric Jorgenson, PhD
NIH Associate Director for Science Policy
Office of Science Policy (OSP)
National Institutes of Health
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

RE: Request for Information: Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants (NOT-OD-26-113)

Dear Dr. Jorgenson,

The Women First Research Coalition (WFRC) appreciates the opportunity to provide input on the request for information on the draft NIH policy for sharing summary level study results with clinical research participants.

WFRC is a coalition comprised of the nation's leading professional medical and research organizations specializing in women's health. Our coalition was formed to address pressing challenges in women's health research and to raise awareness among federal policymakers, Executive Branch officials, and the public about the need for sustained and strengthened investment in women's health research.

WFRC supports the spirit of the proposal and recognizes the importance of sharing high-level findings from clinical trials and other types of clinical research, including trials with negative results, with participants and the public. However, we have concerns about the proposed policy's broad scope, reporting timelines, and administrative burden, particularly for women's health research. While WFRC supports greater transparency and establishing trust with research participants, NIH must ensure that these requirements do not impose undue burdens on investigators.

- **Reporting Timelines:** WFRC is concerned that the proposed one-year timeline may not be feasible, as analysis is often still ongoing at that point. In many circumstances, clinical trials are delayed or need to be extended and preparing a summary that is useful and meaningful to participants may take longer than one year. A two-year timeline would be more realistic, with additional flexibility based on the type of research.
- **Scope**: The proposed scope is also very broad, including epidemiological, behavioral outcomes, and health services research. Qualitative data may take longer to analyze and synthesize and can be difficult to de-identify. Returning results may also be impractical, in large epidemiological studies that involve thousands of participants without specific identifying information or contact information. In addition, participants' desires and concerns about receiving results can change over time. Therefore, NIH should account for these differences when determining appropriate reporting requirements.

SUPPORTING ORGANIZATIONS
AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS • AMERICAN GYNECOLOGICAL & OBSTETRICAL SOCIETY• AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE • AMERICAN UROGYNECOLOGIC SOCIETY• COUNCIL OF CHAIRS OF OBSTETRICS AND GYNECOLOGY • INFECTIOUS DISEASE SOCIETY FOR OBSTETRICS & GYNECOLOGY • NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH • NORTH AMERICAN SOCIETY FOR PEDIATRIC AND ADOLESCENT GYNECOLOGY • SOCIETY FOR ACADEMIC SPECIALISTS IN GENERAL OBSTETRICS AND GYNECOLOGY • SOCIETY OF FAMILY PLANNING • SOCIETY OF GYNECOLOGIC ONCOLOGY • SOCIETY OF GYNECOLOGIC SURGEONS • SOCIETY FOR MATERNAL-FETAL MEDICINE • SOCIETY FOR REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY • SOCIETY FOR REPRODUCTIVE INVESTIGATION • SOCIETY FOR WOMEN'S HEALTH RESEARCH

- **Administrative Burden and Resource Needs:** Developing even a high-level summary takes time and dedicated staff and resources that most grants do not support as separate, allowable costs. Clinical trial staff typically wind down after enrollment ends, while investigators are working to close out studies, analyze and synthesize data, and write manuscripts. Without additional funding, these reporting requirements would place further burdens on investigators. WFRC believes these summaries deserve the time and attention needed to reflect why the study was conducted and thoughtfully contextualize the findings for participants and the public. NIH should provide separate, dedicated dissemination funding within research grants to support this work. To reduce unnecessary paperwork burden and ensure sharing of results that are meaningful to participants, NIH also should establish minimum standards for participant-facing summaries that are flexible across research types and study populations.
- **Exceptions and Implementation Flexibility:** WFRC supports exceptions for circumstances involving participant safety, privacy concerns, small sample sizes, inconclusive findings, or risks of re-identification, particularly in small studies where protecting participant identities may be challenging. However, requiring investigators to request an exception before enrolling the first participant may not be practical, as there may be factors that investigators learn only after a study begins.
- **Interpretation and Communication of Findings:** WFRC also emphasizes the importance of how participants and the public may interpret study findings. In the supplemental guidance that NIH will develop, we encourage inclusion of lay-friendly guidance on how to apply and generalize results in a real-world context. For example, evidence from an observational study carries different implications than evidence from a randomized controlled trial. Participants who are not familiar with the principles of evidence-based medicine may draw conclusions that are not fully accurate, particularly when interpreting the significance of a single study within the broader body of evidence, including studies that may support or refute the findings. This is especially important in reproductive health and other areas of women's health research, where study findings can be misinterpreted or taken out of context. Additional resources are therefore needed to help investigators provide both the findings and the context in which to interpret them.

In conclusion, WFRC encourages NIH to adopt a practical and flexible approach that recognizes many different types of clinical research. Specifically, NIH should consider extending the reporting timeline to two years, clarify or narrow the scope of covered research to exclude studies for which returning results may be impractical or infeasible, streamline the exception process, establish flexible minimum standards for summaries, and provide additional, dedicated funding to support dissemination. We believe these steps would help ensure that results are shared in ways that are meaningful to participants and the public without placing undue burdens on investigators or diverting limited resources from advancing women's health research.

Thank you for your consideration. If you have any questions or need additional information, please contact Erika Miller at emiller@dc-crd.com.

Sincerely,

Brett Einerson, MD, MPH, FACOG
Chair, Women First Research Coalition

Marcelle I. Cedars, MD
Chair-Elect, Women First Research Coalition

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Immediate Past Chair, Women First Research Coalition