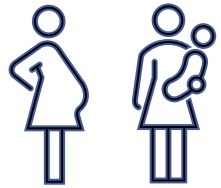
# PRGLAC Implementation Working Group of NACCHD

Meeting Two

January 19, 2024

# PRGLAC Recommendations - Pregnancy

1. Integrate pregnant women and lactating women in the clinical research agenda
2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women
3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics
4. Remove regulatory barriers to research in pregnant women
5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women
6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant and lactating women
7. Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women



8. Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model
9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women
10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research
11. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women
12. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women
13. Optimize registries for pregnancy and lactation
14. The HHS Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019 (extended to March 13, 2021)
15. Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research

# PRGLAC Recommendations - Lactation

1. Integrate pregnant women and lactating women in the clinical research agenda
2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women
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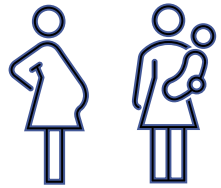

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# Congressional Language

***Report Language from Consolidated Appropriations Act of 2023 (P.L. 117-328).***

**The Committee includes $200,000 for the creation of an Advisory Committee to monitor and report on the implementation of the recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC).** PRGLAC's 2020 Implementation Plan called for the creation of an Advisory Committee to monitor and report on implementing recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical trials. Additionally, the Committee directs the Secretary to submit a report to Congress within 180 days of the date of enactment of this Act outlining the Department's progress on implementing each of PRGLAC's 15 recommendations from the Implementation Plan it submitted to the Secretary in August 2020 (H. Report: 117-403).

# The Working Group of Council and Objectives

- Recommended in the Implementation Plan (Recommendation #15)
- **The Working Group will:**
- Review publicly available materials pertaining to implementation progress
- Invite speakers from relevant Federal agencies or non-federal entities to discuss progress to-date on PRGLAC implementation plan, including possible barriers
- Report their findings to NICHD Council and submit the report to Congress
  - Implementation progress
  - Provide recommendations to facilitate implementation, where necessary
  - Advise reconsideration, as relevant

# Review of Implementation Progress by Cluster

**Cluster A: Conduct clinical research and trials**

**Cluster B: Education, outreach, training, and career development**

**Cluster C: Policy, regulatory, and liability**

**Cluster D: Registries and real-world data**

**Cluster E: Novel drug discovery and development**

# Today's Clusters – Session I

✓ **Cluster A: Conduct clinical research and trials**

**Cluster B: Education, outreach, training, and career development**

**Cluster C: Policy, regulatory, and liability**

**Cluster D: Registries and real-world data**

✓ **Cluster E: Novel drug discovery and development**

# Today's Focus – Session I

1. Integrate pregnant women and lactating women in the clinical research agenda

**2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women**

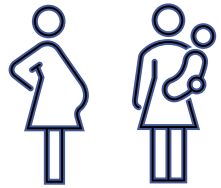
3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics

4. Remove regulatory barriers to research in pregnant women

5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women

6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant and lactating women

7. Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women



**8. Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model**

**9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women**

10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research

**11. Leverage established and support new infrastructures/ collaborations to perform research in pregnant women and lactating women**

12. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women

13. Optimize registries for pregnancy and lactation

14. The HHS Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019 (extended to March 13, 2021)

15. Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research

# Today's Clusters – Session II

Cluster A: Conduct clinical research and trials

Cluster B: Education, outreach, training, and career development

✓ Cluster C: Policy, regulatory, and liability

Cluster D: Registries and real-world data

Cluster E: Novel drug discovery and development

# Today's Focus – Session II

**1. Integrate pregnant women and lactating women in the clinical research agenda**

2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women

3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics

**4. Remove regulatory barriers to research in pregnant women**

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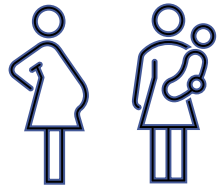

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# Session I

# Recommendation 2: Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women

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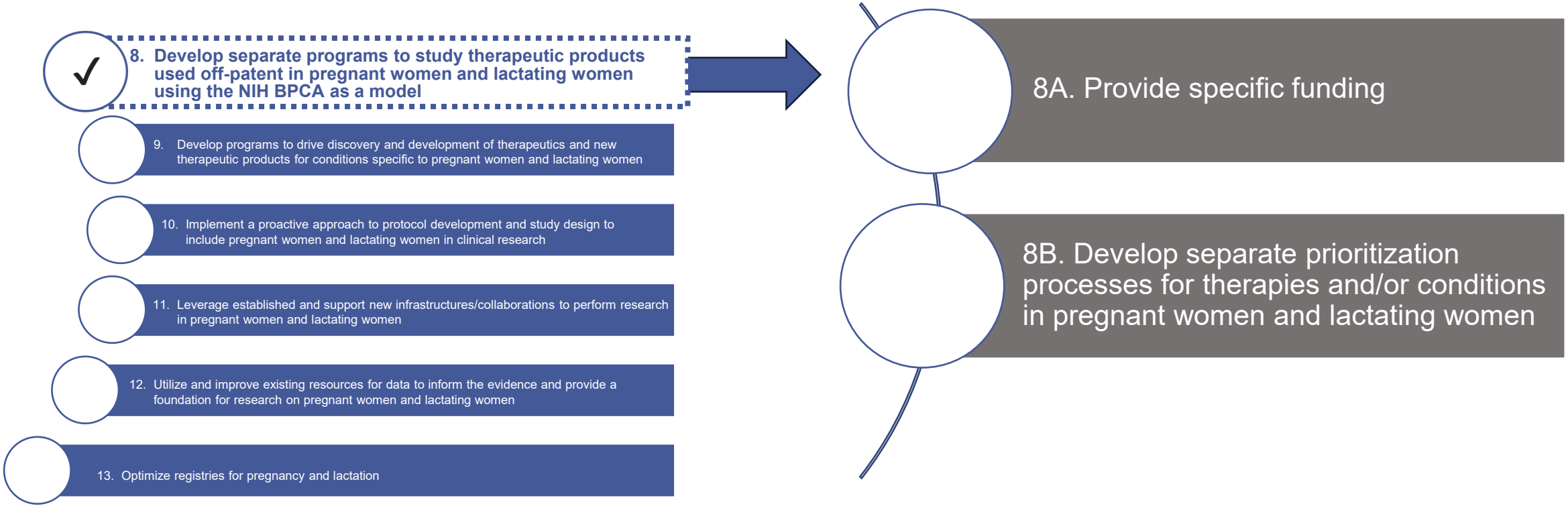
2A. Provide additional resources and funding for research to obtain clinically meaningful and relevant data for specific and co-existing conditions in pregnant women and lactating women

2B. Utilize longer award periods by government funders (beyond the typical 5-year award), when needed, for study design and data collection

# Recommendation 8: Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model




NOTE: Recommendation 8 will not be discussed today as there has not been sufficient work towards its implementation. It is the perspective of the Chairs that additional resources or congressional action is required to action Recommendation 8.

# Recommendation 9: Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women

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13. Optimize registries for pregnancy and lactation

9A. Create separate prioritization processes for pregnant women and lactating women

9B. Consider a Biomedical Advanced Research and Development Authority (BARDA)-like model & the NIH vaccine model that takes clinical development up to phase III

NOTE: Recommendation 9B will not be discussed today as there has not been sufficient work towards its implementation. It is the perspective of the Chairs that additional resources or congressional action is required to action Recommendation 9B.

# Recommendation 11: Leverage established and support new infrastructures/collaborations to perform research in pregnant and lactating women

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11A. Provide financial support and incentives to establish & develop new multicenter infrastructures that capitalize on standard of care procedures (opportunistic studies), innovative designs, and methodologies

11B. Broaden focus of ongoing research networks to include research on therapeutic products in pregnant women and lactating women

11C. Encourage networks/collaborations to engage in public-private partnerships to facilitate research

NOTE: Recommendation 11A will not be discussed today as there has not been sufficient work towards its implementation. It is the perspective of the Chairs that additional resources or congressional action is required to action Recommendation 11A.

# Session II

# Recommendation 1: Include and integrate pregnant women and lactating women in the clinical research agenda

**1.Integrate pregnant women and lactating women in the clinical research agenda**

2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women

3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics

4. Remove regulatory barriers to research in pregnant women

5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women

6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant and lactating women

7. Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women

1A. Remove pregnant women as an example of a vulnerable population in the Common Rule

1B. The Food and Drug Administration (FDA) should harmonize with the Common Rule and remove pregnant women as a vulnerable population

1C. The Department of Health and Human Services (HHS) should develop guidance to facilitate the conduct of research in pregnant women and lactating women

NOTE: Recommendations 1A and C are pending OHRP written update.

# Recommendation 4: Remove regulatory barriers to research in pregnant women

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4A. Modify subpart B of the Common Rule

- maternal consent alone
- Add in the option of “Minor increase over minimal risk”

NOTE: Pending OHRP written update.

# Recommendation 7: Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women

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7. **Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women**

7A. Implement a liability-mitigation strategy for conducting research and evaluating new therapeutic products in pregnant women and lactating women

7B. Consider implementing a targeted incentive program and/or strengthening FDA authority to require clinically relevant data on pregnant/ lactating women to inform dosing and safety

NOTE: Recommendation 7 will not be discussed today as there has not been sufficient work towards its implementation. It is the perspective of the Chairs that additional resources or congressional action is required to action Recommendation 7.

# Recommendation 10: Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research

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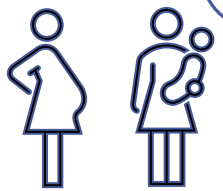

- 10A. Investigators/sponsors must specifically justify exclusion in study design
- 10B. Ensure studies are designed to capture the time dependency of physiologic changes in pregnancy and lactation
- 10C. Develop a systematic plan on how data for pregnant/lactating women will be obtained in a timely fashion
- 10D. Develop guidance for institutional review boards and investigators
- 10E. Develop a systematic plan for if a woman becomes pregnant in a study