DAY 1: APRIL 19

Session 1: Opening Session

Objectives
1. Introduce the workshop topic and rationale.
2. Understand how research advances with induced pluripotent stem cells (iPSCs) are driving innovation in reproductive medicine.
3. Highlight perspectives on the potential impact of IVG on different communities and affected stakeholders.

9:15am  Welcome and Introduction  
Eli Y. Adashi (Brown University) Workshop Chair (virtual)

9:30am  Current State of the Science for Early Human Stem Cell Transitions  
Ali Brivanlou (Rockefeller University) (virtual)

9:50am  Discussion

10:00am  Needs and Concerns in Human Biology and Reproductive Medicine

Session Introduction  
Susan Crockin (O’Neill Institute, Georgetown Law) Moderator

10:05am  Potential Impacts for Stakeholders and Society  
Joel Michael Reynolds (Georgetown University)  
Andrea Braverman (Thomas Jefferson University) (virtual)  
Katherine Kraschel (Yale Law School)

10:30am  Discussion

10:50am  Break
Session 2: State of the Science

Objectives
1. Provide a high-level overview of human germ cell development.
2. Present the current state of science for IVG, including research achievements with other mammalian species and roadblocks for achieving in vitro derivation of human gametes.
3. Highlight near-term prospects for overcoming remaining scientific and technical barriers.

Session 2a: Context and Background

11:10am Session Introduction
Amander Clark (University of California, Los Angeles) and Kotaro Sasaki (University of Pennsylvania) Moderators

11:15am Human Germ Cell Development
Azim Surani (Cambridge University and The Gurdon Institute) (virtual)

11:30am Discussion

Session 2b: The Oogenesis Pathway

11:40am Stem Cell-Derived Ovarian Germ Cells: The Rodent Paradigm
Katsuhiko Hayashi (Kyushu University, Japan)

11:55am Stem Cell-Derived Ovarian Germ Cells: The Primate and Human Paradigm
Mitinori Saitou (Kyoto University, Japan) (virtual)

12:10pm The Importance of Meiosis
Paula Cohen (Cornell University)

12:25pm Discussion

12:50pm Lunch (will be provided)
Session 2c: The Spermatogenesis Pathway

1:50pm    Stem Cell-Derived Testicular Germ Cells: The Primate and Human Paradigm
           Kotaro Sasaki (University of Pennsylvania) Moderator

2:05pm    Spermatogonial Stem Cell Transplantation
           Kyle Orwig (University of Pittsburgh Medical Center)

2:20pm    The Importance of Epigenetic Resetting in Germ Cells
           Petra Hajkova (Imperial College, London)

2:35pm    Germline Mutation and Variation: Considerations for IVG
           Anne Goriely (Oxford University)

2:50pm    Discussion

3:15pm    Break

Session 3: Implications of IVG if it were in Clinical Practice

Objectives
1. Explore how IVG technology could potentially impact fertility care.
2. Examine how IVG technology could intersect with currently available methods of assisted reproductive technology.
3. Highlight how IVG’s potential path to clinical practice may differ between countries due to political, cultural, & religious contexts.

3:35pm    Session Introduction
           Hugh Taylor (Yale University) Moderator

3:40pm    Clinical Considerations
           Gamal Serour (Al Azhar University, Egypt) (virtual)
           Paula Amato (Oregon Health and Sciences University)

4:20pm    Discussion

4:50pm    Concluding Remarks from Day 1
           Susan Crockin (O’Neill Institute, Georgetown Law)

5:00–      Reception (National Academies’ Keck Center Atrium, Washington DC)
6:30pm

3 of 8
DAY 2: APRIL 20

9:30am   Welcome and Orientation to Day 2  
**Hugh Taylor** *(Yale University)*

Session 4: Social, Ethical, and Legal Considerations Raised by IVG

**Objectives**
1. Frame key social, ethical, and legal questions that arise when considering IVG as a potential clinical tool.
2. Discuss issues relating to informed consent, governance, egg donation, surrogacy, and the financialization of third-party reproduction.
3. Consider how attitudes about IVG reflect societal values about genetically related progeny, parenting, and family building.

9:40am   Session Introduction  
**Glenn Cohen** *(Harvard Law School)* **Moderator*

9:45am   Opening Perspectives  
**Michele Goodwin** *(University of California, Irvine) (virtual)*  
**Alana Cattapan** *(University of Waterloo, Canada)*  
**Sonia Suter** *(George Washington University)*  
**Hank Greely** *(Stanford University)*

10:20am   Discussion

11:00am   Break

Session 5: Equity, Access, and Cost Considerations Associated with IVG

**Objectives**
1. Explore how socioeconomic and equity considerations impact who would be able to access IVG as a new and disruptive technology.
2. Contemplate how lessons from existing practices in third-party reproduction inform an understanding of how IVG would affect the global fertility industry.
3. Reflect on how funding sources in public vs private health care systems impact patient access to reproductive medicine.
11:20am   **Session Introduction**  
*Ubaka Ogbogu (University of Alberta, Canada) Moderator*

11:25am   **Opening Perspectives**  
*Lisa Ikemoto (University of California, Davis School of Law)*  
*Amrita Pande (University of Cape Town, South Africa)*  
*Lorian Hardcastle (University of Calgary) (virtual)*

11:50am   **Discussion**

12:30pm   **Lunch (will be provided)**

**Session 6: Imagining a Potential Clinical Research Pathway for Human IVG**

**Objectives**
1. Outline the major scientific and ethical elements that would need to be addressed to move from the laboratory to a clinical trial.
2. Present regulatory frameworks that could apply to IVG.
3. Discuss lessons learned from other pluripotent stem cell therapies that have successfully moved into clinical trials.

1:30pm   **Session Introduction**  
*Jeffrey Kahn (Johns Hopkins University), Moderator*

1:35pm   **U.S. Policy and Legal Approaches**  
*Alta Charo (University of Wisconsin–Madison) (virtual)*

1:45pm   **An Industry Perspective on the Potential Path to Clinical Research**  
*Matthew Krisiloff (Conception Bio, Inc)*

1:55pm   **U.S. Regulatory Frameworks for a Translational Pathway from Lab to Clinical Trials for IVG**  
*Peter Marks (U.S. Food and Drug Administration)*

2:15pm   **Discussion**

**Session 7: Breakout Group Discussions**

2:45pm   **Orientation to Breakout Groups**  
*NASEM staff, Moderators*
3:00pm  Break and Move to Groups

3:20pm  Three Parallel Breakout Groups with Discussion Questions

**Keck 100**  BREAKOUT 1: Societal, Ethical, and Legal Implications of IVG
In anticipation of continued research progress, the ramifications of IVG must be proactively considered. The group will discuss the societal, ethical, and legal issues raised by its potential development and use.

**Keck 101**  BREAKOUT 2: Impact of IVG on the Fertility Enterprise
Fertility care has become a major business enterprise worldwide. The breakout group will discuss the potential impacts of IVG on this burgeoning industry should it ever be used clinically.

**Keck 103**  BREAKOUT 3: Translating IVG from Laboratory to Market
Emerging technologies require extensive testing and approvals before clinical use. The breakout group will discuss pathways for IVG from laboratory to any potential clinical use, including validation assays and regulatory considerations.

4:35pm  Break and Reconvene in Keck 100

4:40pm  Concluding Remarks from Day 2
*Ubaka Ogbogu (University of Alberta, Canada)*

4:50pm  Adjourn Day 2

5:00–  Reception
6:30pm  National Academies’ Keck Center Atrium, Washington DC
DAY 3 - APRIL 21

9:30am  Welcome and Orientation to Day 3  
Glenn Cohen (Harvard Law School)

Session 8: Breakout Group Report Outs

9:45am  Group 1 Report Out and Discussion  
Katherine Kraschel (Yale Law School) (virtual)

10:10am  Group 2 Report Out and Discussion  
Amrita Pande (University of Cape Town, South Africa)

10:35am  Group 3 Report Out and Discussion  
Jeffrey Kahn (Johns Hopkins University)

Session 9: Participatory Public Engagement around Reproductive Science Advances

Objectives
1. Examine public attitudes, values, and perceptions around IVG.
2. Discuss how communities with relevant lived experiences shape research agendas and ongoing technology development.
3. Highlight best practices for effective and productive engagement between stakeholders in research, medicine, regulation, and patient advocacy.

11:00am  Session Introduction  
Melissa Simon (Northwestern University) Moderator (virtual)

11:05am  Opening Perspectives  
Erica Marsh (University of Michigan)  
Hannah Landecker (University of California, Los Angeles)  
Tanika Gray Valbrun (The White Dress Project)

11:30am  Discussion

12:10pm  Lunch (will be provided)
Session 10: Concluding Thoughts

1:00pm    Key Messages from the Workshop
          Amander Clark (University of California, Los Angeles)

2:10pm    Next Steps
          NASEM staff

2:30pm    Adjourn Workshop
          Eli Y. Adashi (Brown University) Workshop Chair