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## **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**  
*Mitunori 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)*
- 5:00–6:30pm **Reception** (National Academies' Keck Center Atrium, Washington DC)

## 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–  
6:30pm **Reception**  
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*