



# Happy Halloween!

October 31, 2023



# My Wife is Always the Father



## Subpart B

- Nyssa Towsley, MS, CIP (they/she)
- Michelle Burgett-Moreno, MS (she/her)
- Ronnie Lichtman, CNM, LM, PhD, FACNM (she/her)
- Kevin Nellis, MS, MT(ASCP), CIP (he/him)

## Moderators:

- Heather Miller, PhD, CIP (she/her)
- Satish Veerla, MS, PharmD (he/him)

# Updates and Housekeeping

Please join us if you are at PRIM&R!-

December 5<sup>th</sup>- 11:30 – 1:00

159AB. Get a boxed lunch from the Exhibit Hall (Hall E) before coming to this room.

## HUMAN RESEARCH PROTECTION Clubhouse



Limited to 50 people.



**Please use the Q & A for questions.**

Well do our best to address them!

# Context: Regulatory Requirements

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## Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

- ❖ “this subpart applies to all research involving pregnant women”
  - ❖ “A woman shall be assumed to be pregnant if...”
  - ❖ “Pregnant women or fetuses may be involved in research if...”
  - ❖ “If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father ...except that the father's consent need not be obtained if he is *unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.*”
- This language is dated/archaic and doesn't account for modern family dynamics such as same-sex partnerships and gamete donation/surrogacy.
  - Paternal consent, exceeds expectations for pediatric research (subpart D).

**Let's talk Subpart B!**



**What do YOU think?**

Why are we  
here today?

The catalyst:  
[Nyssa's  
LinkedIn post](#)



## Why did this come up?

- Gendered language at the forefront of my mind
- Revising the initial IRB submission form – addressing the regulations
- The regulations use specific language and don't define it.



## Why does this matter? - Population Size

**Myth:** it's just a small number of people impacted by gendered language, so we don't need to worry about it or prioritize it.

**Truth:** The [prevalence of LGBTQIA+ individuals](#) in the global population is 9%!

The [number of LGBTQIA+ identified folks in the US is increasing over time:](#)



# Why does this matter? - Discrimination

**Myth:** the use of gendered language has minimal impact on LGBTQIA+ individuals.

**Truth:** gendered language can have an immense impact on LGBTQIA+ individuals



Why does this  
matter? -  
**Underrepresentation**

**Myth:** this work  
belongs in clinical  
contexts, not research  
contexts.

**Truth:** LGBTQIA+  
individuals are  
underrepresented in  
research, especially  
clinical research.



# Evaluation of Gender-Neutral Language in IRB Guidance and Consent Templates

Explored gender identities and expression within informed consent templates and IRB guidance.

- Survey sourced from OHRP FWA and IRB Registration database
- 5.5% response rate: 642 validated responses out of 11,748 surveys

## Respondent demographics:

- 80% non-Hispanic white
- Gender: 65% women (42% women, 23% cisgender women), 44% men (31% men, 13% cisgender men)
- <2% non-binary, gender-nonconforming, or genderqueer



# Gender-Neutral Language:

44% support gender-neutral language in consent documents.

33% have it in their IRB consent forms.

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**Reasons for not using gender-neutral language in consent templates (could select multiple answers):**

- 33% Didn't think about making changes
- 29% Not required under the federal regulations
- 29% Haven't gotten to making changes yet
- 26% Low priority
- 25% Lack of resources
- 19% Too political
- 13% Philosophical differences

- 12% The research participants we serve would not understand the language
- 11% The research participants we serve would be discouraged from participating in the studies
- 7% Institutional culture would not be supportive
- 7% Researchers objections
- 5% Too difficult for researchers
- 4% IRB member objections
- 21% Other
- 8% Unknown

# Survey Insights

- 65% agreed that OHRP and FDA guidance are needed
- 65% support 'they' as singular
- 54% favor 'pregnant person'
- 46% for 'pregnant woman or pregnant person', with equal opposition to 'pregnant woman' alone

**Recommendations:**

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Continued dialogue  
and education

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Need clear guidelines  
from FDA and OHRP

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More research is  
needed

# Who is impacted?

STATE OF CALIFORNIA  
CERTIFICATION OF VITAL RECORD

STATE OF CALIFORNIA  
DEPARTMENT OF PUBLIC HEALTH

CERTIFICATE OF LIVE BIRTH  
STATE OF CALIFORNIA  
USE BLACK INK ONLY

STATE FILE NUMBER LOCAL REGISTRATION NUMBER

1A. NAME OF CHILD - FIRST	1B. MIDDLE	1C. LAST		
2. SEX	3A. THIS BIRTH, SINGLE, TWIN, ETC.	3B. IF MULTIPLE, THIS CHILD 1ST, 2ND, ETC.		
4A. DATE OF BIRTH - MMDDCCYY	4B. HOUR - 24 CLOCK TIME			
5A. PLACE OF BIRTH - NAME OF HOSPITAL OR FACILITY		5B. STREET ADDRESS - STREET AND NUMBER, OR LOCATION		
5C. CITY	5D. COUNTY			
PARENT	6A. LAST NAME	6B. MIDDLE NAME	6C. FIRST NAME	6D. RELATION TO CHILD <input type="checkbox"/> MOTHER <input type="checkbox"/> FATHER <input type="checkbox"/> PARENT
	7A. LAST NAME	7B. MIDDLE NAME	7C. FIRST NAME	7D. RELATION TO CHILD <input type="checkbox"/> MOTHER <input type="checkbox"/> FATHER <input type="checkbox"/> PARENT

CORRECT TO THE BEST OF MY KNOWLEDGE





## Who Is Living Together? Same-Sex Couples in the United States



**543,000**

Same-Sex  
Married Couple  
Households



**469,000**

Same-Sex  
Unmarried Partner  
Households



**191,000**

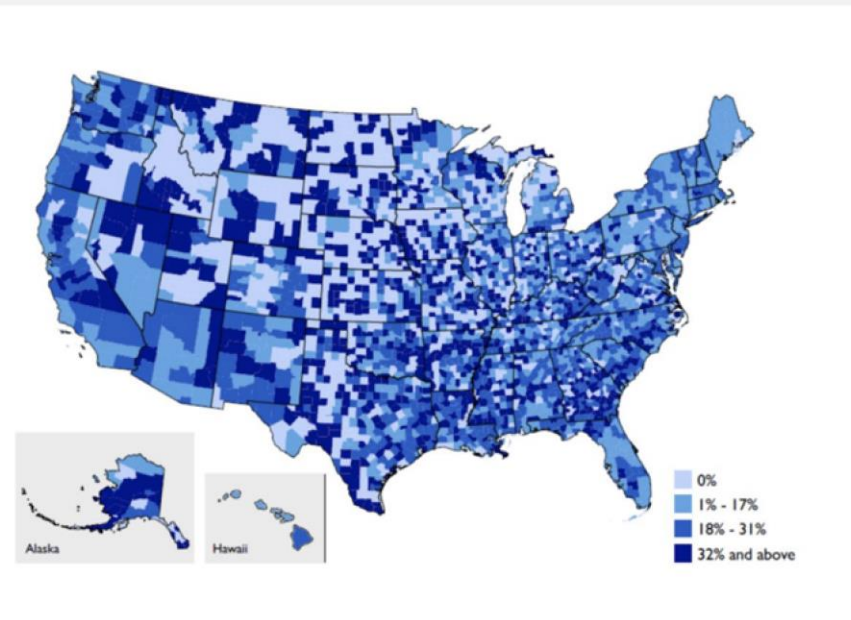
Children Living With  
Same-Sex Parents

United States<sup>®</sup>  
**Census**  
Bureau

U.S. Department of Commerce  
U.S. CENSUS BUREAU  
census.gov

Source: Current Population Survey, Annual Social and  
Economic Supplement, 2019

Figure 6. %Same-sex couples with biological, adopted, or foster children under age 18 in the home



LGBT Parenting in the United States (February 2013)

THE WILLIAMS INSTITUTE

# Worked Examples of using “they”

## **EXAMPLE #1:**

### **PRIOR language:**

When your child reaches age 18, we will try to contact him/her to ask whether he or she wants to continue to be in the study.

### **REVISED language:**

When your child reaches age 18, we will try to contact them to ask whether they want to continue to be in the study.

## **EXAMPLE #2:**

### **Prior language:**

Your child can request additional information when he or she is 18.

### **REVISED language:**

Your child can request additional information when they turn 18.

# Shifting to gender-neutral language:

## **EXAMPLE #1:**

### **PRIOR language:**

If you are a woman who is able to become pregnant your urine will be collected to test for pregnancy.

### **REVISED language:**

If you can become pregnant, urine samples will be collected to test for pregnancy.

## **EXAMPLE #2:**

### **Prior language:**

The effect of the study drug on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these unknown risks, if you are a woman capable of giving birth or a man capable of fathering a child, you and your sexual partner must use adequate birth control measures while you are in this study.

### **REVISED language:**

The impact of the study drug on an embryo or fetus (developing baby in the womb) or on a baby fed with milk released from lactation is unknown and may be harmful. Because of these potential risks, if you can become pregnant or get someone pregnant, you and your sexual partner must use effective birth control measures while participating in this study.



# Be more flexible!

- Adaptable
- Flexible
- Challenging normativity
- Reliance
- Creativity

# Fenway Institute/References?

- [Glossary of LGTQIA+ terms](#)
- [Training on SOGI](#) (sexual orientation and gender identity) data collection
- [Best practices for SOGI data collection in surveys](#) (Williams Institute)
- <https://williamsinstitute.law.ucla.edu/publications/lgbt-parenting-us/>