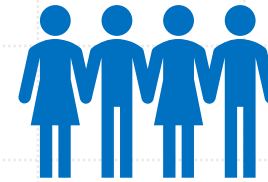




Federal Policy Briefing

Carilion Clinic IRB Member Education
June 2025

Sources of Facts & Interpretations



- Nonprofit organization founded in 1974 that ensures the highest ethical standards in research through education, certification, and professional resources
- Organization serves the research oversight community
 - HRPP, IRB, IACUC
- Advocating for Office of Human Research Protections (OHRP)
- Carilion Clinic Research Community
 - Research Teams
 - Executive Leadership
 - Professional Organizations
 - Academic Partners

January 20, 2025



Executive Order: Terminate all Diversity, Equity, and Inclusion (DEI) programs

Order characterized programs as “illegal and immoral discrimination programs” and reversed Executive Order 13985

- **Requirements:**

- Immediate terminations within 60 days—
 - All DEI, DEIA, and “environmental justice” offices and positions
 - Equity action plans, initiatives, and programs
 - Equity-related grants and contracts

- **Grant Freezes and Reviews**

- Many federally funded researchers have had grants terminated or frozen
- Grant applications are being reviewed for any DEI-related content that could disqualify funding

- **Research Topics Restrictions**

- Studies focused on diversity, equity, and inclusion may lose funding
- Environmental justice research is specifically targeted for termination
- “Gender ideology” is restricted (combined executive order)

[Source](#)

January 20, 2025



Executive Order: Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government

Order establishes a federal policy recognizing only two sexes (male and female) as “immutable biological classifications” and prohibits the use of “gender identity” concepts in federal operations

Key definitions for Research Context:

- **Sex:** Immutable biological classification as male or female (not synonymous with *gender identity*)
- **Female/Male:** Defined by reproductive cell production at conception
- **Gender ideology:** Explicitly rejected as replacing biological sex with self-assessed gender identity

Federal Funding Restrictions

- Federal funds cannot be used to promote gender ideology
- Studies involving gender identity concepts may face funding restrictions

Research Specific Considerations

- Data classification must use order’s sex-based definitions
- Study design may need to modify methodologies to comply with the binary sex classification requirement
- Order rescinds multiple previous policies and guidance documents

[Source](#)

April 4, 2025



Secretary's Advisory Committee on Human Research Protections (SACHRP) disbanded

- **Committee provided specialized guidance to Health and Human Services (HHS) agencies that regulate human subject research**

- Comprised entirely of expert volunteers
- Established in 2003 to provide guidance on issues such as remote & virtual clinical trials, pediatric research, artificial intelligence (AI)
- Part of the Office for Human Research Protections (OHRP) and advised on policies

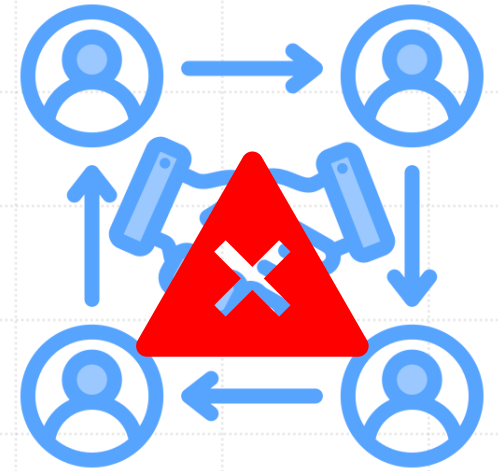
Impact on Research Guidance

- Elimination of expertise on ethical and legal issues
- Potential gaps in developing new human subject protection policies
- Reduced capacity to address innovative research methodologies (ex: AI)

[Source](#)

April 14, 2025

SMART IRB cease work order



- **NIH issued a stop work order for SMART IRB's federal funding contract**

- Harvard is providing minimal support to maintain operations
- Staff can only work on SMART IRB in their capacity as Harvard employees, not federally funded personnel
- Basic services like responding to tickets and activating new agreements will continue by with reduced resources

Scale of Impact

- 1,350+ institutions rely on SMART IRB across the nation
- 12,000+ researchers use the platform
- 2,000+ IRB and HRPP staff depend on system
- Nearly 12,000 studies have used SMART IRB for documentation

SMART IRB facilitates streamlined oversight for multi-site studies, reducing administrative burden.

May 1, 2025

Certificate of Confidentiality (CoC) System is Temporarily Unavailable



The following is stated on NIH website:

“NIH is currently undergoing a renewal of the Paperwork Reduction Act (PRA) approval for the NIH Certificate of Confidentiality (CoC) system. NIH will not be accepting requests to the CoC system or Institutional Official verifications for non-NIH funded research during this time. There will be an update on the [CoCs for Research Not Funded by NIH](#) page by July 2025. **Note that the CoCs for NIH-funded studies (i.e., deemed issued CoCs) are not affected.**”

[Source](#)



Impact on Carilion Clinic HRPO/IRB

- 30+ change/update forms processed and submitted to update “gender” to “sex”
- 2 NIH studies have lost their funding
- CoC issues
 - Potential impact on recruitment taking a bit longer
 - Studies will not have added protections as provided with CoC
- Collaboration and staying informed from professional organizations for emerging guidance



Final thought

“Complying with the regulations is the minimum; ethics is enormous and expands beyond regulations.”

-Jaime Hernandez, JD, MBE (Founder, Practical Ethics-Research Solutions)