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Memo

Reform Proposals for the National Institutes of Health (NIH)

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Executive Summary

On inauguration day, the Trump administration issued a string of executive orders, including two with immediate implications for the future of DEI[1] and gender ideology[2] within the federal government. The first order requires that the executive branch terminate all DEI "mandates, policies, programs, preferences, and activities," and the second requires the recognition of "sex" as a biological reality across all functions of the executive branch. The order makes it clear that "sex" does not mean or include "gender identity." Indeed, the order repudiates the concept of "gender identity" and instructs the organs of the executive branch to purge existing policies, regulations, and communications that "promote or otherwise inculcate gender ideology." Given that the National Institutes of Health (NIH) has long embraced and promoted DEI and gender ideology, the new executive orders will necessitate a transformation of NIH practices, policies, and priorities. This memo offers a roadmap for the incoming NIH leadership to achieve that transformation.

1 "Ending Radical and Wasteful Government DEI Programs and Preferencing," *The White House*, January 20, 2025, https://www.whitehouse.gov/presidential-actions/2025/01/ending-radical-and-wasteful-government-dei-programs-and-preferencing/.

2 "Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government," *The White House*, January 20, 2025, https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/.

In recent years the National Institutes of Health (NIH) have gradually incorporated controversial ideas about "social justice" into all aspects of its organizational life. NIH has built a sprawling Diversity, Equity, and Inclusion (DEI) bureaucracy, launched programs to promote DEI principles in research, and devoted millions of taxpayer dollars to ideologically driven research on gender transition. Since the launch of the Sexual and Gender Minority Research Office (SGMRO) in 2015, the NIH has allocated almost $628 million dollars to transgender research more broadly across over 300 grants.[3]

NIH's initiatives received backwind from the White House's 2021 Executive Order [4] on Diversity, Equity and Inclusion in the Federal Workforce, but the seeds were already planted with the agency's 2021 Unite Initiative,[5] which prioritizes "health-disparity" and "minority health" research, "equity" in biomedical research and the internal workforce, and the promotion of racial and ethnic data collection to help guide "health equity" policy.

Health disparities among racial groups are real and worthy of scientific inquiry. However, the National Institute on Minority Health and Health Disparities' (NIMHD) ideological framework presupposes from the outset that "racist or discriminatory acts" are the driving force behind these disparities.[6] The framework lacks research equipoise and more troublingly, is unlikely to help policymakers formulate effective responses to these disparities, which are presumably complex and multicausal.

NIH's SGMRO has sought to promote, rather than to examine the scientific basis for and clinical outcomes of, a medical approach to managing sex-related distress known as "gender-affirming care." Due to SGMRO's activities in this area, NIH has placed itself at odds with a growing international consensus based on multiple systematic reviews of evidence that the "gender-affirming" treatment model lacks evidence of safety and efficacy.[7] [8] In this memo, we treat NIH's activities on gender transition as one component of its broader commitment to DEI.

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3 "USAspending.gov/search," USASPENDING, accessed January 10, 2025, https://www.usaspending.gov/search/?hash=a3567b1c849db194ecbb494e6bb1cb68.

4 "Executive Order on Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce," *The White House*, June 25, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/06/25/executive-order-on-diversity-equity-inclusion-and-accessibility-in-the-federal-workforce/.

5 "UNITE," National Institutes of Health, November 13, 2024, https://www.nih.gov/ending-structural-racism/unite.

6 "Minority Health and Health Disparities Definitions," National Institutes of Health, n.d., https://www.nimhd.nih.gov/resources/understanding-health-disparities/minority-health-and-health-disparities-definitions.html.

7 Dr. Hilary Cass, *The Independent Review of Gender Identity Services for children and young people: Final Report* (London: Department of Health and Social Care, 2024), https://cass.independent-review.uk/home/publications/final-report/.

8 F.D. Zepf et al., "Beyond NICE: Aktualisierte systematische Übersicht zur Evidenzlage der Pubertätsblockade und Hormongabe bei Minderjährigen mit Geschlechtsdysphorie [Beyond NICE: Updated Systematic Review on the Current Evidence of Using Puberty Blocking Pharmacological Agents and Cross-Sex-Hormones in Minors with Gender Dysphoria]," *Zeitschrift für Kinder- und Jugendpsychiatrie und Psychotherapie* 52, no. 3 (2024): 167–187, https://doi.org/10.1024/1422-4917/a000972

However well intentioned, that commitment imposes ideological litmus tests on employees and grant recipients. NIH's embrace of DEI has created a culture of intellectual homogeneity that inhibits the pursuit of the institute's core mission, to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health." Worse, it has led the institute to fund and promote research programs that harm Americans and undermine public trust in the U.S. health and health research systems. No group is served by a research agenda that funds only favored perspectives and pre-approved narratives.

At a time when that trust is at a historic low, we believe systematic reform of NIH is urgently needed. That reform should be guided by 4 bedrock principles (SITE):

1. Scientific rigor and merit
2. Intellectual diversity
3. Transparency
4. Evidence-based medicine

To realize SITE, we propose the following 6 reforms:

1. Rescind the current "notice of NIH's interest in diversity," and issue in its place a notice of interest committing NIH to the SITE principles and halting all programs that violate those principles.
2. (2.1) Dismantle or reform SGMRO and decentralize research on sex-related distress and treatment. (2.2) Alternatively, reform SGMRO's Health Disparities Research Framework and replace members of SGMRO, SGM Research Working Group, and SGM Research Coordinating Committee who have intellectual and/or financial conflicts of interest.
3. (3.1) Halt funding of research that studies the impact of sex-trait modification procedures on pediatric populations. (3.2) Prioritize research on detransition and medical harm in populations that have experienced gender transition-related interventions.
4. Replace ideologically loaded language (e.g., "sex assigned at birth") with scientifically accurate terms across NIH.
5. End "Culturally Competent Gender Related Communication" (C3) trainings.
6. Rescind the Secretary's Advisory Committee for Human Research Protection (SACHRP) guidance on working with "LGBTQI" participants in human subject research.

1. Rescind the current "notice of NIH's interest in diversity," and issue in its place a notice of interest committing NIH to the SITE principles and halting all programs that violate those principles.

For over a decade, NIH has emphasized its interest and investment in increasing demographic diversity in the biomedical sciences. This priority has shaped the agency's internal policies and its directives to grant recipient institutions, which is notable given the outsized amount of medical research funding that comes from NIH. The agency's avowed priorities create incentives for medical research institutes to enact various diversity, equity, and inclusion policies. Many NIH funded scientists attribute the advent of "woke medicine" to NIH policies.

A defining statement of this priority is the "Notice of NIH's Interest in Diversity,"[9] which urges grant recipients to engage in policies that increase participation of (narrowly defined) "underrepresented populations" in biomedical research. NIH grant announcements and policies frequently cite the notice, and institutes of higher education point to it as a guideline for their conduct.

For example, in 2024 NIH awarded a $384,748 grant to the Promoting Diversity, Group Inclusion and Equity (ProDiGIE) research lab at the New York University School of Medicine.[10] The grant was used to fund a study published in *JAMA* entitled "Race and Sex Disparities Among Emergency Medicine Chief Residents."[11] The study argues that a racially diverse workforce is necessary to advance "health equity" and concludes that racial disparities among those promoted to chief resident must be the product of "interpersonal biases" in decision-making and "institutional racism."

The authors provide no citations for these claims. Their own statistical analysis shows that white women, who are assumed to be at a disadvantage according to the author's theoretical framework, are promoted at the highest rate of all demographic groups. Further, the authors acknowledge that alternative explanations, such as performance gaps on the United States Medical Licensing Examination, could undermine their conclusion.

Thus, even if the authors are right that promoting workforce "equity" falls under NIH's purview, they fail to engage with alternative hypotheses that might better explain the disparities they find troubling.

Grants of this nature are not rare. A cursory look at NIH funded grants between 2017 and 2024 filtered through the keywords "institutional racism" reveals 48 funded projects totaling $122 million in taxpayer money.[12]

Through its intramural practices and extramural funding alike, NIH implements a wide variety of programs and policies intended to provide career opportunities (fellowships, grant funding, administrative roles, and faculty positions) based on demographic categories. Such programs include the Diversity Career Development Program,[13] the Pathway to Independence Awards (K99/R00),[14] and the MOSAIC Postdoctoral Career Transition Award to Promote Diversity award,[15] all of which target and provide various benefits for "underrepresented" researchers.

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9 "UNITE," National Institutes of Health, November 13, 2024, https://www.nih.gov/ending-structural-racism/unite.

10 "RePORT," RePORTER, n.d., https://reporter.nih.gov/search/JhgxyXjIe0uxhBRkTqASWw/project-details/10842562

11 J.W. Tsai et al., "Race and Sex Disparities Among Emergency Medicine Chief Residents," *JAMA Network Open* 7, no. 9 (2024): e2432679, https://doi.org/10.1001/jamanetworkopen.2024.32679

12 "USAspending.gov/search," USASPENDING, accessed January 10, 2025, https://www.usaspending.gov/search/?hash=fc82dfed87fdae2db1a4072f6a40df91.

13 "Diversity Career Development Program," Cancer.gov., November 4, 2024, https://www.cancer.gov/grants-training/training/idwb/dcd-program.

14 "Pathway to Independence Awards (K99/R00)," National Institutes of Health, n.d., https://www.nigms.nih.gov/training/careerdev/Pages/PathwayIndependence.aspx.

15 "MOSAIC Postdoctoral Career Transition Award to Promote Diversity," National Institutes of Health, n.d., https://www.ninds.nih.gov/funding/training-career-development/postdoctoral-fellows/mosaic-postdoctoral-career-transition-award-promote-diversity.

This emphasis likewise extends to the evaluation of lucrative grant applications. Applicants for multi-million-dollar training grants (T23) must submit diversity recruitment and retention plans; the evaluation of these grants has for many years involved an assessment of the demographic makeup of the project's personnel. Moreover, the agency has pointed to the "Select Pay" mechanism—which allows NIH officials to fund proposals that receive an evaluation score high enough to merit funding—as a tool for favoring minority applicants in the review process for R01 grants, the agency's career-defining biomedical research grant. Among biomedical scientists, it's widely understood that demographic characteristics even factor into the selection of the scientists who review grant proposals.

This constellation of policies and programs puts outsized pressure on institutions that intend to collaborate with NIH to engage in practices that are discriminatory and that undermine NIH's core mission. For these reasons, NIH should retract its previous Notice of Interest in Diversity.

A simple notice restating NIH's priorities, in alignment with SITE principles, would undo many of these harmful and anti-scientific practices. The notice should state explicitly that NIH personnel and funding decisions will be made without regard to demographic characteristics. This should include decisions regarding the hiring of NIH employees, the selection of grant recipients, and the selection of grant reviewers. The notice should also encourage grant recipients to foster equality, merit, and nondiscrimination (e.g., in admissions, hiring, promotion, and tenure).

Finally, many NIH programs use or encourage the use of ideological litmus tests. The Faculty Institutional Recruitment for Sustainable Transformation (FIRST)[16] program funds large-scale hiring initiatives at universities and requires its recipients to make heavy use of so-called "diversity statements." NIH FIRST is based on the Distinguished Scholars Program,[17] which hires intramural NIH scientists using the same criteria. The DEIA mentorship supplement award gives up to $250,000 in supplemental funds to investigators with a proven commitment to DEI.[18] Similarly, grant programs have begun using Plans to Enhance Diverse Perspectives, and a 2021 notice requires that individuals seeking NIH support for scientific conferences (R13 and U13) submit a diversity plan, requirements that function as mandatory diversity statements in the grant review process.[19]

This policy raises serious concerns over compelled speech and likely has a chilling effect on eligible researchers who believe DEI stands in the way of their work. An increasing number of universities (including MIT and the University of Michigan) have outright banned the practice. Moreover, in many instances these criteria have served as a smokescreen for racial preferences behind the scenes. NIH should issue a notice stating its intent to take steps to avoid compelled speech and to foster freedom of conscience. Specifically, NIH should not require scientists to demonstrate a commitment to specific social causes as a condition for employment or professional advancement. It should also encourage NIH grant recipients to take similar precautions to avoid compelled speech and foster freedom of inquiry.

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16 "Faculty Institutional Recruitment for Sustainable Transformation (FIRST)," National Institutes of Health, n.d., https://commonfund.nih.gov/FIRST.

17 "NIH Distinguished Scholars Program | Chief Officer for Scientific Workforce Diversity," National Institutes of Health, n.d., https://diversity.nih.gov/act/NIH-distinguished-scholars-program.

18 "DEIA Mentorship Supplements | Chief Officer for Scientific Workforce Diversity," National Institutes of Health, n.d., https://diversity.nih.gov/act/DEIA-mentorship-supplements.

19 "NOT-OD-21-053: Updated Guidelines for Enhancing Diversity and Creating Safe Environments in Conferences Supported by NIH Grants and Cooperative Agreements," National Institutes of Health, n.d., https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-053.html.

Currently, NIH requires that all employees who fall under NIH's "Performance Management Appraisal Program" (PMAP) express a commitment to DEI.[20] As part of the PMAP plan, regular employees must report any policy or practice which "cause or enable inequities in the NIH workforce or the NIH-funded biomedical research" and comply with an updated Manual Chapter 1311 requiring, among other things, that employees "consistently communicate in a manner that promotes and facilitates a safe and civil organizational culture."[21] Managers and supervisors are held to an even higher standard: they must "demonstrate support for diversity, equity, inclusion, and accessibility efforts at NIH" by "actively supporting the implementation of strategies to increase inclusivity and diversity" and by promoting "specific Racial and Ethnic Equity Plans and encourag[ing] employee participation in IC and NIH DEIA initiatives."[22]

A wide variety of programs violate the principles of viewpoint diversity and equality. To ensure quick and clear enforcement of the above recommendations, the agency should ensure that certain high-impact programs and policies are singled out and ended. This would include: the Distinguished Scholars Program; the Advisory Committee to the Director (ACD) Working Group on Diversity; the solicitation and evaluation of Plans to Enhance Diverse Perspectives; Racial and Ethnic Equity Plans; the solicitation and evaluation of Recruitment Plans to Enhance Diversity; and the NIH FIRST program.

2.1. Dismantle or reform SGMRO and decentralize research on sex-related distress and treatment

Because SGMRO's mission is to promote intramural and extramural research on "sexual and gender minority" (SGM) health, the office sets the tone for SGM-related research projects that are more likely to be funded across all NIH Institutes, Centers and Offices (ICOs). SGMRO's health disparities research framework is antagonistic to the spirit of open scientific inquiry because it presupposes a "minority stress" framework in which poor psychological or physical health in people who experience distress over their sex can only be explained by "stigma," "discrimination," and lack of access to "gender-affirming care."[23] Whether this assumption is true is the subject of ongoing debate, but NIH has treated it as the price of entry for grant candidates.

Because the current NIH framework presupposes that sex-trait modification procedures and psychological interventions ("gender-affirming care") are safe and effective, NIH currently sees its mission as that of funding programs that increase "access" to these interventions, including among minors. It does so despite the consistent findings of systematic reviews of evidence that there is

20 "PMAP Mandatory Standard Language," National Institutes of Health, n.d., https://hr.nih.gov/workforce/performance-management/pmap-mandatory-standard-language?utm_source=chatgpt.com.

21 Ibid.

22 Ibid.

23 "Sexual & Gender Minority Health Disparities Research Framework," National Institutes of Health, n.d., https://dpcpsi.nih.gov/sites/default/files/2024-04/NIH-SGM-Health-Disparities-Research-Framework-FINAL_508c_UPDATED-2024.pdf.

no credible evidence that these interventions are safe and effective,[24] and against the backdrop of a growing international consensus in favor of psychotherapeutic approaches over endocrine and surgical ones.[25]

The gender-affirmative framework took shape after NIMHD designated SGM as a population experiencing "health disparities" in 2016.[26] "Research shows that sexual and gender minorities who live in communities with high levels of anti-SGM prejudice die sooner—12 years on average—than those living in more accepting communities," the director explained.[27] Curiously, the director conceded in the same announcement that "the extent and causes of health disparities are not fully understood," and even more curiously, the only study he cited in support of his claim about the presumed cause of earlier mortality was retracted two years later.[28] After reanalysis of their data, the authors of that study conceded that "the association between structural stigma and mortality risk" in "sexual minority populations" was not "statistically significant."[29]

When it comes to youth, NIH's approach has been one of "building the plane while flying it." On the one hand, NIH has devoted millions of dollars to funding research whose official purpose is to study the clinical effects of endocrine interventions, an investment that would only make sense if those outcomes were in doubt. The highest-profile recipient of NIH funding ($9.7 million to date) is the Youth Care Study, led by Dr. Johanna Olson-Kennedy. In 2023, the first outcome paper from the NIH study was published and drew considerable criticism for its methodological problems and unimpressive results (which the authors seemingly tried to conceal).[30] Two of the 315 youths in the study had committed suicide after initiating hormone treatment.[31] In 2024, the *New York Times* reported that Olson-Kennedy had withheld the findings of the study's puberty blocker component for fear that the unimpressive results would be "weaponized" by critics of pediatric gender transition.[32]

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24 Dr. Hilary Cass, *The Independent Review of Gender Identity Services for children and young people: Final Report* (London: Department of Health and Social Care, 2024), https://cass.independent-review.uk/home/publications/final-report/.

25 Ibid.

26 "SGM Designated as a Population With Health Disparities," National Institutes of Health, October 6, 2016, https://www.nimhd.nih.gov/about/directors-corner/messages/message_10-06-16.html.

27 Ibid.

28 Ibid.

29 M.L. Hatzenbuehler et al., "Retraction: Corrigendum to 'Structural stigma and all-cause mortality in sexual minority populations," *Social Science & Medicine* 200, (2018): 271, https://www.sciencedirect.com/science/article/pii/S0277953617307086?via%3Dihub

30 Jesse Singal, "The New, Highly Touted Study on Hormones for Transgender Teens Doesn't Really Tell Us Much of Anything." *Singal-Minded* (blog), February 7, 2023, https://jessesingal.substack.com/p/the-new-highly-touted-study-on-hormones.

31 Diane Chen et al., "Psychosocial Functioning in Transgender Youth After 2 Years of Hormones," *New England Journal of Medicine* 388, no. 3 (2023): 240–50, https://doi.org/10.1056/nejmoa2206297.

32 Azeen Ghorayshi, "U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says," *The New York Times*, October 23, 2024, https://www.nytimes.com/2024/10/23/science/puberty-blockers-olson-kennedy.html.

The study is now being investigated by the Subcommittee on Health Care and Financial Services.[33] It is never acceptable for recipients of NIH grants, paid for by taxpayers, to hold their data hostage to their political agendas.

On the other hand, at the same time NIH was funding research into the safety and efficacy of endocrine treatments, it was devoting resources to the promotion of greater access to "gender-affirming care." For example, NIH funded a "Queering the Curriculum" initiative for primary care residents ($162,000, project #: 1R25LM014550-01) with the goal of expanding access to "gender-affirming care" in primary care settings. A similar project ($162,000, project#1R25LM014555-01) aims to achieve the same by training nurses on a module based on the World Professional Association of Transgender Health's SOC-8. There is growing international opposition to SOC-8 and court documents recently revealed that in the process of developing SOC-8, WPATH suppressed systematic reviews of evidence, relied on political rationales when drafting its recommendations, and ignored or even welcomed financial and intellectual conflicts of interest within its guideline development committee.[34] [35]

This phenomenon, in which clinical practices are adopted at scale before there is evidence of their safety and effectiveness, is known as "runaway diffusion."[36] Rather than support scientific efforts to prevent runaway diffusion and tether clinical practice to sound medical evidence, NIH supercharged that diffusion in the name of reducing "health disparities." In other words, it subordinated medical research to political agendas.

To restore scientific integrity to the field, NIH must reexamine its baseline assumption that people who identify as transgender form a discrete social group. Research suggests that there are different causes to cross-sex feelings and identification[37]; it is a mistake to view transgender identification as a homogenous phenomenon. Individuals who identify as transgender deserve evidence-based care. Unfortunately, given its dogmatic commitment to "minority stress," the NIH's "health disparities" framework makes proper research into the sources of and evidence-based interventions for human distress all but impossible.

Because SGMRO's very existence depends on and perpetuates the "health disparities"/"minority stress" framework, the office should be abolished and research into the health of transgender-identified

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33 United States House Committee on Oversight and Government Reform, "McClain Probes $9.7 Million Taxpayer-Funded Study Buried by Activist Researcher on Puberty Blockers," United States House Committee on Oversight and Government Reform, November 8, 2024, https://oversight.house.gov/release/mcclain-probes-9-7-million-taxpayer-funded-study-buried-by-activist-researcher-on-puberty-blockers%EF%BF%BC/#:~:text=WASHINGTON%E2%80%94Subcommittee%20on%20Health%20Care,has%20been%20hidden%20by%20the.

34 Jesse Singal, "Research Into Trans Medicine Has Been Manipulated," *The Economist*, June 27, 2024, https://www.economist.com/united-states/2024/06/27/research-into-trans-medicine-has-been-manipulated.

35 Leor Sapir, "The Deposition of Eli Coleman," *City Journal*, December 13, 2024, https://www.city-journal.org/article/the-deposition-of-eli-coleman.

36 E. Abbruzzese et al., "The Myth of 'Reliable Research' in Pediatric Gender Medicine: A Critical Evaluation of the Dutch Studies—and Research That Has Followed," *Journal of Sex & Marital Therapy* 49, no. 6 (2023): 673–99, https://doi.org/10.1080/0092623x.2022.2150346.

37 Riittakerttu Kaltiala-Heino et al., "Gender Dysphoria in Adolescence: Current Perspectives." *Adolescent Health Medicine and Therapeutics* 9, (2018): 31–41, https://doi.org/10.2147/ahmt.s135432.

individuals should be decentralized into other NIH ICOs. Distress and suffering associated with one's sexual characteristics is a real phenomenon. "Gender Minorities," however, is not a scientific concept but a political one.

Abolishing the SGMRO does not mean abandoning research on the causes and therapeutic responses to sex distress. Questions about the harms of puberty blockers, cross-sex hormones, and surgeries can still be studied by, e.g., the National Cancer Institute and the National Heart, Lung and Blood Institute. Research pertaining to diagnostics and the etiology of gender dysphoria can be addressed by the National Institute of Mental Health.

2.2. Alternatively, reform the SGMRO's Health Disparities Research Framework and replace members of the SGMRO, SGM Research Working Group, and SGM Research Coordinating Committee that have intellectual and/or financial conflicts of interest

As an alternative to abolishing SGMRO, the office can be reformed to ensure its core members and its officers across NIH ICOs are free from financial and intellectual conflicts of interest. NIH personnel must demonstrate a genuine commitment to the full range of scientific and ethical questions relating to the conceptualization and treatment of sex distress. This includes the leadership of SGMRO as well as the corresponding Sexual and Gender Minority Research Working Group and the Sexual and Gender Minority Research Coordinating Committee (RCC). The SGM RCC is comprised of members from across the NIH's ICOs who are not employees of the SGMRO. However, they function as a coordinating arm of SGMRO to ensure that their respective ICOs align with SGMRO's larger agenda.

The director of SGMRO is a particularly influential position, as the face of NIH-wide efforts to advance SGM initiatives, and as an automatic co-chair of the SGM Research Working Group, which helps shape research priorities by advising the NIH's council of councils on SGM matters. Currently, the RWG has two co-directors and nine members, many with terms ending in September of 2025 and 2026. Members of the RWG are appointed by the Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI).

Members of the SGM Research Working Group who are not NIH employees may exert powerful influence as advisors to the NIH's Council of Councils on SGM research initiatives and priorities. To use just one example, RWG member Kellan Baker is the director of the Whitman Walker Institute, a transgender advocacy group, and a member of the activist organization WPATH. Baker's name has been linked to WPATH's efforts to suppress evidence for pediatric sex trait modification and conceal conflicts of interest in scientific publication.

3.1. Halt funding of research that studies the impact of sex-trait modification procedures on pediatric populations

Recent international developments and the findings of numerous systematic reviews call into question the ethics of experimenting with sex-trait modification procedures on minors. The harms of these treatments are real and the benefits highly uncertain.[38] The capacity of adolescents to give consent to endocrine and surgical interventions, particularly when the diagnosis relies on subjective factors and lacks specificity, remains doubtful.[39]

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[38] Dr. Hilary Cass, *The Independent Review of Gender Identity Services for children and young people: Final Report* (London: Department of Health and Social Care, 2024), https://cass.independent-review.uk/home/publications/final-report/.

[39] Stephen B. Levine et al., Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults." *Journal of Sex & Marital Therapy* 48, no. 7 (2022): 706–27, https://doi.org/10.1080/0092623x.2022.2046221.

The basis for all sex-trait modification procedures in minors, and by extension for the NIH's multiyear and multimillion dollar support for these procedures, are the Dutch Studies.[40] [41] However, scholarly critiques of those studies revealed their high risk of bias and lack of credible findings.[42] The only attempt to replicate the purported positive findings of the Dutch research has failed to do so.[43] The "very low" quality of research in this area has been a consistent finding in systematic reviews, prompting one of the Dutch founders of the field to write that the field should not concern itself over whether the treatments are "effective" or whether they actually lead to "improvement."[44] Some of the leading clinicians in youth gender medicine argue that mental health assessments are unnecessary and even harmful.[45] [46] The point of medical intervention, as they see it, is to facilitate a young person's "embodiment goals."[47] In short, there is growing international recognition, including within the field of gender medicine, that these interventions are either experimental or cosmetic. For this reason, there is a compelling ethical argument for halting research into pediatric sex-trait modification procedures.

3.2. Prioritize research on detransition and medical harm in populations that have experienced gender transition-related interventions

Rather than continue to support an ideological agenda, NIH should encourage research into the following areas, where knowledge gaps still exist:

Detransition Research. Despite being a highly vulnerable and understudied population that theoretically fits under NIH's official definition of SGM populations, detransitioners are not formally recognized under the SGM umbrella and there are no NIH grants dedicated solely to studying detransitioners, their unique physical and mental health needs, or the

40 A.L. de Vries et al., "Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study," *The Journal of Sexual Medicine* 8, no. 8 (2011): 2276–2283, https://doi.org/10.1111/j.1743-6109.2010.01943.x.

41 A.L. de Vries et al. "Young Adult Psychological Outcome After Puberty Blockade and Gender-Affirming Hormone Treatment," *Pediatrics* 134, no. 4 (2014): 696–704, https://doi.org/10.1542/peds.2014-0166.

42 Abbruzzese et al., "The Myth of 'Reliable Research' in Pediatric Gender Medicine: A Critical Evaluation of the Dutch Studies—and Research That Has Followed."

43 Michael Biggs, "The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence," *Journal of Sex & Marital Therapy* 49, no. 4 (2022): 348–68, https://doi.org/10.1080/0092623x.2022.2121238.

44 E.D. Oosthoek et al., "Gender-Affirming Medical Treatment for Adolescents: A Critical Reflection on 'Effective' Treatment Outcomes," *BMC Medical Ethics* 25, (2024): 154, https://doi.org/10.1186/s12910-024-01143-8.

45 W. Verbeek et al., "Mental Readiness' and Gatekeeping in Trans Healthcare," *Canadian Journal of Psychiatry* 67, no. 11 (2022): 828–830, https://doi.org/10.1177/07067437221102725.

46 Florence Ashley, "Gatekeeping Hormone Replacement Therapy for Transgender Patients Is Dehumanising," *Journal of Medical Ethics* 45, no. 7 (2019): 480–482, https://doi.org/10.1136/medethics-2018-105293.

47 Jack L. Turban et al., "Understanding and Supporting Patients With Dynamic Desires for Gender-Affirming Medical Interventions," *JAMA Network Open* 5, no. 7 (2022): e2224722, https://doi.org/10.1001/jamanetworkopen.2022.24722.

factors associated with detransition. Given the low rate of diagnostic persistence for gender dysphoria,[48] and more recent studies suggesting higher rates of medical discontinuation (up to 30%),[49] NIH should prioritize research into all aspects of detransition and desistance.

Studying Harms. If NIH does not see fit to halt research on endocrine interventions for gender dysphoric youth, it should at least redirect its resources to study the safety of these interventions. The full course of "gender transition" may lead to sterility and sexual dysfunction.[50] [51] Some research shows that "gender-affirming" interventions are associated with increased risk of cancer,[52] [53] cardiovascular disease,[54] bone density problems,[55] and cognitive deficits.[56] In 2012, NIH's LGBT Research Coordinating Committee acknowledged "large gaps" in the research on health impacts.[57] Those gaps remain, but NIH seems no longer to believe that they justify caution in the administration of "gender-affirming care" to vulnerable populations.

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48 Leor Sapir. "Adolescent Gender Dysphoria Is a Temporary Diagnosis for Most Teens," *City Journal*, September 1, 2024, https://www.city-journal.org/article/adolescent-gender-dysphoria-is-a-temporary-diagnosis-for-most-teens.

49 Christina M. Roberts et al., "Continuation of Gender-Affirming Hormones Among Transgender Adolescents and Adults," *The Journal of Clinical Endocrinology & Metabolism* 107, no. 9 (2022): e3937–e3943, https://doi.org/10.1210/clinem/dgac251.

50 L.M.B. da Silva et al., "Pelvic Floor Dysfunction in Transgender Men on Gender-Affirming Hormone Therapy: A Descriptive Cross-Sectional Study," *International Urogynecology Journal* 35 (2024): 1077–1084, https://doi.org/10.1007/s00192-024-05779-3.

51 P.J. Cheng et al., "Fertility Concerns of the Transgender Patient," *Translational Andrology and Urology* 8, no. 3 (2019): 209–218, https://doi.org/10.21037/tau.2019.05.09.

52 E.M. Shanker et al., "Exploring the Incidence of Testicular Neoplasms in the Transgender Population: A Case Series," *Archives of Pathology & Laboratory Medicine* (2024): https://doi.org/10.5858/arpa.2024-0218-OA.

53 C.J.M. de Blok et al., "Breast Cancer Risk in Transgender People Receiving Hormone Treatment: Nationwide Cohort Study in the Netherlands," *BMJ* 365 (2019): l1652, https://doi.org/10.1136/bmj.l1652.

54 D. Getahun et al., "Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study," *Annals of Internal Medicine* (2018), https://doi.org/10.7326/M17-2785.

55 Marta Chuncia-Ileczko et al., "Impact of Gonadotropin-Releasing Hormone Analogue and Gender-Affirming Hormone Therapy on Bone Mineral Density in Transgender Adolescents," *Quality in Sport* 37, (2025): 57200, https://doi.org/10.12775/QS.2025.37.57200.

56 Sallie Baxendale, "The Impact of Suppressing Puberty on Neuropsychological Function," *Authorea*, (2024): https://doi.org/10.22541/au.170446841.14546991/v2.

57 Meredith D. Temple O'Connor et al., "Consideration of the Institute of Medicine (IOM) Report on the Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals," *National Institutes of Health*, 2013, https://report.nih.gov/sites/report/files/docs/LGBT%20Health%20Report_FINAL_2013-01-03-508%20compliant.pdf.

Etiology and Epidemiology. More data is needed on the etiology and epidemiology of gender-incongruence, particularly among today's novel patient cohort which is often disproportionately female and plagued by preexisting mental health diagnoses and neurocognitive conditions.[58] [59] More specifically, NIH should consider funding research that attempts to understand the causes of the unbalanced sex ratio of clinic-referred youth; if and how comorbid mental illness and neurocognitive difficulties contribute to gender dysphoria; if and how interpersonal factors/social contagion influence dysphoria; and the relationship between an emerging homosexual orientation and the development of gender dysphoria. Other priority areas include longitudinal studies on the natural history of gender dysphoria in different sub-populations (e.g., childhood-onset versus adolescent-onset), which are necessary for understanding rates of desistence and persistence.

Diagnosis Research. Research suggests that diagnoses of dysphoria and or gender incongruence have low stability, with recent analyses of electronic health records in Germany and the U.S. suggesting that >60% of youth no longer have a diagnosis after 5 years.[60] [61] This suggests that the diagnoses may not be as robust as previously thought. More research is needed to assess the accuracy of diagnostic tests for dysphoria/incongruence, diagnostic stability, and the clinical utility of the diagnosis in determining treatment protocols.

Psychosocial Interventions. Given the low-quality evidence for the benefits of affirming medical care, and a move towards psychosocial interventions in the European context, pilot studies of psychotherapy interventions for sex distress are sorely needed. As it has done in the past, the NIH can issue a Notice of Special Interest to address these research areas.

4. Replace ideologically loaded language (e.g., "sex assigned at birth") with scientifically accurate terms across the NIH

Since the SGMRO launched, ideologically loaded language pertaining to sex and gender have been introduced throughout the NIH's ICOs (e.g., "Two-Spirit," "genderqueer"). Moreover, one of SGMRO's main initiatives is to increase data collection, particularly as it relates to "gender identity." Despite its popularity in mainstream and clinical discourse, "gender identity" lacks a scientific definition. Existing definitions rely on circular reasoning, sex stereotypes, or some combination of the two.[62] The effort to collect data on "gender identity" and report it alongside data on sex categories (male and female) implicitly validates the former concept. It can also obscure critical epidemiological information and the enduring relevance of sex differences to healthcare and health policy.

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58 Teresa A. Becerra-Culqui et al., "Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers," *Pediatrics* 141, no. 5 (2018): e20173845, https://doi.org/10.1542/peds.2017-3845.

59 Kaltiala-Heino et al., "Gender Dysphoria in Adolescence: Current Perspectives."

60 C.J. Bachmann et al., "Gender Identity Disorders Among Young People in Germany: Prevalence and Trends, 2013–2022. An Analysis of Nationwide Routine Insurance Data," *Dtsch Arztebl Int* 121 (2024): 370–371, https://doi.org/10.3238/arztebl.m2024.0098.

61 Leor Sapir, "Adolescent Gender Dysphoria Is a Temporary Diagnosis for Most Teens," *City Journal*, August 30, 2024, https://www.city-journal.org/article/adolescent-gender-dysphoria-is-a-temporary-diagnosis-for-most-teens.

62 Alex Byrne, *The Trouble with Gender* (Chicago: University of Chicago Press, 2022).

For example, anecdotal evidence suggests that natal females whose "gender identity" is recorded as male and whose sex is unrecorded are prescribed testosterone with the justification that they have an "endocrine disorder" (low levels of T relative to "other boys").[63] NIH's continued reliance on pseudoscientific concepts such as "assigned sex" and "gender identity" makes such fraudulent and harmful practices possible. NIH should insist on the importance of scientifically accurate, sex-based language across all its divisions and functions.

5. End "Culturally Competent Gender Related Communication" (C3) trainings

NIH (via the SGMRO) currently conducts a training on "Culturally Competent Gender Related Communications (C3)" intended for "program officers (POs), scientific review officers (SROs), grants management specialists (GMSs), reviewers, study section members, human resources staff, reviewers, research investigators, and trainees."[64] SGMRO's communication training is essentially an indoctrination tool that treats highly contested and controversial ideas as incontrovertible fact. For example, it regards sex and gender are distinct and existing on a spectrum, and "2Spirit" and "genderqueer" as natural entities. Imposing this contested worldview on the entire NIH, especially those in positions to review grants and studies, has significant implications for the type of research NIH funds.

6. Rescind the Secretary's Advisory Committee for Human Research Protection (SACHRP) guidance on working with "LGBTQI" participants in human subject research

In July of 2024, SACHRP issued controversial "Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research."[65] SACHRP falls under the Office of Human Research Protections (OHRP). OHRP is responsible for ethical guidelines for research conducted or supported by the U.S. Department of Health and Human Services. SACHRP is composed of advisory committees that develop guidance for IRB approval of ethical biomedical and social-behavioral research.

SACHRP's July recommendations include encouraging researchers to acquire waivers of parental consent for research on "LGBTQ+" minors, prevent disclosure of data obtained in children to parents, maintain secrecy that data were collected, and integrate "LGBTQ+" advocacy organizations into NIH funded research.[66] The recommendations also include involving "LGBTQ+" community stakeholders in all aspects of the research process, including the shaping of research priorities. The guidance also recommends "Establish[ing] confidential communication channels tailored for minors to express their concerns or questions about the research without fear of disclosure. This can include secure messaging systems or private, one-on-one discussions with researchers, ensuring that these methods are appropriate for younger participants based on their development stage."[67]

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63 Christopher F. Rufo, "The Murky Business of Transgender Medicine" *City Journal*, June 18, 2024, https://www.city-journal.org/article/the-murky-business-of-transgender-medicine.

64 "C3Training | DPCPSI," National Institute of Health, August 25, 2023. https://dpcpsi.nih.gov/sgmro/c3training.

65 Secretary's Advisory Committee on Human Research Protections (SACHRP), "Recommendations for the Ethical Review and Inclusion of LGBTQI+ Participants in Human Subjects Research," *U.S. Department of Health & Human Services*, July 24, 2024, https://www.hhs.gov/ohrp/sachrp-committee/recommendations/ethical-review-inclusion-lgbtqi-participants-human-subjects-research/index.html.

66 Ibid.

67 Ibid.

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While the scope of the problem is unclear, at least some researchers who have received NIH funds to study "LGBTQ+" minors have circumvented parental approval and received IRB waivers of parental consent—even before the SACHRP recommendations were formalized—despite arguably not meeting the criteria necessary to receive a waiver under the Common Rule Subpart D.

For example, in the girl2girl study (5R01HD095648-02, Eunice Kennedy Shriver National Institute of Child Health and Human Development, $1,099, 353), which is also supported by the HHS Office of Population Affairs, the methods section of an article in the *Journal of Adolescence* states that "a waiver of parental permission was granted in order to prevent disclosure of the underage participants' sexual identity to a parent, which could potentially place them at risk of physical or psychological harm."[68] This waiver was facilitated by the Advarra IRB. Under the Common Rule Subpart D, waivers are allowed under certain circumstances, but circumstances would have to suggest that a child is actively neglected or abused, not subject to hypothetical psychological harm. Another study funded by NIH regarding sexual violence perpetration among the trans-identified teens (5R01HD083072-03, Eunice Kennedy Shriver National Institute of Child Health and Human Development, $536, 422) also obtained waivers for parental permission via Advarra and Pearl IRBs citing participant confidentiality against parents.[69]

Conclusion

Under new directorship, NIH is well-positioned to lead the way in regaining public trust in the American healthcare system. Due to its outsized role in shaping the research priorities of the U.S. medical community, there is an urgent need for NIH to end ideologically driven research agendas and recommit itself to scientific rigor and merit, intellectual diversity, transparency, and evidence-based medicine.

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68 Michele L. Ybarra et al., "Girl2Girl: How to Develop a Salient Pregnancy Prevention Program for Cisgender Sexual Minority Adolescent Girls," *Journal of Adolescence* 85 (2020): 41-58, https://doi.org/10.1016/j.adolescence.2020.08.004.

69 Michele L. Ybarra et al., "Youth Characteristics Associated With Sexual Violence Perpetration Among Transgender Boys and Girls, Cisgender Boys and Girls, and Nonbinary Youth," *JAMA Network Open* 5, no. 6 (2022): e2215863, https://doi.org/10.1001/jamanetworkopen.2022.15863.