ASRS American Society of Retina Specialists

March 18, 2026

The Hon. Jay Bhattacharya, MD, PhD
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Re: NOT-OD-26-023: Request for Information on Draft NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy

Dear Director Bhattacharya,

The American Society of Retina Specialists (ASRS) is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

Thank you for the opportunity to provide feedback on the National Institutes of Health (NIH) draft Controlled-Access Data Policy and Genomic Data Sharing (GDS) Policy. ASRS appreciates NIH's efforts to protect human clinical data but is strongly opposed to these draft policies because they misinterpret the risk of re-identification of retinal images. Moreover, they would have disastrous unintended consequences, hampering clinical research and the dissemination of medical education by implementing unreasonable and unwarranted restrictions on sharing and storing clinical data. ASRS and other educational or scientific organizations will be unable to meet the onerous requirements this policy would establish.

Executive Summary
ASRS recommends NIH modify its proposed Controlled-Access Data Policy and GDS policy to **remove the classification of de-identified retinal images (fundus photography and Optical Coherence Tomography [OCT]) as restricted "biometric identifiers"** that cannot be shared for research or educational purposes without expressed patient consent or only through Controlled-Access consistent with NIH standards. In particular, these proposed policies are problematic because they:

- Misinterpret the risk of re-identification of retinal images;
- Will prevent the reasonable sharing of retinal images for medical education; and
- Will have a catastrophic impact on clinical research and innovation, particularly in new, AI-guided cures and discoveries.

20 North Wacker Drive
Suite 2030
Chicago, IL 60606

phone 312 578 8760
fax 312 578 8763
www.asrs.org

ASRS strongly recommends that NIH not move forward with these proposed policies in their current format and work with the medical community to develop a workable, risk-based alternative. Our full comments are below.

Misclassified Risk of Re-Identification - The Unique Nature of Retinal "Biometrics"
ASRS recommends that NIH not classify retinal images as biometric identifiers because they do not pose the same level of risk that other information, such as personal health information, does. While we acknowledge that retinal vasculature is unique to the individual, the context of risk is fundamentally different from other biomarkers, such as facial or fingerprint recognition.

The proposal incorrectly conflates biometric uniqueness with biometric risk. Facial recognition risks privacy because faces are public; they appear on social media and ID cards. Retinal images exist *only* in secure medical records. If a bad actor possessed a de-identified retinal image, they would have to match it against a database of identified images. This would likely mean they would have access to the original, identified medical record. If an attacker has access to the medical record, they already have the patient's identity, rendering the restriction on the image itself moot.

Threats to patient privacy are real and should be taken seriously. However, classifying retinal images as biometric identifiers would not meaningfully protect patient safety. Existing, reasonable patient consent practices that include the physician's duty to maintain patient confidentiality should be considered sufficient to protect privacy through the dissemination of retinal images. We strongly recommend NIH reverse this classification.

Negative Impact on Medical Education
Ophthalmology is a visual discipline. Retina fellows learn to interpret the subtle signs of disease in retinal images to make diagnoses by studying hundreds, if not thousands, of images. Day-to-day, retina specialists compare multiple images per patient to tailor their treatments with a specific medication administered in dosing intervals unique to the patient. To expand their clinical knowledge and advance science, retina specialists meet and publish regularly, sharing images to illustrate the topic under discussion.

Unlike internal medicine, where a patient's condition can often be summarized by lab values (e.g., HbA1c, Creatinine), retinal disease is defined by morphology. To restrict the presentation of retinal images is to effectively blind the educators of the next generation of surgeons. If NIH were to retain the classification of retinal images as biometric identifiers subject to the parameters of the proposed Controlled-Access policy, retina specialists would have no way to fulfill their educational requirements and organizations such as ASRS could not fulfil our mission of providing the forum for that education.

ASRS is an accredited provider of continuing medical education (CME). Members regularly present and publish clinical information through our scientific symposia, the *Journal of Vitreoretinal Disease, Retina Times,* and presentation materials from past events are archived on

our website. All these outlets require a member log-in, but are not protected at the level NIH proposes in this policy.

The ability to include de-identified images in educational exchange is fundamental. The information presented in the formats mentioned above is meaningless without the corresponding visual of the retinal image. This reliance on visuals is so important, in fact, that ASRS has developed the Retina Image Bank, which includes nearly 30,000 unique and downloadable images available to the retina community to advance patient care. Were NIH to implement its policy as proposed, this resource would likely no longer be available to clinicians and researchers.

Image sharing is also vital for diagnosing rare retinal conditions, such as inherited retinal dystrophies. These conditions are often seen by only a handful of specialists globally. Diagnosis and progress toward identifying treatments relies on the ability to share and compare images across borders. A biometric restriction would silo this data, halting progress on diseases that affect the most vulnerable populations.

Maintaining the classification of retinal images as biometric identifiers in the final policy will have significant negative impacts on education for the current and future workforce. Because of the low risk to patient privacy and re-identification discussed above, NIH should modify its policy and allow retina specialists and the research community to continue sharing de-identified images for educational purposes.

Chilling Effect on Research and Innovation

Recognizing NIH's guiding role at the heart of much of medicine's greatest breakthroughs, we are particularly concerned about the tremendous threat this policy would pose to future research and innovation. The greatest promise for eliminating preventable blindness lies in AI tools capable of screening populations for diabetic retinopathy, macular degeneration, and other retinal disorders.

Development of those tools is already underway but would be effectively stopped if this policy was not modified. Studies have demonstrated that deep learning systems can detect diabetic retinopathy and other retinal diseases at levels comparable to retina specialists—but only when trained on very large, heterogeneous datasets drawn from multiple clinical settings, camera types, and patient populations.[1],[2],[3] High-fidelity AI requires training on millions of diverse retinal images.

[1] Ting DSW, Cheung CY, Lim G, et al. Development and Validation of a Deep Learning System for Diabetic Retinopathy and Related Eye Diseases Using Retinal Images From Multiethnic Populations With Diabetes. JAMA. 2017;318(22):2211–2223. doi:10.1001/jama.2017.18152

[2] Gulshan V, Peng L, Coram M, et al. Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs. JAMA. 2016;316(22):2402–2410. doi:10.1001/jama.2016.17216

[3] Dai, L., Sheng, B., Chen, T. *et al.* A deep learning system for predicting time to progression of diabetic retinopathy. *Nat Med* 30, 584–594 (2024). https://doi.org/10.1038/s41591-023-02702-z

The restrictions proposed in this policy would force developers to rely on small, single-institution datasets that lack the statistical power and heterogeneity required for robust model development. Worse, patient care could suffer. Studies also show that algorithms trained primarily on homogeneous populations can underperform in rural, minority, and underserved communities. In ophthalmology, image quality, fundus pigmentation, comorbidities, and access patterns vary significantly across populations; without broad data representation, AI tools may miss disease in precisely the communities that have the highest burden of disease, exacerbating disparities rather than alleviating them. [4],[5]

For retinal AI to reach its full public health potential, researchers must be able to access large, diverse, multi-institutional datasets under appropriate privacy safeguards. As proposed, NIH's policy would prevent that exchange of information and create an insurmountable barrier to innovation and the next generation of cures. As a convener and incubator of breakthrough research, NIH must modify its policy to exclude retinal images from restrictions on sharing and controlled access.

Conclusion

The theoretical risk of re-identifying a patient from a retinal photograph—without access to their private medical record—is low. The risk of blinding patients because researchers could not validate a treatment, or because a resident could not study a disease, is a certainty. We urge NIH to reevaluate its proposal to classify retinal images as biometric identifiers to preserve retina specialists' ability to continue to innovate and educate the next generation. We stand ready to assist the NIH develop reasonable standards that protect patient privacy, while ensuring they will have access to the highest quality of care.

If you have questions or need additional information, please contact Allison Madson, vice president of health policy, at allison.madson@asrs.org.

Sincerely,

Geoffrey G. Emerson, MD, PhD, FASRS
President, ASRS

[4] Matheny ME, Whicher D, Thadaney Israni S. Artificial Intelligence in Health Care: A Report From the National Academy of Medicine. JAMA. 2020;323(6):509–510. doi:10.1001/jama.2019.21579

[5] National Academy of Medicine. 2025. An Artificial Intelligence Code of Conduct for Health and Medicine: Essential Guidance for Aligned Action. L. Adams, E. Fontaine, M. Matheny, and S. Krishnan, editors. NAM Special Publication. Washington, DC: National Academies Press. https://doi.org/10.17226/29087.