UNIVERSITY OF MICHIGAN
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Subject: Approval for Repository Continuing Review [REP00000049_CR07]

SUBMISSION INFORMATION:
Repository Continuing Review eResearch ID: REP00000049_CR07
Repository Name: U-M Ophthalmology Data Repository
Date of this Notification from IRB: 2/8/2024
Review: Expedited
Initial IRB Approval Date: 2/8/2024
Current IRB Approval Period: **2/8/2024 - 2/7/2026**
Expiration Date: Approval for this expires at **11:59 p.m. on 2/7/2026**
UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration date, please visit the UM HRPP Webpage)
OHRP IRB Registration Number(s): IRB00000244

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRBMED has reviewed and approved the repository continuing review referenced above. The IRB determined that the proposed research repository conforms with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION:
The approval period for this repository is listed above. Please note the expiration date. Note that this repository application has been granted a two year approval period as

1. the maintenance of repository data/biospecimens poses no more than minimal risk to subjects and
2. there is no federal funding associated with this research effort and
3. *there is no Certificate of Confidentiality associated with the data*

If your funding source(s) should change to include federal funding, please notify the IRB. Federally funded research must follow federal regulations, one of which is an approval period not to exceed one year. For further information, see U-M HRPP Innovation and

Demonstration Initiative at http://research-compliance.umich.edu/hrpp-innovation-demonstration-initiative.

If the approval lapses, you may not conduct repository activity, including data/biospecimen intake or disbursement procedures, until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit either a continuing review to renew the repository approval, or a termination report. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the repository. If all repository activity at U-M ends, please submit a termination report.

AMENDMENTS:
Proposed changes to the repository that relate to compliance with human subjects protections regulations, and/or with University policy, must be approved by the IRB prior to implementation through the amendment process in the eResearch Regulatory Management system (eRRM).

UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECT OR OTHERS (UPIRSOs or UaPs):
Repository directors and repository staff are responsible for notifying the IRB of any potential Unanticipated Problems in a timely manner in accordance with the terms of the IRB's approval and published IRB guidelines. Submit potential UaPs through the ORIO process in eResearch. See https://az.research.umich.edu/medschool/guidance/unanticipated-problems-involving-risks-subjects-or-others.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study (referenced above).

MORE INFORMATION ON U-M POLICIES AND FEDERAL GUIDANCE:

- U-M Human Research Protection Program (HRPP) - Operations Manual and other documents http://research-compliance.umich.edu/human-subjects.
- U-M Medical School Policies – Tissue Sample Collection, Ownership, Usage and Disposition http://msa.med.umich.edu/node/137.
- Office of Human Research Protections (OHRP) Policies and Guidance - Biological Tissues and Data - Issues to Consider in the Research Use of Stored Data or Tissues http://www.hhs.gov/ohrp/regulations-and-policy/guidance/issues-to-consider-in-use-of-stored-data-or-tissues/index.html.
- National Institutes of Health (NIH) HIPAA Privacy Rule: Information for Researchers - Research Repositories, Databases, and the HIPAA Privacy Rule http://privacyruleandresearch.nih.gov/research_repositories.asp.

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