IRBMED Record Keeping Guidelines

Records may be kept in hard-copy or electronically. Record retention must be consistent with

- IRB-approved methods for data confidentiality in eResearch section 11 and the protocol
- U-M Safe Computing guidance (e.g. Compliance and Sensitive Data Guide)
- HRPP Data Security Guidelines and Guidance on Protecting Participant Privacy and Maintaining Confidentiality of Data

Study Descriptors → **What to keep** ↓	***Federally Funded***	***All Data Abstracted from Clinical or Dental Records***	***Health Information Abstracted from Non-Clinical Sources***	***Health Related Data Collected through Interaction or Intervention with Subjects***	*Dental Research* ***Involving Interaction or Intervention with Subjects***	***Non-Health Related Data Collected through*** **Interaction with Subjects**	***Findings Submitted to FDA***	***Gene Therapy/Cell Therapy Research***
Research Records, including signed consent documents and case report forms	**3 years** from the date the grant is made or the study is completed, whichever is later	No retention requirements on records that are simply duplicates of existing clinical or dental records	**7 years** from the date the study is completed	**7 years** from the date the study is completed	**10 years** from the date the study is completed	**3 years** from the date the study is completed	**2 years** from study termination or submission (by sponsor or researcher) to FDA, whichever is later	**Forever**, until further notice
HIPAA Waiver Documentation	Included as part of the application to the IRB, stored in eResearch workspace for the study							
Record of PHI Disclosures outside the Michigan Medicine Covered Entity	Submit tracking logs for disclosures to Michigan Medicine Corporate Compliance Office in accordance with UMHS Policy 01-04-335 *(link requires level-2 or UMHS VPN)*, which shall retain the tracking information for six (6) years from the date when the information was created or was last in effect							
IRB Notice of Outcome (Approval letter; exempt or not-regulated determination)	Stored in eResearch workspace for the study • Original determination letter available in HUM workspace, "Activities and Correspondence" heading • Determination letters under Ame, CR, and Adv workspace for each subsequent submission							

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