 <b>Maine Medical Center</b>	<b>Human Research Protection Program</b> <b>Good Clinical Practice</b> <b>Research Record Keeping and Retention-</b> <b>Administrative Records Relating to Research</b>	
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**RECORD**

**RETENTION PERIOD**


**PRIMARY/SECONDARY SOURCE**

**CONFLICT OF INTEREST (COI) RECORDS**

<b>COI Records:</b> For PHS-funded research (includes all NIH awards): Records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest.	<b>At least 3 years</b> (From the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations)	<a href="#">42 CFR 50.604</a>
<b>COI Records:</b> For research funded by non-governmental sponsors	2 years (following the date a marketing application is approved for the drug; or, if an application is not approved for the drug, until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified) or not less than 7 years	<a href="#">21 CFR 312.57</a>

**INSTITUTIONAL REVIEW BOARD (IRB) RECORDS**

IRB records: Reviewed research proposals	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<a href="#">45 CFR 46.115 Protection of Human Subjects*</a> <a href="#">21 CFR 56.115 IRB Records</a>
IRB Records: Scientific evaluations	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects*</b> <b>21 CFR 56.115 IRB Records</b>
IRB Records: Approved sample consent documents	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects*</b> <b>21 CFR 56.115 IRB Records</b>
IRB Records: Progress reports	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects*</b> <b>21 CFR 56.115 IRB Records</b>
IRB Records: Reports of unanticipated problems involving risks to subjects or others	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects*</b> <b>21 CFR 56.115 IRB Records</b>

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IRB Records: Minutes of IRB meetings (as specified in 45 CFR 46.115(a)(2) and 21 CFR 56.115(2))	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects* 21 CFR 56.115 IRB Records</b>
IRB Records: Records of continuing review activities	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects* 21 CFR 56.115 IRB Records</b>
IRB Records: Copies of all correspondence between IRB and investigators	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects* 21 CFR 56.115 IRB Records</b>
IRB Records: List of IRB members (as specified in 45 CFR 46.115 and 21 CFR 56.115)	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects* 21 CFR 56.115 IRB Records</b>
IRB Records: Written IRB procedures	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects* 21 CFR 56.115 IRB Records</b>
IRB Records: Statements of significant new findings provided to subjects	At least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research)	<b>45 CFR 46.115 Protection of Human Subjects* 21 CFR 56.115 IRB Records</b>

**HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) RECORDS**

HIPAA-related documents, as specified (policies and procedures, communications etc.)	6 years (from the date of creation or the date when it last was in effect, whichever is later)	<a href="#"><u>45 CFR 164.530(j)(1)</u></a>
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**RESEARCH MISCONDUCT RECORDS**

Research misconduct proceedings records, as specified	7 years (after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation – whichever is later)	<a href="#"><u>42 CFR 93.317</u></a>
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	<p>Human Research Protection Program Good Clinical Practice <b>Research Record Keeping and Retention- Administrative Records Relating to Research</b></p>	
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**FOOD AND DRUG ADMINISTRATION (FDA) RECORDS**

<b>Investigational New Drug Applications</b>		
Records of drug disposition (to be retained by investigator)	2 years (following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified)	<a href="#"><u>21 CFR 312.62</u></a>
Case histories (to be retained by investigator)	2 years (following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified)	<a href="#"><u>21 CFR 312.62</u></a>
Records of receipt, shipment or disposition of an investigational new drug (to be retained by sponsor)	2 years (following the date a marketing application is approved for the drug; or, if an application is not approved for the drug, until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified)	<a href="#"><u>21 CFR 312.57</u></a>
Records showing any financial interest (to be retained by sponsor)	2 years (following the date a marketing application is approved for the drug; or, if an application is not approved for the drug, until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified)	<a href="#"><u>21 CFR 312.57</u></a>