**GUIDANCE 31**

 **GUIDANCE FOR RECORD KEEPING**

1. **IRB POLICY FOR RECORD KEEPING**

This guideline does not supersede Rowan University policy governing data ownership and use of social security numbers and personally identifiable information.

Data and research records must be maintained in accordance with Rowan University and Division of University Research Policies.

The IRB at Rowan University maintains all official protocol-related documents in the IRB database to meet the regulatory obligations for record keeping.

The following guidelines are provided to assist investigators and research staff with recordkeeping at various stages of human research studies being reviewed and approved.

1. **Records to keep while the study is being reviewed**

The IRB database serves as the repository of study documents submitted to the IRB. Investigators, study coordinators and study staff have full access to their studies at any time during the review process.

2. **Records to keep once a study is approved by the IRB**

a. Hard copies all approved and stamped consent forms, which includes all alternate consent forms as approved.

b. All copies of signed consent forms and records showing that a copy of the consent form was provided to the prospective research participant/subject.

c. All hard copies of approved survey instruments, questionnaires and approved material.

d. All hard copies of completed surveys and questionnaires.

3. **Protocol Modifications**

a. Keep all copies of all versions of protocols, consent forms or alternate consent forms demonstrating that the most recent versions of protocol, consent forms, surveys, questionnaires, screening instruments, advertisements/recruitment letters and other IRB-approved materials are used.

4. **Continuing reviews**

Investigators must keep copies of all documents submitted as part of the continuing review.

5. **Record Retention**

Rowan University has its record retention policy posted at https://confluence.rowan.edu/display/POLICY/Records+Retention . Retention of research records are sometimes mandated by the funding agency and FDA. Therefore, Investigators should contact the Office of Research, IRB Administration at 856-256-4078.

**6. Data Ownership**

Rowan University has its data ownership policy posted at [https://confluence.rowan.edu/display/POLICY/Data+Ownership+Policy](https://confluence.rowan.edu/display/POLICY/Data%2BOwnership%2BPolicy).

7. **Use of SSNs and PII in Human Subject Research**

Rowan University has its use of SSNs and PII policy posted at [https://confluence.rowan.edu/display/POLICY/Use+of+SSNs+and+PII+in+Human+Subject+Research](https://confluence.rowan.edu/display/POLICY/Use%2Bof%2BSSNs%2Band%2BPII%2Bin%2BHuman%2BSubject%2BResearch).

1. **GENERAL POLICY FOR RECORD KEEPING AND RETENTION**
2. It is the policy of Rowan University to comply with federal and state requirements regarding sponsored programs record retention. The policy applies to all sponsored program files regardless of where files are stored.
	1. **Federal Award Files**
	2 CFR 200.333 outlines the record retention requirements as well as the access guidelines for universities receiving grants from the federal government:
	"Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the Federal awarding agency. The only exceptions are the following.
		1. If any litigation, claim, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.
		2. Records for real property and equipment acquired with Federal funds shall be retained for 3 years after final disposition.
		3. When records are transferred to or maintained by the Federal awarding agency, the 3-year retention requirement is not applicable to the recipient.Indirect cost rate proposals, cost allocations plans, etc. as specified below:
			1. If submitted for negotiation. If the recipient submits to the Federal awarding agency or the subrecipient submits to the recipient the proposal, plan, or other computation to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts on the date of such submission.
			2. If not submitted for negotiation. If the recipient is not required to submit to the Federal awarding agency or the subrecipient is not required to submit to the recipient the proposal, plan, or other computation for negotiation purposes, then the 3-year retention period for the proposal, plan, or other computation and its supporting records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation."
	2. **State of New Jersey Records Retention and Disposition Schedule**
		1. Per the Records Retention and Disposition Schedule of the State of New Jersey, Agency number S510204, schedule number 001 and record series number 0001-0001, State, Federal and Private Grant Files that were approved should be retained 7 years after termination of the grant. After such time, unless in litigation, the files should be destroyed.
		2. Declined Files
		Per the Records and Retention and Disposition Schedule of the State of New Jersey, Agency number S510204, schedule number 001, and record series number 0001-0002, State, Federal and Private Grant Files that were denied should be retained for a period of 3 years. After such time, the files should be destroyed.
		3. Withdrawn Files
		Withdrawn files may be retained for a period of up to 1 year beyond the date of initial proposal
3. Changes to this policy will be made in accordance with federal and state requirements.