

UConn HEALTH

POLICY NUMBER 2003-42

April 11, 2017

POLICY: DATA OWNERSHIP POLICY

POLICY STATEMENT:

Research data are the foundation of scholarly work at UConn Health. In order to assure the principles of academic freedom, free publication of new knowledge and research integrity, research data must be preserved in a manner that makes them available to those individuals (faculty, students and other research staff) who provided significant input into their generation and analysis. In addition, such data must be preserved in a manner that satisfies UConn Health's legal obligations under federal and state law. It is equally important, however, that research data not be subject to premature or inappropriate disclosure. Additionally, UConn Health's ability to preserve the value of intellectual property through legal means such as patents is entirely dependent upon a complete data record. Thus, it is the policy of UConn Health that all faculty, students and staff exercise reasonable efforts to preserve research data as outlined in this document, comply with requirements of federal and state laws and/or regulations governing access to research data and refrain from capricious or unauthorized dissemination of research data. The principles below shall be adhered to in fulfilling the mandate of this policy. The UConn Health data ownership policy shall be distributed to all members of research groups and the principal investigator (PI) should discuss with each member of the group policies specifying the rights and responsibilities of those participating in the research, with respect to access, custody and publication of research data and materials generated as a result of the research activity.

Definitions

Research Data – recorded information necessary to validate or reconstruct research findings. Examples of research data include but are not limited to field notes, completed questionnaires, data abstraction forms, laboratory notebooks, patient charts, cage cards, audio tapes, video tapes and electronic data files. Research materials and devices include but are not limited to chemical or biological reagents, field specimens, devices and copyrightable instruments used in the collection of data (e.g., questionnaires, scales, psychosocial assessment and personality inventories, etc.), created as a result of research. Research materials and devices are considered property, not research data.

Principal Investigator (PI) – the person, usually a faculty member, who is the senior member of a research team, responsible for proposing, conducting and administering research by that team. In large, multidisciplinary research programs funded by mechanisms such as program project or

center type grants, the PI is generally the person responsible for one of the component projects of the program.

Collaborators: Individuals engaged in a joint intellectual effort on a given research project. These individuals may include but are not limited to scientists, engineers, physicians, students and trainees and other health care providers from diverse multidisciplinary fields.

Principles

1. Research materials, inventions or devices developed through the use of UConn Health resources are the property of UConn Health. Rights to such property may be transferred to other parties (such as commercial sponsors) with the express written authorization of UConn Health. Copyrightable materials are generally not the property of the University.
2. With the exception of the situations described in paragraph (5) and (6) below, research data are considered the property of the PI, or the joint property of collaborating individuals when research data are generated by a principal investigator working with collaborators. Research data generated by postdoctoral fellows, graduate students, research trainees or others who have had significant intellectual input, shall be considered the joint property of the collaborating individuals. The individual named as PI by the organization sponsoring the work shall, however, retain the principal responsibility for custody of the data. Where permitted under this policy, only a copy of the research data may be taken by the PI, or by a collaborating individual.
3. The PI will assure the safe and orderly collection and management of research data. The data must be retained for a minimum of three years after the “final closeout” of grants or contracts that supported the research generating the data. In addition, data must be retained for as long as may be necessary to allow students to complete degree requirements; to protect intellectual property resulting from the work; and/or to allow completion of any administrative actions (e.g., research misconduct investigations or litigation) involving the research.
4. Research data subject to a research sponsor’s disclosure requirements, such as outlined in the federal OMB Circular A-110, the Public Health Service Grants Policy Manual (or other such policies) represent special situations which place obligations for the stewardship of research data on the Health Center. Data generated in projects supported by grants or contracts containing such provisions shall be jointly owned by UConn Health and the PI. UConn Health shall have an irrevocable right to obtain such data from the PI at any time, even if that individual has left the institution. Custody of the data will continue to be the responsibility of the PI.
5. Research data may not be released for publication or for commercial uses without the expressed permission of all individuals who made significant intellectual contributions to the project. In case of dispute, the Vice President for Research (VPR) will appoint an ad hoc faculty committee of three to make recommendations to the VPR to resolve the dispute.

6. Any research data that includes Protected Health Information (PHI) as defined by the HIPAA Privacy Rule may not be transferred/disclosed outside of UConn Health until the IRB determines whether to issue a waiver of HIPAA Authorization¹ or to require that each study subject authorize the transfer or disclosure. When disclosure of PHI is permitted by the IRB, only a copy of the research PHI may be taken by the PI, or by a collaborating individual.
7. When a contractual agreement is established between a principal investigator and consultants, service facilities, or other individuals or corporations, the research data resulting from the contractual relationship remains the property of the principal investigator, and the research materials, inventions or devices resulting from the contractual relationship remain the property UConn Health unless otherwise specified in the contractual agreement.
8. Nothing in this policy shall be construed as negating State, Federal or University policies regarding patent rights.
9. Nothing in this policy shall be construed as interfering with the investigation of alleged misconduct under the policies of UConn Health, including the responsibility of whistleblowers to sequester data in good faith that relate to allegations of research misconduct.

Jeffrey Seeman (Signed)

5/11/17

Jeffrey Seemann, PhD
Vice President for Research

Date

New Policy: 10/1/03

Revised: 4/11/17

¹ 45 CFR 164.512(i) Waiver of Authorization – Permission granted by the IRB to a researcher on a case by case basis to access PHI without patient consent if:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.