Responsible Office:

Office of the Vice Provost for Research February 19, 2019

Effective Date: February 19, 2019 Revision Data: February 15, 2019

INTRODUCTION

Consistent with the University's overarching goals of creation and dissemination of knowledge, it is important that research data be shared and distributed openly. There may be legitimate and compelling reasons why data must be kept confidential; for instance, when its release would reveal proprietary ideas and techniques of researchers and their partners or when it includes personal information regarding individual research subjects. There are also circumstances when questions arise regarding the ownership of the data generated from research projects, with one party claiming full ownership and preventing its use by other collaborators. These disputes often result in complaints and lengthy investigations, or even litigation, with lasting negative effects on all participants. In the most deleterious cases, withholding of data has delayed students in completing their theses and receiving their degrees. The University has the proper resources to secure and manage research data, as well as protect associated intellectual property rights, and therefore is the appropriate administrator of such data.

Consequently, the rights, responsibilities, and principles that determine how research data should be handled ultimately belong to the University. This is true as a matter of federal law and regulation in the case of federally sponsored research, as a contractual requirement when collaborating with many public and private organizations, and as a matter of good stewardship in all other cases. These rights and responsibilities are, of course, shared with the faculty and other researchers who generate and acquire the research data and who work with it directly.

Ultimately, the University is responsible for complying with laws, regulations, and requirements of its research sponsors, many of which pertain to research data. To ensure its ability to satisfy those requirements, the University asserts ownership over research data generated at Harvard for projects conducted at the University, under the auspices of the University, or with University resources. Although the University is the owner of all such research data, sound management practice and common-sense call for the University and researchers to work in partnership to fulfill these obligations. This policy defines "research data," assigns roles and responsibilities to key actors, and describes its relationship to other relevant University policies.

POLICY STATEMENT

The University asserts ownership over research data for projects conducted at the University, under the auspices of the University, or with University resources.

Nothing in this Data Ownership Policy is intended to supersede or contradict any portion of the <u>University Statement of Policy in Regard to Intellectual Property</u> (the "IP Policy"). To the extent that any research data, as defined below, also qualifies as any defined term in the IP Policy (including without limitation "Supported Invention," "Incidental Invention," "Unpatented Materials," "Sponsored Computer Software," or "Sponsored Computer Invention") all terms of the IP Policy shall apply.

DEFINITIONS

Pursuant to the <u>General Record Schedule</u> and the Office of Vice Provost for Research's (OVPR) <u>Guidance on</u> Retention and Records of Research Records and Data, "research data and materials" is defined as follows:

Research Data and Materials include recorded, tangible, or intangible research information, regardless of form or the media on which it may be recorded, that is created or collected in the process of performing research, whether supported by University resources or by external funders. Research Data and Materials include, but are not limited to, computer software (computer programs, computer databases, and documentation thereof), materials such as unmodified and modified biological

specimens, new or modified chemical entities, laboratory notebooks, notes of any type, materials submitted to and/or approved by IRB, IACUC, or other research oversight committees (e.g., applications, outreach/advertising materials, consent forms, survey routines/questionnaires and debriefing scripts), photographs, films, audio recordings, digital images, original or modified biological and environmental samples, gels, spectra, cell lines, reagents, protocols, algorithms, graphs, charts, numerical raw experimental results, instrumental outputs, other deliverables under sponsored agreements; intangible data such as statistics, findings, conclusions, other deliverables under sponsored agreement; and any other records of, or in any form that could be used for, reconstruction and evaluation of reported or otherwise published results of research.

POLICY AND PROCEDURES

1. OWNERSHIP AND ROLES

A. <u>The University</u>: The University asserts ownership over research data for all projects conducted at the University, under the auspices of the University, or with University resources.

B. <u>Principal Investigators</u>: Principal Investigators (PIs) and other researchers are stewards and custodians of research data. However, if PIs choose to delegate responsibility within their research groups, the PIs remain accountable to the University for the stewardship of research data.

Research data may be made available to other members of the Harvard community and/or to research collaborators at other institutions, as appropriate, within the discretion of the PI, and subject to the terms of any applicable data use agreement (DUA), or other governing agreement, which outlines the security and confidentiality requirements and other terms of any sponsored agreement or human-subjects protection requirements. When it is necessary to secure access (e.g. during an investigation of alleged research misconduct) the University may take custody of research data in a manner described in the relevant research integrity policy or as directed by the Vice Provost for Research.

2. RESPONSIBILITIES

Harvard's responsibilities with respect to research data include, but are not limited to:

- i. Ensuring compliance with the terms of research agreements;
- ii. Protecting the rights of researchers, including, but not limited to, their rights to access to data from research in which they participated;
- iii. Securing intellectual property rights;
- iv. Facilitating the investigation of charges such as research misconduct or financial conflicts of interest;
- v. Maintaining appropriate confidentiality and security protections over research data; and
- vi. Complying with applicable federal, state, and local laws and regulations.

The University's rights and obligations are not subject to negotiation and may not be altered in any agreement or proposal prepared by any faculty member or administrator.

The PI's responsibilities with respect to research data include, but are not limited to:

- i. Ensuring proper management and retention of research data in accordance with this policy and the Guidance on Retention and Records of Research Records and Data.
- ii. Establishing and maintaining appropriate procedures for the protection of research data and other essential records, particularly for long-term research projects;

- iii. Ensuring compliance with program requirements;
- iv. Maintaining confidentiality of research data, where appropriate;
- v. Maintaining appropriate data use agreements for the sharing of research data, and
- vi. Complying with applicable federal, state, and local laws and regulations.

3. Data Retention

Harvard's policies and the retention of research data and materials are set forth in the <u>Guidance on Retention and Records of Research Records and Data</u>.

4. Transfer in the Event a Researcher Leaves Harvard

If a PI leaves Harvard and a project is to be moved to another institution, ownership of the original data may be transferred from Harvard to the PI's new institution upon request from the PI subject to: (a) the prior written approval of the Vice Provost for Research; (b) written agreement from the PI's new institution that guarantees (1) its acceptance of ongoing custodial responsibilities for the data and (2) Harvard having access to the original data, should such access become necessary for any reason; and (c) relevant confidentiality restrictions, where appropriate.

When individuals, other than PIs, who have been substantively involved in research projects at Harvard leave the University, they may take with them copies of research data resulting from these projects, subject to relevant confidentiality restrictions and any requirements of the original research project, and conditioned upon the approval of the individual's Department Chair or Dean. In this event the ownership of the research data remains with the University and original data must be retained at Harvard by the PI.

In either of these instances, the remaining members of the research team retain the rights to use the original data. Any publications resulting from the data will be subject to the Harvard University Authorship Guidelines as well as the specific requirements of the journal in which publication occurs.

RELATED POLICIES AND INFORMATION

Harvard Policies and Guidance Documents:

Guidance on Retention and Records of Research Records and Data

Policy in Regard to Intellectual Property.

Harvard Research Data Security Policy

Harvard University Publication Guidance

Open Access policies

Federal Regulations and Policies:

<u>2 CFR 200.315</u>; <u>45 CFR 75.322</u>: Rights in intangible property acquired under federal awards belong to the institution as the grantee.

<u>NIH Grants Policy Statement §8.2.1</u>: "In general, [grant] recipients own the rights in data resulting from a grant-supported project."