

# Guidelines for Attribution of Credit and Disposition of Research Products

## INTRODUCTION

Over the last two decades, the Harvard Medical School Faculty Council has approved a series of guidelines relating to scientific conduct, conflict of interest, and authorship, developed to create a consistent set of policies that apply to all faculty, trainees, and staff. This document presents similar guidelines for the appropriate attribution of credit and disposition of research products. These guidelines are intended to apply to research products in the broadest sense and to encompass research activities and materials spanning a continuum from quantitative analysis of experimental data to qualitative interpretation of anthropological narratives.

Conflicts over the attribution of credit and disposition of products can arise as a result of legitimate differences of opinion over the relative importance of individual contributions to a research program, over the timing or circumstances that led to a discovery, or as an outgrowth of a breakdown in communication among colleagues. Conflict may arise when scientists who have worked together separate because one of them leaves the institution or establishes independent research activities. In such cases it is particularly important that these guidelines not be unduly influenced by academic rank or laboratory seniority or position. As enumerated in the existing policies, frequent discussion before, during, and after the conduct of research can prevent potential conflicts. However conflicts still may arise, and these guidelines, along with the previously published Faculty Policies on Integrity in Science, are designed to provide a framework for conflict resolution. Implementation of these guidelines and, generally, resolution of conflict are ordinarily best carried out at the laboratory or clinical unit level.

It should be noted that these guidelines do not address issues of legal ownership of data and materials among collaborators. Legal ownership of research data and materials produced in the course of an institution's research activities resides with the institution, either the Medical School or the affiliated hospital or research institution, and not with the individual investigator.

It should also be noted that on March 1, 2002, the National Institutes of Health (NIH) issued draft guidelines for data sharing which would require that applicants for federal funding submit a data sharing plan at the time of grant submission or an explanation as to why data sharing is not possible. The draft NIH guidelines are found at

[http://grants2.nih.gov/grants/policy/data\\_sharing/index.htm](http://grants2.nih.gov/grants/policy/data_sharing/index.htm).

## A. COLLEGIALLY IN RESEARCH

When disagreements arise over the maintenance and disposition of research materials, data and related publications and/or inventions, the effectiveness of those involved inevitably suffers. The rancor that can result undermines not only the good will but also the productivity and reputation of those involved, as well as of their community of peers. Misunderstandings and failed communication nearly universally underlie such disagreements. Many past conflicts involving research data and intellectual property might have been dissipated -- or averted entirely -- by early clarification of the prevailing standards of the group together with a clear explanation of the manner in which the

group was to interact with the broader academic community as well as with the sponsors of the research. The ability to rely upon a previously articulated and impartially applied set of standards should greatly reduce the potential for conflict.

Confidence in impartiality depends to a great degree upon the uniformity with which policies are applied and the transparency of the process that leads to their implementation. Science and society can be expected to create new situations unanticipated by those who frame guidelines, so the first injunction and most important principle of these guidelines is to be collegial: to communicate, be reasonable and be fair. While implementation of policy entails more than the articulation of a few general precepts, the principle of collegiality is at the heart of all of the specific prescriptions that follow. This principle suggests:

1. that research teams should discuss data handling, credit, publication, disposition of data and research materials, and future directions of the research early in the course of their work. The goals of the unit should be clear and shared with all members. Transparency and fairness in the application of standards are essential to prevent breach of confidence. To promote this, policies should be shared with every member of a research unit -- at entrance, at intervals, and when the composition of the group or its direction change.
2. that disputes are best settled locally by the several involved parties and the laboratory or unit chief. If such efforts fail, then there are other pathways for dispute resolution (see Section G below).
3. that each group should post its policies and discuss them as part of orientation of new members.
4. that disposition of research materials should be a component of research-ethics courses offered to or required of faculty, fellows and staff at Harvard Medical School.
5. that policies should be reviewed regularly, as scientific investigation and distribution practices change.

## B. GUIDELINES FOR ATTRIBUTION OF CREDIT

### 1. **Authorship**

"Authorship is an explicit way of assigning responsibility and giving credit for intellectual work."

The conduct of a scientific experiment or other research project has many components, including formulation of a hypothesis, development or application of methods, collection of data, analysis of results and creation of a public description of the work. To the degree that contributions to any of these components require not only technical skills but also intellectual input, they are appropriately recognized by authorship. However, authorship does not imply any legal ownership of an idea, method, research materials or data.

### 2. **Use of Published Data**

All participants in a scientific process should have the ability to use published data resulting

from that work in future development of their own research objectives, including use of such data in both publications and grant proposals. Reproduction of figures, quotation from texts, and other usage of published work should be appropriately acknowledged. If substantial portions of the work of others is to be included (entire charts and figures, long quoted passages, photographs) then copyright permission should be obtained.

### **3. Use of Unpublished Data Generated by HMS Investigators**

Unpublished data should be considered products of a work in progress and/or supplementary material supporting the conclusions of a research publication. Such data can be the subjects of legal action and must be treated with the same attention to preservation and protection from corruption as published data. Guidelines for the use of unpublished data, including use in publications, grant applications, and in future works should be explicitly established whenever investigators leave institutions, establish independent research activities, or otherwise have a change in their relationships. In general it is difficult to prescribe broadly applicable principles for the use of unpublished data beyond the suggestion that all parties behave as though continuing in a collaborative and mutually beneficial research exercise. Although participants in a research project often have access to more information and insights than external parties, it is a general principle of these guidelines that in subsequent independent research activities, former participants be no more restricted in the scope of their activities than any investigator unaffiliated with the research group.

### **4. Use of Proprietary Data Supplied by Others**

Non-laboratory data used in health services research, clinical trials and observational epidemiological research falls in two broad categories: existing and secondary data sets from federal, state or private organizations and new or primary data derived directly from subject or patient contacts or through their health care providers with their permission. Some existing and secondary data sets are completely in the public domain and can be purchased or obtained by any party without special permission or agreements. In these instances, simply telling a requestor how to obtain the data set should be sufficient. In other cases, secondary data sets are privately-held (e.g., by a health insurance company) or available from a government agency only after researchers meet specified privacy and security provisions, pay certain fees, or agree to other restrictions. In both instances, the organizations or agencies providing the data typically restrict investigators' scope of inquiry (e.g., researcher can only perform pre-specified analyses using the data sets), length of time that investigators may retain the data, and explicitly prohibit transferring the data to another party. Researchers, therefore, are prohibited from sharing the data. Before entering into this kind of restrictive agreement, investigators should consult with the appropriate officials at their institution. In addition, whenever possible, investigators should facilitate requests by indicating the source of the data sets, contact information, and the nature of restrictions of the use of the data. Obtaining the data then becomes the responsibility of the requesting party.

### **5. Intellectual Property**

Authorship is not the same as inventorship or entitlement to copyright; the latter have a legal definition under federal statutes, whereas the former does not. Thus legal tests must

be applied to determine who among the authors or other contributing parties are inventors and/or entitled to copyright and who are not. Under most situations inventors and copyright holders will be authors, but authors need not be inventors or copyright holders. In addition, inventors must be mindful of their obligations to assign their rights to their employing institutions.

## C. DISPOSITION OF RESEARCH PRODUCTS

### 1. General Principles for Sharing of Material Research Products

Academic scientists bear a responsibility for the provision of information and materials to qualified investigators for the purposes of replicating, extending, or testing the results and methods reported in a research publication. This responsibility includes the extension of materials and methodological detail in sufficient quantity and quality to allow the recipient to carry out the experiments reported in the publication. It also includes provision of materials and information to allow the recipient to carry out novel studies founded on the reported work. Any reasonable request for such materials and information should be honored as a matter of course, and the burden for justification of any denial of such a request, or failure to comply within a reasonable period of time, rests on the party creating the materials and information. Investigators should consult with their institutional technology-transfer offices for guidance in the appropriate procedures for transferring materials and data. In some situations, existing material transfer agreements or prior or potential licensing rights may require limitations on the use of materials by others.

### 2. Acceptable Grounds for Denying a Request

Acceptable grounds for denying a request include:

- a. that the satisfaction of the request would compromise existing legal agreements or binding obligations of the institution or would violate local, state or federal statutes or regulations that prevent the disclosure of certain data or the transmission of regulated materials.
- b. that the recipient or recipient's institution is unwilling to abide by the terms imposed by a materials transfer agreement between the host institution and the recipient or recipient's institution.
- c. that provision of the materials would allow substantial inference of the identity of any of the participants of a study involving human subjects (see below). Investigators should keep abreast of evolving federal and state regulations protecting the privacy of human subjects.
- d. that the requested information exceeds the quantity and quality necessary to replicate the reported data.
- e. that the request calls for materials that require an unreasonable consumption of a reagent that is difficult to prepare. In such a case the responding investigator should provide the materials and information needed to create the reagent.

f. that the request has a scope beyond the ordinary capacity of an academic laboratory to provide, e.g., a collection of samples representative of a broad array of a group's accumulated research materials.

g. that the request is for an unpublished resource that can reasonably be expected to be made the subject of a future publication.

h. that the information requested includes implementation-specific assistance that may go beyond the expertise or reasonable assistance expected of the provider, for example, in the adaptation of software to other system configurations, the provision of source-code documentation or related aids to interpretation of software implementation, or the adaptation of innovative instrumentation designs or analogous underlying methodologies.

i. that the materials and/or data being sought are clearly being requested for non-academic purposes, and the investigator is not legally required to provide the materials and/or data.

### **3. Unacceptable Grounds for Denying a Request**

Unacceptable grounds for denying or unreasonably delaying a response to a request include:

a. that the provision of the materials and information would allow the recipient to compete directly with the person or group providing the materials.

b. that the materials and information have a commercial value that would be eroded or compromised by transmission of the materials to others.

c. that the provider has made personal commitments to another party or parties not to release the materials or information (this does not apply to institutional commitments). In the event that the requested materials incorporate a third party's materials for which only verbal agreements are made, it may be appropriate to send the requestor to the third party.

Compensation for the provision of materials, to cover the expenses involved in preparing, documenting and shipping materials, can be requested in the amount appropriate to such provision. If more than incidental costs are involved, the investigator should seek guidance from the institutional technology transfer office. Compensation should not take the form of inappropriate intellectual attribution, for example in the form of an authorship request. Request for unreasonable compensation should not be used as a means to prevent or restrain dissemination.

## **D. RETENTION OF DATA AND DATABASES**

### **1. General Principles**

"Primary data should remain in the laboratory at all times and should be preserved as long as there is any reasonable need to refer to them ... a minimum of 5 years from the first major publication or completion of an unpublished study."

Provision of grants, contracts, or other research support to academic institutions usually takes place within the context of a legal agreement between the sponsor and the institution. Although in some cases it is possible to arrange for the responsibilities of the institution to be transferred when an investigator leaves to conduct research elsewhere, in general the obligations of the institution to the sponsor do not terminate with the departure of an investigator. Among those obligations are often

duties to preserve data, to protect intellectual property and to honor various agreements for the disposition, preservation, or destruction of materials (for example if they have been provided by the sponsor). Thus when any investigator or other research participant leaves the laboratory, the primary data remain the property of the institution and should remain there. Copies of laboratory notebooks, electronic media, source-code, and other records of research, as well as appropriate quantities of research materials, can, at the request of departing or former participating investigators, be made as needed and removed with the permission of the laboratory director and the assent of the institution, but the original data should under most situations remain. Archival systems should be in place to preserve the data and other laboratory records.

## **2. Databases Bearing Information on Human Subjects**

Databases that contain information about human subjects require careful attention to identifiers and information that could lead to the identification of the subjects. It is appropriate to release only aggregated data describing the study population or subpopulations if use of the original data could lead to a substantial inference of the identity of any of the participants. These precautions are especially important where genetic data and family histories are involved, but should be applied as a matter of course whenever a medical record of significant complexity is present in the data. Investigators should be mindful that the transfer of any data that potentially contains human subjects identifiers (including coded data if the code link still exists) requires Institutional Review Board (IRB) review and approval. Specific attention must be made to ensure that, when appropriate, the informed consent includes the fact that an individual's data may be disclosed to other investigators. Investigators should consult with appropriate institutional officials to ensure that their informed consent documents comply with current privacy laws and regulations.

## **3. Departure of a Principal Investigator of a Multi-Dimensional Grant**

Complex data sets may be generated through collaborations between principal investigators underwritten by multiple grants from different funding sources. The departure of one or more of the participating investigators should not result in any compromise of the integrity of the research. It is the institution's responsibility, as delegated to the department heads and through the department heads to the principal investigators, to work out, as appropriate, ongoing collaborative arrangements that allow the departing principal investigator continued intellectual input into projects in which they have been involved. This may be satisfied by the provision of copies of the data applicable to specific projects or by arrangements to permit continued access to data files in the institution(s) with which the data remain. However the departing principal investigator in a collaborative study does not have an intrinsic right to a copy of all data collected by the entire investigative team. In general, continued involvement after departure as discussed below should be encouraged.

## **E. RESPONSIBILITIES OF INVESTIGATORS UPON SEPARATION**

When investigators leave a group there can be a tension between the departing and remaining investigators as well as between such investigators and sponsors of the research that arises from the possible formation of a competitive relationship. Insecurities on both sides may relate to the unusually close relationship that has existed and the opportunities that each side has for exploiting unpublished research information or materials in competitive or antagonistic ways. These

insecurities, coupled with the difficulty of providing an objective assessment of the relative value of each individual's contribution, can make difficult the division of labor and appropriate conduct of subsequent research. However the fair and open discussion of issues related to future research effort can greatly mitigate conflict and can suggest opportunities for collaborative, rather than competitive, relationships. Senior investigators in particular should recognize the conflict inherent in their potential roles as mentor and competitor and should not seek agreements in which the departing investigator is at a greater disadvantage than a competing investigator at a distant institution. Ongoing intellectual input to existing projects developed with the contribution of an investigator who leaves the laboratory should be encouraged. However, as that investigator's role changes with time following departure, he/she should not expect recognition to continue at the same level.

There is also a responsibility incumbent upon the remaining investigators to continue to involve departing investigators to a mutually agreed-upon degree in projects ongoing at the time of the departure. This may take the form of extending a continued opportunity to provide intellectual input into the project, to the degree that the departing investigator is able and willing to produce analyses, review drafts of manuscripts describing the work, and speak publicly, in mutually agreed-upon forums, about the data. As interests diverge, less involvement over time is anticipated.

## **F. SOME ILLUSTRATIVE EXAMPLES**

Cell lines, viruses, DNA, antibodies, other proteins, animal strains, laboratory protocols, computer source-code, primary and refined data, and databases and their definitions (not containing substantial medical information - see below) are all research materials and information that, unless subject to institutional agreements that identify them as proprietary materials or information, should be made available, as a matter of course, subsequent to any publication reporting results that are dependent on those materials and information. If a material resource is difficult to prepare, such as a purified protein, the investigator who has reported the work should provide the cell lines, methods, and specialized intermediate materials, if any, to allow the requestor to prepare the resource as reasonably expediently as possible. For example if the investigator does not wish to provide antibodies, the hybridoma should be made available. An acceptable method for the provision of materials is by contract with a commercial vendor (executed through the institutional technology transfer office); however the existence or anticipated execution of such a contract should not be used to deny or unreasonably delay the fulfillment of a request. Sponsored-research agreements that do not provide a pathway for obtaining research materials after publication are antithetical to the principles of these guidelines, as well as to the principles of other documents such as the DHHS and NIH "Principles and Procedures for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Recourses" and the policies of many foundations and international funding organizations, and should be avoided.

With regard to primary data sets, issues of confidentiality of both identity and consent for the use of the data require special consideration. If an outside request is made, an investigator who wishes to collaborate with the requesting outside party must insure that the data that have been received or collected subject to a formal data use agreement are released only if the terms of the data use agreement permit the specific release, and then under the terms of the agreement. Data that have been received subject to informal agreements should be handled in accordance with the spirit of

those agreements. Data sets that contain identifiers or potentially identifying information must be redacted before they are released. In cases in which repeated measurements have been made on subjects or patients over time, adequate documentation of databases and continued involvement of the primary investigators will generally be necessary to avoid potentially wasteful use of resources. Because observational studies are not planned experiments, repeated analysis of the same data without prespecified additional hypotheses will not necessarily contribute to the advancement of knowledge, and should be discouraged. There are times, however, when replication of the published analysis is needed and for these occasions (for example when major public policy decisions are to be made) selected data sets with adequate documentation can be created.

## **G. RESPONSIBILITIES OF THE DIVISION OR DEPARTMENT**

### **1. Distribution of Guidelines**

The division or department should insure that these guidelines are distributed to all faculty and other members of the division or department and that all faculty and members of the division or department (including students and trainees) have an opportunity to discuss them among themselves and with the department or division leader.

### **2. Dispute Resolution**

Even under the best of circumstances, conflicts over intellectual property ownership and data collection or analysis may occur. It is the responsibility of the laboratory or clinical unit director to attempt to mediate promptly any such disputes. Consultation with the Office of Faculty Affairs can provide assistance in this effort. When the laboratory or clinical unit director is directly involved, the Department Chair should be promptly informed.

## **H. RECOMMENDED PATHWAYS FOR RESOLVING DISPUTES CONCERNING ATTRIBUTION OF CREDIT AND DISPOSITION OF RESEARCH DATA AND MATERIALS**

Conflicts arising over attribution of credit and disposition of research data and materials frequently differ fundamentally from conflicts that are founded in allegations of scientific, fiscal or interpersonal misconduct because conflicts over credit and future research scope can be attributable to legitimate and unresolved differences of opinion over the relative importance of individual contributions. There is no single pathway prescribed here for addressing disputes concerning attribution of credit and disposition of research data and materials nor would such a pathway be appropriate. Not only are the facts of such disputes highly variable, but they often involve miscommunication or misunderstanding and not fault or misconduct. As a result, there is an expectation that, if at all possible, these kinds of disputes should be resolved informally at the local level. If contractual obligations are involved, assistance should be sought from appropriate institutional administrators.

However a local resolution acceptable to all parties is not always possible. In such instances, it is important that the parties, and in particular those who are more junior in status, have other pathways open to them in the event that local dispute resolution fails. The following resources are available for dispute resolution.

### **1. Informal Resolution at the Laboratory/Clinical Unit Level**

It is expected that most disputes will be resolved at this level.



## **2. Informal Resolution at the Departmental Level**

If the dispute cannot be resolved at the local level, it is the responsibility of the Department Head or his/her designee to take the lead in effecting a resolution of the dispute, assuming that the Department Head is not a direct party to the dispute and does not have a conflict of interest.

## **3. Informal Resolution at the School/Hospital Level**

If the Department Head is not able to effect a resolution or the Department Head is a party to the dispute or has a conflict of interest, various officials in the School and in the affiliated institution may appropriately work to resolve the dispute informally. These officials include, but are not limited to, the HMS Ombudsperson, designated members of the Office of the Dean (including the Office for Faculty Affairs, Office for Graduate Programs, and Office for Student Affairs), affiliated institutions' CEOs, Hospital Chief Medical Officers, General Counsels' staffs, and Research Administration officers. These officials should also be available for review and counseling throughout the dispute process.

## **4. Voluntary Mediation**

With the consent of all parties in conflict, a mediator identified by common accord works in a structured way to reach a mutually accepted resolution.

## **5. Voluntary Binding Arbitration**

With the consent of all parties in conflict, one or more arbitrators reviews the facts and determines the appropriate resolution. The decision of the arbitrator is binding and final, and no further recourse is available to dissenting parties.

## **6. Formal Committee Process**

In some disputes the appropriate institutional officials may determine that a formal committee review process is necessary. A committee is more likely to be formed if there is a possibility that institutional policies have been violated. Depending upon the parties involved and the circumstances of the case, the formal process may be conducted pursuant to appropriate policies including the Principles and Procedures for Dealing with Allegations of Faculty Misconduct, the Procedures for Resolving Complaints of Discrimination, Harassment, or Unprofessional Relationships and Abuse of Authority, the Policy on Student Conduct and Responsibility, and/or appropriate policies and procedures of affiliated institutions.

## **7. Conclusion**

While there is not a single prescribed pathway for resolution of disputes involving attribution of credit and disposition of research data and materials, it is important that all members of the HMS community understand that these disputes are taken seriously, that there are ways to prevent them from arising, and that multiple pathways are available to resolve such disputes.