

Policy on Transfers to Third Parties
Of Tissues, Other Specimens, and Data
Obtained by Mass General Brigham-Affiliated Providers from Patients and
Research Subjects

I. INTRODUCTION

The study of materials –including tissue, DNA, blood and serum, and research and clinical data – derived from patients as well as study volunteers can be critical in furthering biomedical research and education, and thereby advancing the prevention, diagnosis and treatment of disease. Scientists at Mass General Brigham Hospitals and elsewhere are spending increasing time and effort in studies that require access to such human specimens and data. The conduct of these studies often includes collaborations with scientists in other academic institutions and in industry, particularly when using cutting-edge, expensive technology developed primarily by for-profit entities. These collaborations often require the transfer of specimens and/or data outside of Mass General Brigham Hospitals to other academic health centers as well as to industry. This raises ethical, moral, legal and other issues. The purpose of this Policy is to assure that the appropriate standards and processes are in place for such transfers.

Of course, it is impossible to anticipate every scenario that might occur, and therefore this Policy does not attempt to provide answers to all possible situations. Rather, it articulates governing principles and provides guidelines (supplemented by attached examples), and also articulates a decision-making process for unclear cases.

II. DEFINITIONS AND GENERAL PRINCIPLE

This Policy applies to the transfer of Clinical Specimens, Research Specimens, and Patient Data to any outside person or entity.¹ “Clinical Specimens” refers to tissues, blood, serum, DNA and other biological materials that are obtained from patients at Mass General Brigham-affiliated Hospitals (or from patients of Mass General Brigham-affiliated physicians) *as part of their regular clinical care*, but that are in excess of clinical need and would otherwise be discarded or archived. “Research Specimens” are tissues, blood, serum, DNA and other biological materials obtained either (i) from individuals who are participating in clinical research and who agree to donate such materials for research or tissue repositories; or (ii) from individuals who are receiving clinical treatment and who agree that extra of such materials may be taken and donated for research or tissue repositories. (Clinical Specimens and Research Specimens are sometimes collectively referred to in this Policy as “Specimens.”) “Patient Data” is data obtained from patients as the result of their

¹ For the purpose of this Policy, the term “transfer” is not intended to include providing Specimens to outside entities for the sole purpose of the outside entity performing lab tests or other similar sorts of services or analysis for the patient care or other charitable use by Mass General Brigham or its physicians. While such arrangements generally should be covered by an appropriate agreement, they are not intended to be covered by this Policy.

clinical care or from patients or human subjects as a result of their participation in research activities, including tissue repositories (“Patient Data”).

The general principle underlying this Policy is that the transfer to third parties of Clinical Specimens, Research Specimens, and Patient Data must be done as part of an activity that is consistent with, and in furtherance of, the charitable missions of Mass General Brigham and its affiliated Hospitals – patient care, biomedical research and education. In addition, the transfer must be done in a manner that is consistent with applicable law, including those laws and regulations governing patients’ privacy, the processes of informed consent, and other rights.

III. UNDERLYING ASSUMPTIONS

All of the subsequent sections of this Policy are based on the following underlying assumptions:

- A. Regulatory Requirements: The transfer of Specimens and Patient Data must comply with applicable regulatory requirements, including, for example, requirements relating to informed consent (or approved waiver of informed consent) and authorization; other requirements of the Common Rule and the HIPAA Privacy Rule; and all pertinent institutional policies.
- B. Absence of Conflict of Interest. Any physician or investigator involved in obtaining Specimens, or in obtaining informed consent for procuring or transferring Specimens, or in providing Specimens to a for-profit company or other entity, may not have any financial interest in that same entity that exceeds the allowable *de minimis* thresholds for participating in clinical research under existing institutional conflict policies.² In addition, such a physician/investigator may not have a fiduciary relationship³ with a for-profit entity-recipient of Specimens. Other restrictions may apply as determined by the IRB, the Committee (described below in III.), or by other institutional review processes. Financial and fiduciary relationships of physician/investigators who have responsibility for managing or controlling the procurement or transfer of Data raise the same concerns and are therefore subject to the same restrictions. Cases in which there is a question as to whether an individual has such management or control responsibility shall be referred to the Committee.

² This Policy adopts that rule even for situations that may not technically constitute “participating in clinical research” under the Harvard Medical School conflict of interest policy. With respect to the *de minimis* thresholds, under current conflict policies the thresholds are \$20,000 in income per year, or equity that meets all of the following: (i) is in a publicly-held, widely traded company; (ii) the value of the equity does not exceed \$30,000; and (iii) there is no relationship between acquisition of the equity and the research to be conducted. See more specifically <http://www.hms.harvard.edu/integrity/conf.html>.

³ A fiduciary relationship is created when one serves on the Board of Directors or has an executive position with a company. Fiduciary relationships create legal obligations of loyalty toward the company and legal obligations to look out for the best interests of the company; hence they are considered to create particularly problematic conflict concerns because those fiduciary obligations may conflict with obligations that physicians and other investigators may have to their Mass General Brigham-affiliated institution, to their patients, and to the conduct of research for charitable purposes. Generally being on a company’s Scientific Advisory Board, or being a consultant to a company, does not create a fiduciary relationship.

IV. HUMAN SPECIMENS AND DATA TRANSFER COMMITTEE. A Human Specimens and Data Transfer Committee (“HSDTC” or “the Committee”) shall be formed consisting of such members as are determined jointly by the Mass General Brigham Professional and Institutional Conduct Committee, the IRB, and the Mass General Brigham Research Council. The purpose of the Committee shall be to oversee the implementation of this Policy and achieve consistency between all Mass General Brigham affiliated institutions on issues pertaining to Specimens and Patient Data transfer. In so doing, it shall also address issues that arise relating to the transfer of Specimens and Patient Data that are not resolved by this Policy. The Committee shall have the authority to establish guidelines and/or policies for specific categories of transfers and to provide such review of specific transfers as it deems appropriate.

V. TRANSFER OF SPECIMENS TO NOT-FOR-PROFIT ENTITIES

Transfers of Clinical or Research Specimens to not-for-profit institutions are considered inherently closely-related to the charitable mission of Mass General Brigham if:

- A. The recipient institution shares the same charitable missions (biomedical research, and education, and/or patient care) as Mass General Brigham and its Hospitals;
- B. The transfer is for the recipient institution’s charitable purposes; and
- C. The Specimens may *not* be re-transferred to a for-profit entity.

Accordingly, such transfers are generally acceptable as long as they adequately address Privacy and Common Rule requirements; are reviewed by the IRB where such review is required by the IRB; and meet such other requirements and processes as are determined appropriate for the particular transfer or category of transfer by the Committee. In many cases these transfers will require review by the IRB; where IRB review is *not* required, the Committee may establish criteria for which transfers to not-for-profits require Committee review.

VI. TRANSFER OF SPECIMENS TO FOR-PROFIT ENTITIES

Mass General Brigham and its affiliated Hospitals have long recognized that our charitable missions, particularly our patient care and research missions, are best served by an active collaborative effort between our Hospitals and scientists and industry and industrial scientists. Each “partner” to this collaboration brings important and valuable skills and capabilities, fostering medical breakthroughs and advances that likely could not be achieved by either partner working in isolation. This Policy rests on the belief that while the transfer of Specimens from the Hospital to industry may have commercial implications, such transfers are appropriate as long as they support and are in furtherance of our charitable missions of patient care, research, or education. It is also important that any arrangements with a for-profit entity not limit or compromise our own investigators’ freedom to pursue other activities that are consistent with those charitable missions.

Accordingly, in contrast to transfers to not-for-profit entities described above, Specimens should not be transferred to a for-profit entity unless and until the procedures described below are

followed in order to ensure that the transfer is part of an activity that furthers our institutional charitable missions.

- A. HSDTC Guidelines and Determinations. The HSDTC shall be responsible for establishing guidelines and policies for acceptable transfers of Specimens to for-profit entities, governed by the overriding principle that all such transfers must be made in activities that further the Hospital charitable missions. The Committee shall review each individual proposed transfer (1) that is made before specific guidelines and/or policies are developed and implemented, and (2) that fall outside guidelines and/or policies that have been developed by the Committee. The Committee may determine that it need not review specific transfers that clearly fall within its previously established specific guidelines and/or policies.

In determining whether a transfer furthers the Hospital charitable missions, the Committee shall consider the following:

1. Research Collaborations.

- a. General Rule. Transfers of Specimens to for-profit entities that are done as part of a genuine research collaboration between Mass General Brigham-affiliated scientists and the for-profit recipient entity will generally be considered to be in furtherance of the Hospitals' charitable missions. The Committee may seek to define more precisely what constitutes a sufficient "research collaboration;" factors that may be considered in this assessment include:
- i. An active, on-going involvement between the Hospital investigator and company investigators or other representatives that is pertinent to the specific transfer of Specimens;
 - ii. Collaboration in an area of science that is of on-going interest to the Hospital investigator;
 - iii. Data that the collaborator at the for-profit entity generates using the Specimens is made available in a timely manner to the Hospital's investigator;
 - iv. The Hospital investigator's right to publish results of this research collaboration is preserved, with any restrictions on publication with regard to time delay or confidentiality of certain data consistent with institutional policy;
 - v. The Hospital investigator believes that it is reasonably likely that a publication may result.
- b. Transfer of Specimens in the context of IRB-reviewed Clinical Studies. Unless otherwise decided by the Committee, a "genuine research collaboration" is presumed to exist when Research Specimens are transferred to a sponsor of an IRB-reviewed clinical study, provided that the sponsor's use pertains to the study as approved, and is in accordance with the attendant protocol and informed consent document for the study. The IRB in addition may determine that use of the Specimens by the

sponsor for other purposes, e.g. for pharmacogenomic studies of unspecified diseases or disorders, is acceptable under this Policy, provided that such use meets criteria that are satisfactory to the IRB.

2. Other Potentially Allowable Situations. If a situation does not meet the criteria for a “research collaboration,” the Committee may approve the transfer if it makes a written determination that the transfer furthers our charitable mission in some other way. Examples of such potentially allowable situations include:
 - a. Where the Hospital physician involved will receive information from the company pertaining to the Specimens that will directly apply to the physician’s treatment of his/her own patients.
 - b. Where the transfer of Specimens to a company may assist the company, on its own, to develop a medical drug or device or other patient-care improvement that the Committee determines is medically compelling, would not likely be achieved or would be much more difficult to achieve absent the transfer, and the development would generally help to improve medical care for the public.

B. Additional Process for Transfers of Patient Specimens to For-Profit Companies

Every such transfer must be covered by an appropriate Materials Transfer Agreement (or Research Collaboration Agreement or Clinical Trial Agreement where applicable) that has been specifically reviewed, approved and signed by CSRL, in consultation with OGC as necessary or appropriate. In addition to CSRL’s standard review of such agreements, it will review the financial arrangements regarding specimen transfer, using the following criteria:

1. The agreement may include appropriate payments to support the research collaboration or clinical trial. But these payments must be consistent with payments for clinical trials and research collaborations that do not include the transfer of Specimens.
2. The only additional payments that are permissible are for reimbursement for costs, as accrued, of handling and transporting the Specimens. The agreement cannot have the intent or the effect of providing a “profit” to the Hospital in exchange for the transfer of Specimens.
3. Payments must be in accordance with other Committee and IRB policies, for example policies relating to incentive payments.

VII. TISSUE REPOSITORIES

In general, Specimens may be transferred to internal and external tissue repositories. Issues relating to re-transfer from such repositories to subsequent recipients outside the Mass General Brigham shall be addressed by the Committee, which shall adopt guidelines pertaining to such transfers

that involve a limited data set or deidentified data. If a proposed re-transfer involves identifiable data, the IRB shall review it as appropriate.

VIII. TRANSFER OF PATIENT DATA TO ANY THIRD PARTY

The transfer to third parties of data collected from patients during clinical care or from research subjects may generally be less problematic than the transfer of Specimens, particularly when the data is pre-existing and is non-identifiable and/or in aggregate form. However, in some circumstances, transfers of Patient Data may raise similar or additional issues to transfers of Specimens. Accordingly, as with transfers of Specimens, all transfers of Patient Data must be consistent with and in furtherance of one of the institution's charitable missions and must not have the intent or effect of providing a "profit" to the institution. Transfers must be reasonably likely to improve patient care or related operations, advance biomedical knowledge, or provide some other direct benefit to a population of patients of a Mass General Brigham Hospital. As with transfers of Specimens, transfers of Patient Data to not-for-profits are generally presumed to be in furtherance of the institution's charitable missions.

In addition to any more specific guidelines or rules developed by the Committee, all transfers of Patient Data to outside entities or individuals shall be subject to the following guidelines⁴:

- A. The transfer of Patient Data to a third party must comply with all applicable laws and institutional policies concerning confidentiality.
- B. Whenever possible, Patient Data should be de-identified or limited to a Limited Data Set.
- C. The transfer of Patient Data to a third party to measure, improve, or report the quality of patient care or related services provided by our institutions should be coordinated with Mass General Brigham Clinical Affairs. If the primary (or part of a dual) intent of such a quality measurement initiative is research (to be conducted by individuals at a Mass General Brigham Hospital or by the third party or others), then the transfer must also be reviewed by the IRB.
- D. The transfer of Patient Data to a third party shall require such review by the IRB as is required by the IRB, and/or such other review as otherwise determined by the Committee to be appropriate for the particular transfer or category of transfer.

⁴ This Policy is not intended to restrict data transfers that may be required by law (such as required reporting to public health agencies), as long as such transfers are conducted in accordance with other legal requirements concerning confidentiality.

Other Related Policies

Faculty of Medicine of Harvard University: Policy on Conflicts of Interest and Commitment
<http://www.hms.harvard.edu/integrity/conf.html>

Human Research Administration Policy on Recruitment of Research Subjects
<http://healthcare.partners.org/phsirb/recruit.htm>

The Mass General Brigham Code of Conduct (Including Conflicts of Interest Policy)(<http://intranet.partners.org/OGC/policies/index.html>)

Mass General Brigham IRB Policy on Review of Quality Measurement Initiatives.Policy on Payments in Clinical Trials

The Use of Tissue in Research

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