



University of Chicago
Biological Sciences Division

Report of the
Biospecimen Collection and Allocation Working Group

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Working Group Members: Yellow highlighting indicates comments incorporated

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Executive Summary

Background and Working Group Charge. Human specimens have emerged as a critical resource for basic, translational, clinical, and population research, and the collection, storage, and allocation of biospecimens has become increasingly important to a wide range of investigators in the BSD. Moreover, inventions and data arising from research using biospecimens may have commercial value. Within the Biological Sciences Division, the collection and storage of biospecimens is largely conducted under the auspices of a Division-wide Shared Resource developed over a decade ago by the Department of Pathology, the Human Tissue Resource Center (HTRC). The National Cancer Institute (NCI) Best Practices for Biospecimen Resources (2010) recommends that each biorepository establish clear guidelines for access to biospecimens and their associated clinical data. In April 2011, Dean Polonsky charged the Biospecimen Collection and Allocation Working Group to explore these issues, including institutional policies for tissue collection, and policies governing the distribution of tissue to investigators, and to develop recommendations for consideration by the Research Advisory Committee (RAC). The Working Group was constituted to have broad representation, including leadership of the HTRC and Pathology, senior Divisional leaders, Divisional researchers and tissue bank users.

Process. The Working Group met on four occasions between April-September 2011 and reviewed current institutional practices for (1) the initiation of tissue banking protocols; (2) selection of tissues for banking; (3) tissue distribution; and (4) the current financial model for the HTRC. In addition, the Working Group reviewed the NCI Best Practices for Biospecimen Resources, as well as a series of “use cases” generated by the HTRC. A small working group (Le Beau, Lingen, Schilsky) met on three additional occasions to review the above materials, and to frame discussions and draft guidelines for consideration by the full group

Specific Recommendations.

1. The Working Group recommends that the BSD develop an institutional policy that biospecimens collected for research should preferentially be stored in the HTRC.
2. The HTRC, Office of the Chief Research Informatics Officer (CRIO), and Office for Clinical Research (OCR) should establish guidelines for clinical data sharing consistent with institutional policies, as well as ethical considerations. It is imperative that the institutional informatics efforts include developing the mechanisms to link clinical data to biorepository specimens.
3. General banking protocols should undergo an administrative review by the HTRC to evaluate feasibility, and whether they meet institutional standards for tissue collection and storage. IRB review and approval for a banking protocol should require prior administrative review and approval by the HTRC.
4. The Division should develop a **BSD Biospecimen Resource Committee** charged with oversight of the HTRC, and ensuring adherence to institutional tissue collection and distribution policies, and compliance with the Common Rule, and other federal, state, and local regulations, as well as timely, equitable and appropriate access to human specimens for research. The guiding principle for tissue distribution should be the scientific merit of the project proposing use of the tissue.
5. Based on federal case law precedent (*Catalona v. Washington University*), the Working Group strongly supports the position that **ALL** tissues collected using resources administered by the institution belong to the institution, regardless of the mechanism by which they were collected.
6. The Working Group recommends that the BSD Biospecimen Resource Committee develop a policy that guards against the exhaustion of any given type of specimen, an inherent concern for uncommon diseases.

7. The BSD should recommend that investigators seek approval for scientific use of tissue from the BSD Biospecimen Resource Committee prior to the submission of a grant application. In this situation, the HTRC can provide a letter of support indicating the numbers/types of specimens available.
8. The BSD Biospecimen Resource Committee must be vigilant in its operations to avoid placing junior investigators, who may not yet hold peer-reviewed funding, at a competitive disadvantage. The BSD is encouraged to develop a mechanism(s) to provide institutional support to junior faculty to support access to tissue banking services.
9. The Working Group identified a need to review the financial model for the HTRC, particularly the existing contributions of various groups to the banking enterprise, to integrate, consolidate and subsidize, if needed, and to develop recommendations to the RAC and BSD Dean's Office regarding institutional support, and charge-back levels. The Working Group strongly advocates that centralized banking should be supported, at least in part, by the institution. Furthermore, the Working Group recommends that the Committee develop innovative financial models, such as institutional support (including resources from UCCCC, ITM, etc.) for coverage of upfront costs (consenting process, tissue collection, etc.) to ensure future access by all faculty members, particularly junior faculty.
10. With respect to intellectual property, the Working Group advocates that research conducted using biospecimens obtained from the HTRC falls under the IP considerations of UChicagoTech, and guidelines of the University. Similarly, authorship on publications resulting from research utilizing tissues should conform to the current standards for intellectual contributions adopted by the field, e.g., medical and scientific journals.
11. Future considerations include (1) the development of institutional policies and implementation of procedures for broad-based consenting of UCMC patients and biospecimen collection; (2) the ongoing need to ensure transparency and full integration of developing cores, e.g., the UCCCC Epidemiology Research Recruitment Core, and Subject Recruitment Core currently being planned by the Institute for Translational Medicine, with the HTRC; (3) development and adoption of an unambiguous tissue policy by the institutional Clinical Research Policy Board, and development of standard language for the IRB to include in consent forms that is consistent with University ownership of the samples; and (4) the development of institutional guidelines regarding eligibility of external entities to access tissue and associated clinical data, and other relevant, institutional resources.

Background and Charge to the Committee:

Unprecedented advances in high-throughput and other technologies have substantially increased the power and precision of analytical tools in biomedical research, which form the foundation of personalized medicine. Human specimens that are analyzed using these new platforms have emerged as a critical resource for basic, translational, clinical, and population research, and the collection, storage, and allocation of biospecimens (blood, tissue, etc.) has become increasingly important to a wide range of investigators in the BSD. In the past, the absence of a centralized system for the collection and storage of biospecimens resulted in the implementation of independent tissue banking protocols, and tissue banks, by many Divisional PIs to meet their specific needs. The development of a Division-wide Shared Resource over a decade ago by the Department of Pathology, the Human Tissue Resource Center (HTRC), has resulted in the consolidation of most tissue banking activities under the auspices of this Core Facility. The National Cancer Institute (NCI) Best Practices for Biospecimen Resources (2010) recommends that each biorepository establish clear guidelines for access to biospecimens and their associated clinical data. However, there are no extant institutional policies for prioritizing among these protocols in the event of limited tissue, nor policies governing the distribution of tissue to investigators, e.g., researchers other than the PI of IRB-approved collection protocols. In some disease areas, where there are no investigators with an immediate interest, no tissue is being banked, resulting in potentially missed opportunities for future research.

In this context, Dean Polonsky asked Michelle Le Beau, PhD, to chair a Working Group to explore these issues, and develop recommendations for consideration by the Research Advisory Committee (RAC). The Biospecimen Collection and Allocation Working Group was constituted to have broad representation, including leadership of the HTRC and Pathology, senior Divisional leaders, Divisional researchers and tissue bank users, experienced IRB members, and a representative from the MacLean Center for Clinical Medical Ethics.

The Working Group considered the following issues:

- Tissue collection, e.g., in circumstance of limited tissue and/or more than one protocol requesting tissue banking for the same disease;
- Tissue distribution (how to ensure fair and equitable distribution of tissue that has been banked under either an investigator-specific protocol or an institutional protocol);
- Tissue "ownership";
- Special considerations for "rare diseases";
- Human Subjects considerations;
- Intellectual Property/Guidelines for publications, presentations, and attribution;
- Cost recovery; and
- Process for resolving disputes.

Process and Findings:

The Working Group has met on four occasions between April-September 2011 and has completed the following activities:

- Reviewed current institutional practices, which are summarized briefly below:
 - **Scope:** The HTRC currently banks tissues for 57 investigators from 14 different Departments under 144 IRB-approved protocols.
 - **Protocol initiation:** Investigators seeking to initiate new protocols meet with the HTRC to discuss their plans. The HTRC requests that investigators meet with them BEFORE submitting their IRB protocol, to address any issues that might arise regarding feasibility of the proposal from a tissue banking perspective.

- Once investigators receive IRB approval, they inform the HTRC of the exact approved banking requirements for their specimens. They receive training in using the eSphere database, if needed, to learn how to enter consents. The HTRC currently does not prioritize banking of tissue, and tissue is banked in temporal order of protocol submission.
- **Selection of Tissues for Banking:** For the most part, individual investigators determine which tissues to collect, where to store the samples, and how specimens are utilized.
- **Tissue Distribution:** If an investigator has her/his own IRB-approved protocol, she/he may withdraw the protocol-associated tissue from the HTRC at any time after the 30-day embargo period. If an investigator has no protocol and is planning to use tissue from the HTRC unlinked bank, tissue allocation is implemented on a first-come, first-served basis until the specimens are exhausted. At present, requests for tissue do not undergo scientific review. If an investigator wishes to use another investigator's protocol to obtain tissue, permission must be granted from the PI of that protocol before tissue can be released. The majority of IRB-approved protocols do NOT have associated Tissue Distribution Committees. An exception is that some center-type grants, e.g., the Breast Cancer SPORE, have defined processes for reviewing proposals, and follow NIH recommendations, such as prioritizing projects with peer-reviewed funding.
- **Current Financial Model for the HTRC:** The HTRC currently employs a staff of 11 FTEs, with an annual operating budget of approximately \$1 million. The HTRC comprises four subcores: Biobanking Subcore, Laser Capture Microdissection Subcore, Histology Services Subcore, and the Pathology Image Analysis Subcore. The operating budget is derived from chargeback revenues (~\$600,000) and institutional support (~\$400,000).
 - The ~\$600,000 chargeback revenue is derived mainly from the Histology Services Subcore (~\$400,000), whereas the remaining ~\$200,000 is derived from Image Analysis Subcore, the Laser Capture Microdissection Subcore, and the Biobanking Subcore.
 - The ~\$400,000 in Institutional support is largely derived from cancer-related funding: Cancer Center Support Grant (\$250,000 in 2011), UCCRF Women's Board (\$100,000 in 2011), and Breast SPORE (~\$50,000 in 2011).
- Reviewed NCI Best Practices for Biospecimen Resources:
 - The Working Group determined that these guidelines addressed general concepts leaving specific implementation to individual institutions.
- Solicited input from other NCI-designated Cancer Centers with respect to policies and guidelines:
 - The majority of Centers had no clear guidelines. Moreover, the variability among institutions makes adoption of generic policies difficult.
- Reviewed a series of "use cases" (specific scenarios generated by Dr. Mark Lingen and HTRC colleagues) as a vehicle for establishing policies and guidelines.

Working Group Recommendations/Considerations:

A. General Recommendations

1. The Working Group recommends that the BSD develop an institutional policy that biospecimens collected for research should preferentially be stored in the HTRC. Should investigators choose to use another institutional bank, it must meet equivalent performance standards, such as HIPAA security/privacy criteria, and local and national regulatory

requirements, and have SOPs in place that comply with the NCI and other national Best Practices guidelines.¹

2. To serve the needs of the research community, the HTRC, Office of the Chief Research Informatics Officer (CRIO), and Office for Clinical Research (OCR) should establish guidelines for clinical data sharing consistent with institutional policies, as well as ethical considerations.
3. The Working Group strongly recommends that the institutional informatics efforts include developing mechanisms that in a seamless manner: i) link clinical data to biorepository specimens; ii) facilitate requests for clinical data by the Clinical Research Data Warehouse (CRDW); and iii) facilitate requests for tissues by the HTRC. In addition:
 - a. The CRDW must freely interoperate with any institutional biorepository infrastructure through unfettered, programmatic access to biospecimen data. By this we mean through an application programming interface (API), not through a manual process.
 - b. The biorepository infrastructure must be able to scale up to manage hundreds of thousands of specimens/aliquots.
 - c. High-throughput technologies require that the request process for tissue must scale to easily manage requests for specimens/aliquots in batches of 1000 or more in size.
 - d. Programmatic access to biospecimen data by the CRDW, by CRDW related datamarts or other systems, and by the HTRC should not be burdened by incremental or ongoing charges.
4. The Working Group recognized the distinction between tissue collected as part of a specific hypothesis-driven finite, research project, e.g., an R01 in which biospecimens would be reserved for use by the PI, and more general banking of tissue for future research studies. General banking protocols should undergo an administrative review by the HTRC to evaluate feasibility, and whether they meet institutional standards for tissue collection and storage. IRB review and approval for a banking protocol would require prior administrative review and approval by the HTRC.
5. The Division should develop a **BSD Biospecimen Resource Committee** charged with oversight of the HTRC, and ensuring adherence to institutional tissue collection and distribution policies, and compliance with the Common Rule, and other federal, state, and local regulations, as well as timely, equitable and appropriate access to human specimens for research. The guiding principle for tissue distribution should be the scientific merit of the project proposing use of the tissue. Implementing a scientific review will ultimately result in higher quality research, as well as improved stewarding of institutional resources, e.g., limited resources, such as tissues, can be utilized by the most meritorious research. IRB review and approval for a research request for tissue would require prior review and approval by the BSD Biospecimen Resource Committee. Institutional precedence for this type of scientific review exists, e.g., the UCCCC Clinical Trials Review Committee.

Functions of the committee include, but are not limited to:

- a. Development of a standardized “HTRC Request for Tissue” form, including information on the number and types of tissues requested, processing and storage requirements, clinical parameters if applicable, proposed uses of the tissues, approved or proposed IRB protocol under which tissue is requested, and funding sources. Upon receipt of a new protocol, the HTRC would provide documentation of tissues available prior to Committee review.
- b. Development of standing procedures for protocol review in conjunction with the HTRC and IRB leadership. For example, the Committee may elect to administratively delegate review

¹ “2010 Revised NCI Best Practices for Biospecimen Resources”, Office of Biorepositories and Biospecimen Research National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services. (<http://biospecimens.cancer.gov/practices/2010bp.asp>).

- and approval authority to the HTRC for certain types of requests for tissue, e.g., studies requesting ≤10 samples, or studies that have already undergone scientific review in the course of a grant review.
- c. Review and prioritization of all requests for tissue based on scientific merit. Additional considerations may include (1) proven investigator experience with the proposed methods; (2) a research plan appropriate to answer the study question, which may include consultation with the PI of the tissue banking protocol, or another appropriate clinical disease expert; (3) availability of funding to complete the proposed research; (4) availability of tissues sufficient for the nature of the scientific investigations, i.e., discovery, prevalence, initial validation, and hypothesis testing; (5) appropriate biostatistical evaluation that shows that the study question can be addressed with the samples requested/available; (6) confirmation that the investigator will acknowledge the appropriate institutional Core Facilities and supporting grants; and (7) confirmation that the investigator will publish or provide public information about the project outcome according to applicable NIH policies. The Committee should have the authority to request revisions to or disapprove a tissue allocation request based on lack of merit; investigators would have the opportunity to respond to the committee's comments/concerns, as well as access to an appeal process should the protocol be denied;
 - d. Coordinate review process with disease programs, e.g., Disease Program Leaders in the case of cancer research, or representatives from disease programs should be invited to serve as ad hoc members for review of relevant requests for tissue (See Number 5);
 - e. Ensuring that investigators whose protocols are approved have subsequent access to the tissue for the purposes stated in their protocols;
 - f. Ensuring equitable access to tissue for all faculty with meritorious proposals.
 - g. Ensuring that the distribution and use of tissue falls within the scope of the original consent form;
 - h. Keeping abreast of the numbers and types of samples in the bank to ensure that specimens for specific diseases are not exhausted, e.g., the committee could limit the number of samples to be given in response to a particular request;
 - i. Working with the IRB to develop appropriate procedures for broader consenting and biospecimen collection at UCMC.
6. The Working Group recommends that disease site programs develop a single IRB-approved protocol covering tissue collection, including optimal methods for collection and storage. These Committees would work closely with the BSD Biospecimen Resource Committee, which would include Disease Program leaders or their representative(s) as ad hoc members for review of relevant requests for tissue.
 7. Based on federal case law precedent (*Catalona v. Washington University*)², the Working Group strongly supports the position that **ALL** tissues collected using resources administered by the institution belong to the institution, regardless of the mechanism by which they were collected. Recommendations for specific use cases include:
 - a. If tissue is collected under an investigator's funded project, that investigator should be granted first priority for access/use to the tissue for research covered by the original protocol. Should the investigator leave the University, access to the tissue for a period not to exceed the period covered by the grant should be subject to approval by the University, similar to the process used by the University to consent to transfer the grant under which the specimens were collected. Thereafter, the tissues become available to other investigators, which may include the original investigator.

² The *Catalona vs. Washington University* decision rested very much on the specific language used in the consent forms, which made clear that the University owned the specimens.

- b. The institution owns ALL tissue collection funded under any grant obtained by an investigator or group of investigators at the institution. Investigators who funded the biospecimen collection are granted first priority for access/use to the tissue for research proposed in the original study. If no additional funding is available, tissue collection may end and further tissue distribution to any investigator will be based on the scientific merit of the proposal(s).
8. The Working Group strongly supports the position that **ALL** data linked to biospecimens belong to the institution, regardless of the mechanism or infrastructure by which the data are collected, managed or stored.
9. In the event that there are multiple banking protocols for a particular tissue type, the HTRC may refer the protocols to the BSD Biospecimen Resource Committee for prioritization, based on factors such as scientific merit, peer-reviewed funding, or the requirement for a limited number of samples. If no basis for prioritization can be identified, the HTRC can elect to alternate allocation of samples, e.g., Protocol 1, Protocol 2, Protocol 3, Protocol 1, Protocol 2, etc.
10. In the event that there is excess tissue available, beyond that required for a specific banking protocol(s), the HTRC/Institution may elect to bank the tissue for research under the auspices of an IRB-approved HTRC protocol. Consent to bank excess tissue in this manner is not required from the treating physician, or PI of extant protocols. Such tissue would then be available to the research community pending approval of the request for tissues by the BSD Biospecimen Resource Committee.
11. The Working Group recommends that the BSD Biospecimen Resource Committee develop a policy that guards against the exhaustion of any given type of specimen, an inherent concern for uncommon diseases. Such a policy might include the provision of “rights of first refusal” for use of the last sample to the investigator who collected it. A caveat is that the Committee may deem a research proposal to be of sufficiently high scientific merit to warrant the use of all available material.
12. The BSD should recommend that investigators seek approval for scientific use of tissue from the BSD Biospecimen Resource Committee prior to the submission of a grant application. In this situation, the HTRC can provide a letter of support indicating the numbers/types of specimens available.

B. Special Considerations

1. The Translational Research Initiative – Department of Medicine (TRIDOM), a large scale sample collection and study being conducted by the University of Chicago, currently banks DNA, serum and plasma that can be utilized by the University of Chicago faculty and their collaborators. The BSD Biospecimen Resource Committee should maintain a close working relationship with the TRIDOM oversight bodies. Many requests for TRIDOM samples may be considered exempt human subjects research as they require no “protected health information” and, thus, do not require an IRB protocol. The Committee may elect to administratively delegate review of proposals for use of TRIDOM specimens to the TRIDOM-based committee.
2. The BSD Biospecimen Resource Committee must be vigilant in its operations to avoid placing junior investigators, who may not yet hold peer-reviewed funding, at a competitive disadvantage. The BSD is encouraged to develop a mechanism(s) to provide institutional support to junior faculty to support access to tissue banking services.

C. Financial Model for the HTRC

1. The Working Group identified a need to review the financial model for the HTRC, particularly the existing contributions of various groups to the banking enterprise, to integrate, consolidate and subsidize, if needed, and to develop recommendations to the RAC and BSD Dean’s Office regarding institutional support, and charge-back levels (see “Process and Findings” section for a summary of the current HTRC financial model).

2. The Working Group strongly advocates that centralized banking and storage of tissue should be supported, at least in part, by the institution. Furthermore, the Working Group recommends that the Committee develop innovative financial models, such as institutional support (including resources from UCCCC, ITM, etc.) for coverage of upfront costs (consenting process, tissue collection, etc.) or storage costs for tissue collected under the auspices of a grant or funding sources that is terminated to ensure future access by all faculty members, particularly junior faculty. Based on the FY11 operating budget for the HTRC, we estimate that the cost of consenting patients and tissue collection is \$500,000. Assuming a 50% increase in tissues collected by expanding the collection to additional tumors and biospecimens, the projected costs would be \$750,000 annually.³ For example, in 2010, or FY11, there were 87 UCCCC faculty users of the HTRC. Grant and contract support from these investigators totaled over \$46 million annually in direct costs, and over \$60 million annually in total costs. Similarly, there are numerous users of samples from TRIDOM. A robust tissue banking operation, and availability of biospecimens places BSD investigators in a strong position for securing peer-reviewed funding; thus, an institutional investment in tissue banking may be offset by increased revenues from indirect cost recovery.

D. Guidelines for Intellectual Property, Publications, and Attribution

1. **Intellectual Property (IP).** Inventions and data arising from research using biospecimens may have commercial value. Research conducted using biospecimens obtained from the HTRC falls under the IP considerations of UChicagoTech, and guidelines of the University. As custodian of biospecimens, biospecimen resource staff are not generally considered a *priori* inventors under patent law for inventions made using materials distributed by the biospecimen resource; however, “inventorship” is determined by patent law, and is considered on a case-by-case basis by legal personnel. Requests for tissues from investigators external to the University involving the transfer of materials among academic, non-profit, and/or industrial organizations require a Material Transfer Agreement (Appendix A), with terms consistent with NIH Research Tools Policy, NIH Data Sharing Policy, and institutional IP guidelines.
2. **Publications.** The Working Group advocates that authorship on publications resulting from research utilizing tissues conform to the current standards for intellectual contributions adopted by the field, e.g., medical and scientific journals. Although a common practice historically, the collection of a biospecimen is no longer universally considered adequate for inclusion as an author.
3. **Attribution.** Shared Research Facilities, such as the HTRC, that are supported by NIH resources are mandated to report usage of the facility and publications. In addition, the core should be credited in all publications, posters, and presentations reporting research based on the use of biospecimens. The “HTRC Request for Tissue” form developed by the HTRC and BSD Biospecimen Resource Committee should clearly delineate the recommended language for attribution of the HTRC.

E. Future issues

1. The BSD Biospecimen Resource Committee, the HTRC and the OCR, should work with the IRB to develop institutional policies and implement procedures for broad-based consenting of UCMC patients and biospecimen collection. Recent, preliminary discussions with the IRB

³ This is a conservative estimate based on an estimated 50% increase in sample volume. The costs of collecting and storing some types of samples, e.g., stool samples, as well as the informatics costs related to integrating the HTRC and CRDW databases may be greater.

indicate that, in principle, a broad-based approach to consenting would be considered. Such an initiative may become more pressing in light of proposed changes in legislation that would require written informed consent for the banking of unlinked tissue to be used for future research. The following issues were raised for future discussion:

- How can we ensure that patients consenting to tissue banking for future research (if embedded in a general surgical consent) are adequately informed?
- Would patients be given a set of options to provide consent, e.g., tissue, tissue and blood, medical data?
- How would this information be tracked?

The new cancer intake specialist (patient navigator) program was suggested as a vehicle through which patients could be consented to an institutional banking protocol.

2. In the past, the University has taken the position that the University, not the faculty member, owns the tissues, at least when the collection, storage and ongoing usage of the tissues made substantial use of University facilities. However, further work is needed to make this position the unambiguous policy of the University. As per Mr. Russell Herron (Associate General Counsel), this should include the adoption of a tissue policy by the Clinical Research Policy Board (to be endorsed by Dean Polonsky), and development of standard language for the IRB to include in consent forms that is consistent with University ownership of the samples (while at the same time clearly disabusing subjects of any notion that they themselves retain any rights in donated specimens).
3. The Epidemiology Research Recruitment Core (ERRC) is a developing UCCCC core focusing on facilitating population-based research. Services include survey/questionnaire development, subject ascertainment and recruitment, and biological specimen collection. As the ERRC develops, there will be a need to review standard operating procedures to ensure transparency, and full integration with the HTRC. The Subject Recruitment Core currently being planned by the Institute for Translational Medicine is subject to the same considerations.
4. Various academic units, investigators, and entities, such as the HTRC, receive requests for access to tissue and associated clinical data. These requests come from a variety of sources, including other academic institutions, researchers, industry, etc. The Committee and UCMC should evaluate the need for guidelines regarding eligibility to access these, and other relevant, institutional resources.