

**Policy and Procedure Manual
Administrative Manual
Administrative Institutional
Department: Research Operations**



Written: 05/12/15

Reviewed:

Revised:

Page: 1 of 3

APPROVALS:

SLT: 05/21/15; BOD: 2Q-15

Scope: Medical Center Beckman Research Foundation

**Allocation of COH
Human Specimens for
COH Use and to
External Entities**

I. PURPOSE / BACKGROUND

The City of Hope (“COH”) recognizes that human specimens represent a valuable and unique patient resource that must have proper acquisition and custodianship. The purpose of this policy is to assure that the release of specimens to COH researchers and to external entities is conducted after reviews to ensure the utilization is scientifically justified and that appropriate agreements are in place. This policy applies to both stored and freshly collected specimens.

This policy and the procedure described below do not apply to requests to use less than 10 samples for feasibility assay testing. For transfer of specimens when an investigator departs the institution, please see the COH institutional policy, *Equipment, Materials and Specimen Transfer*.

II. POLICY

- A. As a general policy, COH does not provide specimens for third party use or research if there is no benefit to COH patients (e.g., improved patient care/experience, therapeutic benefit) or to COH researchers (e.g., publication) or a COH research program (e.g., collaborative scientific project).
- B. COH specimens may be used for research and/or shared with an outside entity under the following circumstances:
1. The request to use and/or share specimens is to support scientifically sound and appropriate research or for a use consistent with the purposes described in Section II. A above.
 2. The proposed use of the specimens must not hinder or compete with ongoing COH interests/activities, especially in the case of rare and/or limited tumor specimens.
 3. COH is appropriately reimbursed for costs of participation in any approved transfer of specimens to the outside entity, if applicable. Such cost reimbursement must not include sale of specimens to the outside entity. Such cost reimbursement may include time and material costs associated with obtaining, processing, shipping, and tracking samples.
 4. If specimens will be transferred to an external entity, a written agreement with the external entity has been executed before human biospecimens collected by COH are shared with any researchers or entities outside of COH. Clinical Trials Support Services (CTSS) and/or Office of Technology Licensing (OTL) will assist researchers in this process, with input from the Office of General Counsel (OGC), as needed.

- C. COH specimens may be shared with an outside entity, upon endorsement and/or approval as follows:
1. Disease Team endorsement (a link to information, including points of contact, is provided under References below).
 2. CPRMC approval, if request is non-exempt human subject research.
 3. IRB approval, if request is non-exempt human subject research.
 4. COH Biospecimen Repository Committee approval (a link to information, including points of contact, is provided under References below).
 5. CTSS and/or OTL confirmation that a written agreement has been executed as described in Section B.4 above.

The investigator is responsible for coordinating the shipment of the specimens once the above have been obtained.

III. PROCEDURE

RESPONSIBLE PERSON(S)/DEPT.	PROCEDURE
Investigator	<p>Investigators initiate Disease Team review in one of two ways:</p> <ul style="list-style-type: none"> (a) <i>Clinical trials and prospective specimen collection studies</i>: Investigator must submit the request to share COH patient specimens with external entities via the research endorsement request form (see ‘related forms’ below). (b) <i>Research involving fresh tissue or archived specimens that are not part of a clinical trial or prospective collection</i>: Investigator should follow the Pathology Letter of Intent process for requesting the use of specimens as outlined at http://www.coh.org/shared-resources/pathology/Pages/Letter-of-Intent-Process.aspx. This process directs investigators to complete the iRIS application and solicits pertinent information related to the use of existing specimens that will be routed for review by the committees and departments below.
Disease Team	<p>The Disease Team will assess and endorse protocols that share specimens with external entities if the research:</p> <ul style="list-style-type: none"> (a) is of scientific merit and in alignment with the mission and research focus of the disease area, (b) does not compete with other pending or approved research studies, (c) holds the prospect of benefit to COH or its patients as set forth in Section II.A above. <p>The Disease Team will ensure there is written documentation that these criteria have been met.</p>
COH Biospecimen Repository Committee	<p>Once endorsed by the Disease Team, the Tissue Bank Administrator will review the request to determine whether it:</p> <ul style="list-style-type: none"> (a) involves the use of COHBR specimens, or (b) requires Department of Pathology resources. <p>All COH-related research and requests for use of fresh tissue or archived specimens from the COH Biospecimen Repository, including those by a third</p>

RESPONSIBLE PERSON(S)/DEPT.	PROCEDURE
CTSS	<p>party, must be reviewed and approved by the COH Biospecimen Repository Committee.</p> <p>Once endorsed by the Disease Team, CTSS will receive a notification and evaluate the reimbursement for costs of participation in the transfer of specimens to the outside entity. CTSS will also develop the budget and coverage analysis and process the research agreement as appropriate. Where the research involves sending archived specimens to non-industry external entities without informed consent, CTSS will notify OTL to process the Material Transfer Agreements.</p> <p>CTSS and/or OTL will obtain approval from the SVP Research Operations on reimbursements and budgets.</p>
Cancer Center Protocol Review & Monitoring Committee (CPRMC)	All COH non-exempt cancer related research must be reviewed by the COH Cancer Protocol Review & Monitoring Committee (CPRMC). The CPRMC will review research to confirm it satisfies COH standards for scientific merit and priorities.
Institutional Review Board (IRB)	All COH non-exempt human subject research must be reviewed by a COH-designated IRB.

Author: Amanda Hammond, Senior Director, Research Protections

Collaborating Authors: John Zaia, MD, COH Institutional Official; Dennis Weisenburger, MD, Pathology Chair; Eileen Smith, MD, IRB Chair; Karen Reckamp, MD, CPRMC Chair; Jennifer Ing, JD, General Counsel; George Megaw, Director, Office of Technology Licensing; Torie Fechner, Manager, Clinical Trial Support Services

Sponsor: Ashley Baker Lee, Senior Vice President, Research Operations

Related Policy:

1. [Equipment, Materials and Specimen Transfer](#)

References:

1. COH Multidisciplinary Disease Teams: <http://www.coh.org/clinical-trials-office/Disease%20Team/Pages/default.aspx>
2. COH Biospecimen Repository: <http://www.coh.org/shared-resources/pathology/Pages/default.aspx>

Related Forms:

1. Disease Team Endorsement Request Form available at: <http://www.coh.org/clinical-trials-office/Disease%20Team/Pages/default.aspx>
2. Pathology Letter of Intent to Use Specimens Process: <http://www.coh.org/shared-resources/pathology/Pages/Letter-of-Intent-Process.aspx>

Appendix One – Acronyms, Terms and Definitions Applicable to this Policy:

1. **City of Hope (“COH”)** – City of Hope National Medical Center (“COHNMC”), Beckman Research Institute (“BRI”), and City of Hope Medical Foundation (“COHMF”), collectively referred to as City of Hope (“COH”) for purposes of this policy.
2. **Medical Center** – Refers to all facilities covered by City of Hope National Medical Center’s hospital license.