

Executive Summary: OHSU Knight BioLibrary

The Knight BioLibrary at Oregon Health & Science University is a CAP-accredited laboratory that collects, stores and disburses human biospecimens for use in research and test development. Operating under the **Knight Diagnostic Laboratories**, the Biolibrary houses a large tissue collection that is focused primarily on oncology specimens, with some expansion into other disease areas. It also manages samples for 21 cancer registries and repositories, as well as archival materials from the OHSU Department of Pathology.

The Knight Cancer Institute at Oregon Health & Science University is the only National Cancer Institute-designated Comprehensive Cancer Center between Sacramento and Seattle, offering its patients the latest treatments and technologies. The institute's director, Brian Druker, M.D., is a pioneer in the field of precision cancer medicine. One of the NCI's largest research collaboratives, SWOG, is headquartered at the institute, which also conducts hundreds of research studies and clinical trials.

Oregon Health & Science University is the state's only academic health center. It provides an uncommon array of services, ranging from the state's most comprehensive health care, to educating the next generation of clinicians and biomedical researchers, to achieving breakthroughs and innovations. Its hospitals and clinics serve more than a quarter of a million patients every year.

Primary Services Offered by the Biolibrary:

- ❖ Collection, storage, and distribution of human biospecimens for research use.
- ❖ Clinical and molecular data acquisition and curation.
- ❖ Molecular testing and histopathology services, including digital slide imaging.

BioLibrary Repository & Database: The BioLibrary contains more than 500,000 cases, represented in approximately 3 million individual samples deriving from 230 anatomical sites. Data is stored in a customized Laboratory Information Management System that is 21 CFR Part 11 compliant. Donor authorization and the full lifecycle of every specimen is fully tracked by this system. The BioLibrary has been accredited by the College of American Pathologists since October 2012, and has a complete set of policies and procedures in place governing consenting, acquisition, storage and distribution practices.

Donor Consent & Authorization: The BioLibrary was established with the express intent of collecting residual clinical specimens so that they may be offered for use in unspecified future research. All OHSU patients are presented with a research opt-out notice and informational brochure to authorize the collection and use of residual materials. The BioLibrary also has a disease-agnostic repository protocol utilizes a traditional opt-in consent that authorizes a broader range of activities including:

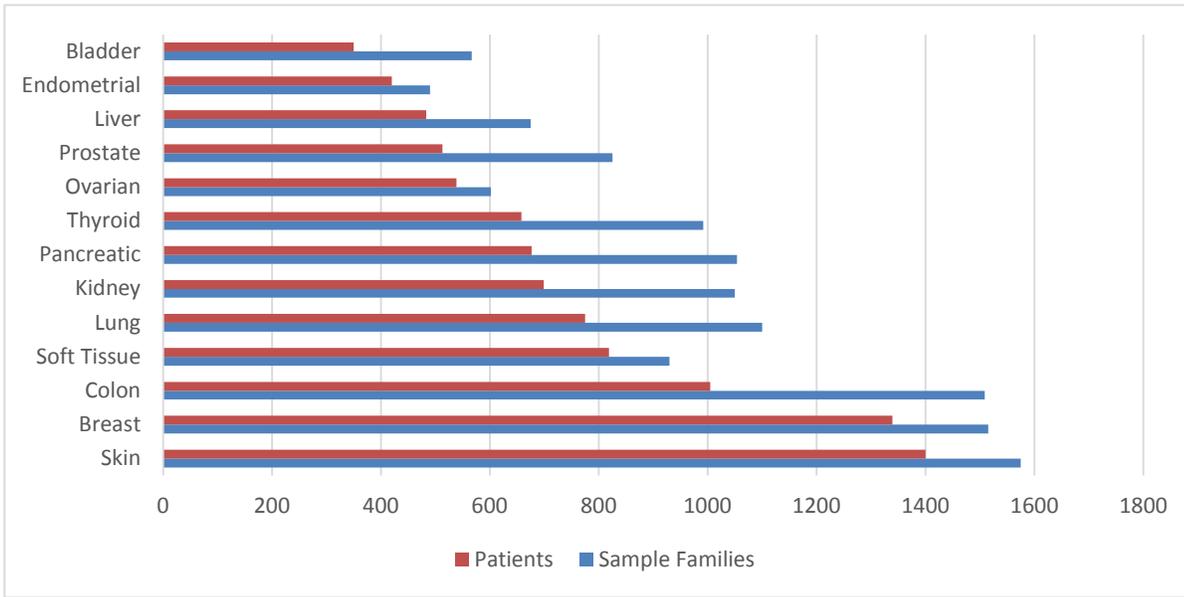
- ❖ Collection of new biological specimens including whole blood, marrow aspirates, saliva, and others.
- ❖ Access to complete medical records, including health surveys and questionnaires.
- ❖ Storage and use of existing specimens, either clinically collected or from other research studies.
- ❖ Authorization for future –omic (genomic, proteomic, etc.) studies on specimens without re-consent.
- ❖ Re-contacting of participants for longitudinal follow-up and study referrals.

Available Specimen Types: Tumor tissues compose the majority of specimens, but matched non-cancerous tissue and/or blood derivatives are also available for many cases. In addition, tumor mutation data are available for many specimens. Common specimen types include:

- ❖ Fresh tissue, flash frozen in liquid nitrogen.
- ❖ Formalin fixed, paraffin embedded (FFPE) tissue with paired hematoxylin and eosin (H&E) slide.
- ❖ Optimal Cutting Temperature (OCT) embedded tissue for cryosectioning.
- ❖ Frozen blood derivatives: serum, plasma, buffy coat, white blood cells, and isolated nucleic acids.
- ❖ Prospective collection of fresh tissue, whole blood, or other specimen types available by request.

Available Data: Basic patient demographics and specimen data are available on all samples. De-identified pathology and imaging reports, genetic testing results, treatment histories and clinical outcomes are also available on request.

Unique patients and tissue collection events ('sample families') by major disease groups.



BioLibrary sample totals by specimen type and preparation.

