NWBioTrust: A Cross-Institutional Informatics Infrastructure for Requesting and Managing Annotated Human Biospecimens

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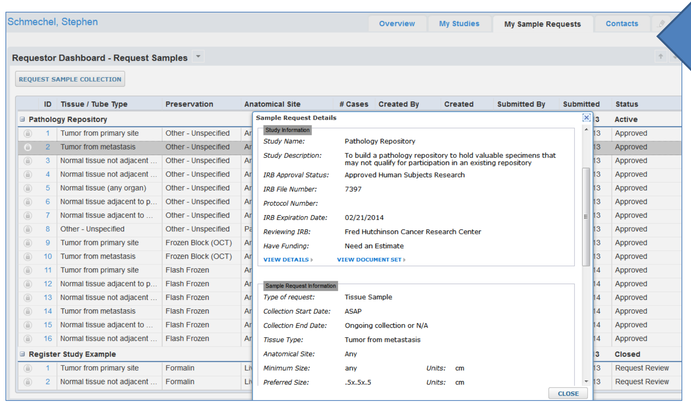
INTRODUCTION

The acquisition of high quality, richly annotated human biospecimens for translational and clinical research is a challenge for investigators. Northwest BioTrust (NWBT) was formed as a collaboration between the University of Washington (UW), Seattle Cancer Care Alliance (SCCA) and Fred Hutchinson Cancer Research Center (FHCRC) for the purpose of providing rapid, reliable and cost-effective access to human tissue, blood and other body fluid samples, and associated clinical and specimen annotations for innovative diagnostic, therapeutic and public health sciences research.

Consent for the use of specimens and clinical data, and for potential re-contact for participation in clinical trials, is sought from UW Medicine and SCCA patients. Consents are obtained either using an electronic system integrated into the check-in process at UW Medicine and SCCA clinics, or through paper-based consent forms from which consent responses are subsequently entered into the NWBT informatics system.

The NWBT informatics system additionally allows investigators to register research studies and desired patient and specimen characteristics, facilitates identification of patients and specimens suitable for registered studies, supports procurement and distribution of materials and data to investigators, and provides reports on business metrics for invoicing and operations management.

METHODS



Investigator view within Study Registration system: one of several approved sample requests for an investigator's study. Details of the investigator's study are included in this view.

Study Registration

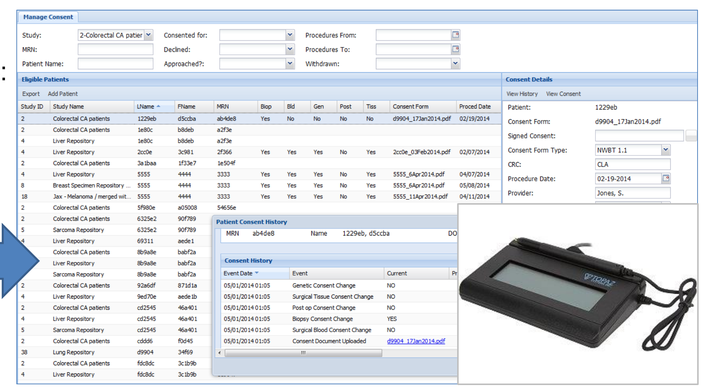
Samples are requested by investigators using a custom version of LabKey Server that supports:

- Tracking of study details including IRB documentation, contacts and budget information
- Tracking of sample request details including desired patient and sample types and quantity
- A review and interactive approval process for studies and individual sample requests
- Publicly accessible 'self-serve' model for any investigator/study staff with valid UW NetID's

Consent Management

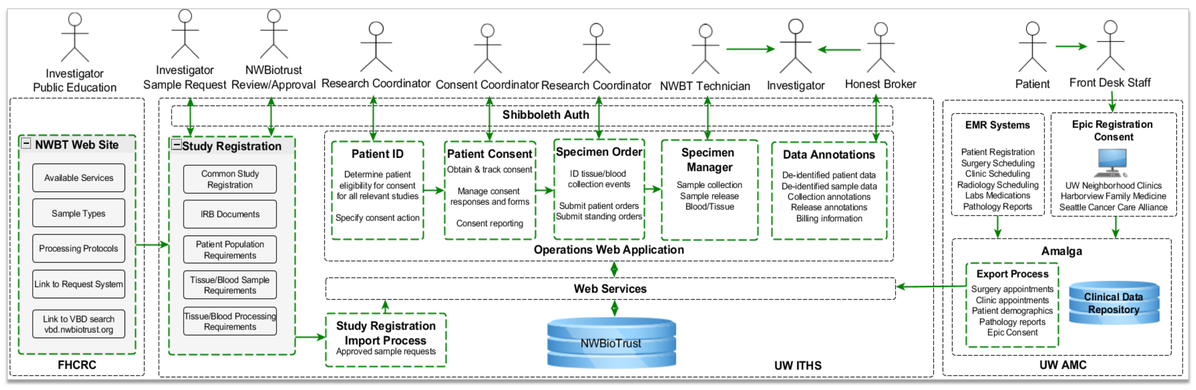
Includes two primary consent collection methods:

- Electronic capture of a) consent for use of remnant clinical specimens and clinical data and b) consent to be re-contacted in the future for research studies. Consent responses are collected via Epic Prelude/Registration and signatures are collected using Topaz Systems Inc. signature pads
- Consent information is uploaded into the NWBT informatics systems. This includes uploading images of signed paper consent forms and collecting and storing discrete consent responses



Screenshot of the consent management module used to track consents. *Inset*: Image of Topaz signature pad used to collect patients signature via Epic Registration.

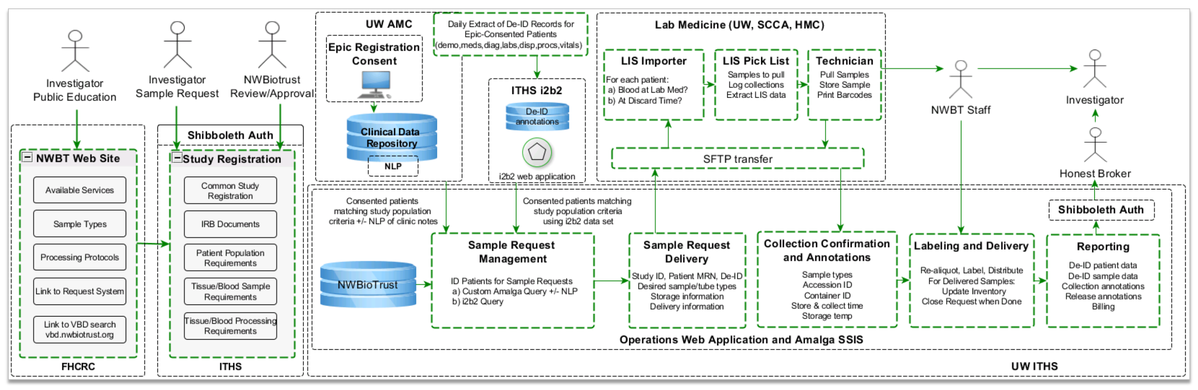
Prospective Specimen Collection (PSC)



Summary: PSC supports the identification and collection of remnant clinical samples or additional research-only samples during upcoming patient surgical and clinic appointments for which the patient phenotype and sample characteristics match the research study request criteria

- Investigators request sample collections through the Study Registration system
- After approval, requests are imported into the operations system, which is intentionally separated from the Study Registration system and accessible only to NWBT Honest Broker staff using limited network addresses to maximally secure protected health information
- The operations system identifies patients eligible to be approached for consent using EMR data imported from the UW Amalga Clinical Data Repository (80TB from 26 data feeds)
- Consent and sample collection events are scheduled and managed through this system
- PSC provides the means to track the NWBT or study-specific consent obtained for sample acquisition.
- Communications between various system components utilize secure REST-based web services

High Throughput Discarded Specimen Collection (HTDSC)



Summary: HTDSC includes the electronic capture of consent for use of leftover specimens and supports the automated identification and collection of discarded blood samples matching the research study and sample request criteria

- Investigators request sample collections through the Study Registration system
- After approval, queries to identify consented patients matching an investigator's desired patient phenotypes and sample characteristics are developed and executed in the i2b2 or Amalga CDR environments
- HTDSC issues automated requests for blood samples from consented patients that are about to be discarded and that match sample request-specific patient phenotypes and sample characteristics
- Pull confirmations and de-identified sample annotations are imported back into the operations system to support inventory management and tracking of sample collection and storage details
- HTDSC provides detailed reports of consent & sample collection status as well as complex de-identified patient phenotype data to allow honest-broker mediated delivery of annotations to investigators

RESULTS AND DISCUSSION

The NWBT IT system consists of a Study Registration system that is publicly available to all investigators with UW NetID's that supports collecting investigator requests for PSC and HTDSC collections; two web applications supporting operations for both PSC and HTDSC programs and a database which acts as a centralized data store for all approved studies, requests, patients, collected samples and sample annotations. A secondary data store of de-identified patient data for patients consented for remnant discarded blood collections supports the delivery of complex annotations for the HTDSC program. Although not discussed in detail here, NWBT also includes a separate LabKey server (VBD) that is open to the public that provides a means for researchers to query for specimens from existing, decentralized cancer repositories.

The current implementation of the NWBT system produces "top level" barcoded specimens. Through work currently underway, additional functionalities will be added: 1) the ability to track data on derivatives such as specimen types (tissue aliquots, derived histologic sections, derived purified DNA aliquots, etc.), diagnostic codes per derivative, quality metrics per derivative (%neoplasia, %necrosis, etc.), and storage location of each derivative (freezer maps, etc.); and 2) ability for researchers to customize forms to enter study-specific data (biologic assay results, etc.) on specimens received from NWBT. To meet these needs, we are configuring LabMatrix (BioFortis, Inc.) to mesh with the systems described above.

The NWBioTrust IT system currently supports 35 active studies. In the 2+ years since launch of NWBT, annualized specimen delivery has increased from 627 specimens in 2012 to 1195 specimens in 2013 to over 3500 in 2014 (estimated, based on 2014 first quarter metrics), for an average annualized growth in specimen delivery of ~140% per year.

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