nwbiospecimen
annotated research biospecimens

NWBioSpecimen / University of Washington Department of Pathology

NWBioSpecimen Archival Biospecimens Research Guide

Introduction to Procedures and Services for Archival Biospecimens

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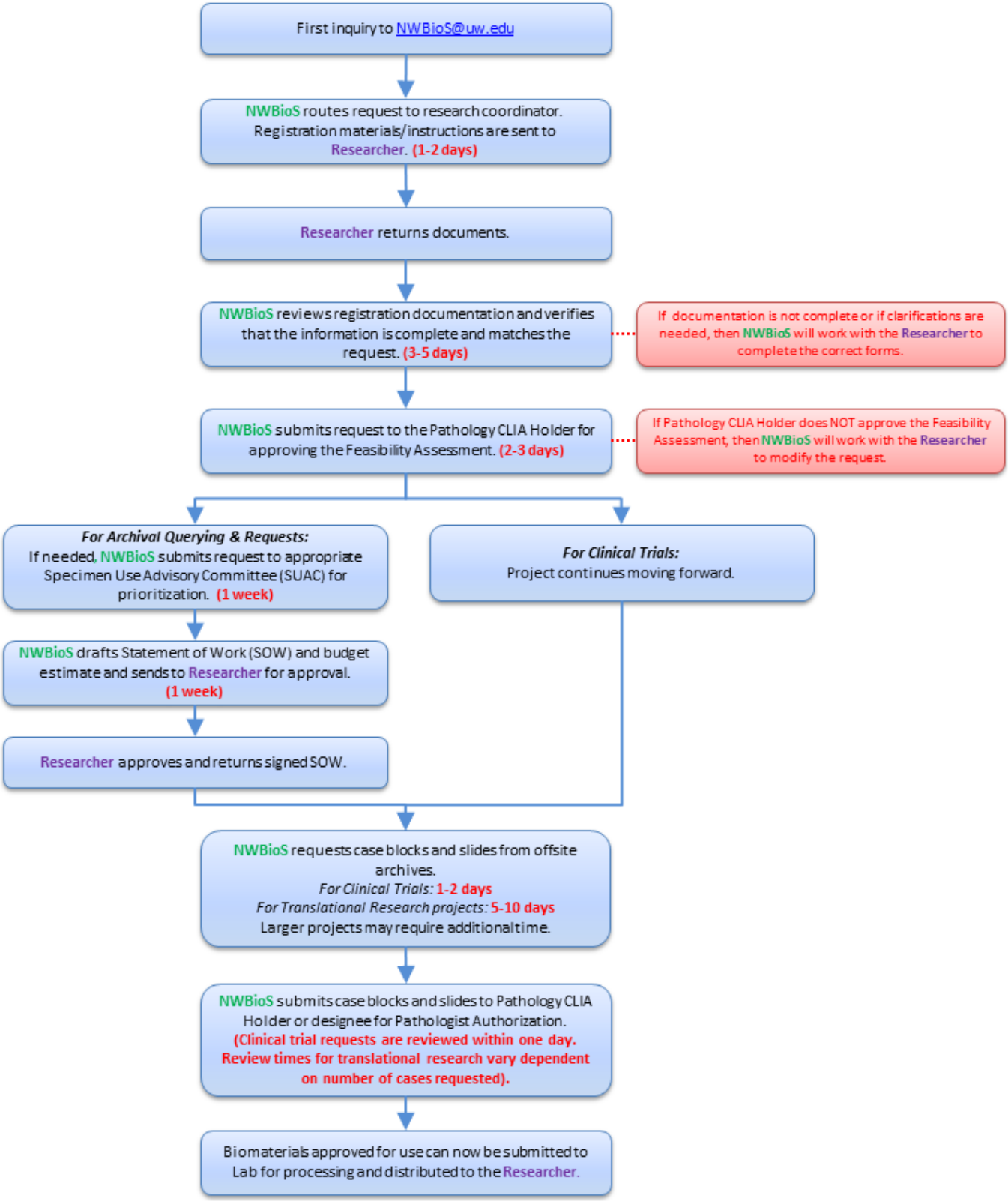
Introduction

Thank you for your inquiry! NWBioSpecimen, a core facility housed within the University of Washington Department of Pathology, is a collaborative effort between the University of Washington (UW), Fred Hutch (FH), and Seattle Cancer Care Alliance (SCCA) to facilitate access to well-characterized human research biospecimens. NWBioSpecimen provides biospecimen procurement, annotation data associated with study participants and their biospecimens, and distribution of materials for research and education. *NWBioSpecimen brochure: https://goo.gl/4gwa64*.

NWBioSpecimen provides researchers with a single point of contact (NWBioS@uw.edu) for:

- Study feasibility assessment and study registration
- Procurement and distribution of biospecimens and annotation data
- Tissue microarray (TMA) construction and coring for molecular analysis
- Histopathology services
- Digital slide scanning and image analysis services
- Billing, accounting, and reporting services

An overview of the NWBioSpecimen (NWBioS) research process for use of archival specimens in the Department of Pathology is presented in the following flow chart. This outlines the workflow for average-size projects --- Please allow additional time for large case requests.


First inquiry to NWBioS@uw.edu
NWBioS routes request to research coordinator. Registration materials/instructions are sent to Researcher. (1-2 days)
Researcher returns documents.
NWBioS reviews registration documentation and verifies that the information is complete and matches the request. (3-5 days)
If documentation is not complete or if clarifications are needed, then NWBioS will work with the Researcher to complete the correct forms.
NWBioS submits request to the Pathology CLIA Holder for approving the Feasibility Assessment. (2-3 days)
If Pathology CLIA Holder does NOT approve the Feasibility Assessment, then NWBioS will work with the Researcher to modify the request.
For Archival Querying & Requests:
If needed, NWBioS submits request to appropriate Specimen Use Advisory Committee (SUAC) for prioritization. (1 week)
For Clinical Trials:
Project continues moving forward.
NWBioS drafts Statement of Work (SOW) and budget estimate and sends to Researcher for approval. (1 week)
Researcher approves and returns signed SOW.
NWBioS requests case blocks and slides from offsite archives.
For Clinical Trials: 1-2 days
For Translational Research projects: 5-10 days
Larger projects may require additional time.
NWBioS submits case blocks and slides to Pathology CLIA Holder or designee for Pathologist Authorization.
(Clinical trial requests are reviewed within one day. Review times for translational research vary dependent on number of cases requested).
Biomaterials approved for use can now be submitted to Lab for processing and distributed to the Researcher.

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Step 1: Inquiry

Researchers interested in NWBioSpecimen services first make an initial inquiry to NWBioS@uw.edu that includes a project description. Once your initial request is received, you will be directed to a NWBioSpecimen research coordinator (RC) for coordinating your research:

Prospective Collection Requests: *Prospective Biospecimen RC (this procedure is covered in another document)*
Archival Biospecimen Requests: *Clinical Trials and Archival Request RC*
Archival Biospecimen Requests: *Archival Querying & TMA Construction RC*

A staff member will respond to your request and provide you with study registration materials and instructions on how to begin your project.

Step 2: Study Registration Documents

A number of documents must be submitted to NWBioSpecimen to ensure that all parties are compliant with their IRB's and regulatory agencies. Your Research Coordinator will help you through this process. We need the following documents completed for study registration:

1. **NWBioSpecimen Registration Form** *(including a full project description, collection protocols, services requested, & budget number)*
2. **NWBioSpecimen Gatekeeping Form** (*required anytime research is being performed using UW specimens)*
3. ***Full* IRB application, modifications, and approvals including:**
    a. **UW Confidentiality Agreement** (*required anytime research is being performed using UW specimens and under Waiver of Consent / Waiver of HIPAA Authorization*)
    b. **Waiver of HIPAA Authorization** *(if applicable)*
    c. **Waiver of Consent** (*if applicable)*

NWBioSpecimen provides biospecimens and data that are stripped of identifiers and coded and only releases links between the code and the identifiers to studies with appropriate IRB approvals in place (and signed patient consent and HIPAA authorization if applicable per the IRB approval). Research projects involving coded data/specimens stripped of identifiers may not require IRB approval. For example, refer to the UW Human Subjects Division SOP "Human Subjects Research" (http://www.washington.edu/research/hsd/docs/1253). Please check with your IRB for requirements. If the IRB determines that the request is not Human Subjects research, we ask that you provide documentation of the determination.

Research projects involving *transfer* of data/specimens to anyone outside of UW require a **Materials Transfer Agreement (MTA)** and/or **Data Use Agreement (DUA)**. Please contact us for more information.

Step 3: Feasibility Assessment

Once IRB approvals and documents are verified, study documents are sent to the Pathologist CLIA holder (or designee) for approving the Feasibility Assessment. Several pieces of information are taken into account at this step including whether the study will deplete precious resources and if it is line with their IRB requirements.

Step 4: Specimen Use Advisory Committees (SUACs)

For clinical trials, this step is omitted secondary to time sensitivity and importance in the patient's clinical care since a predetermined study protocol was already provided and approved during Feasibility Assessment. However, Specimen Use Advisory Committees (SUACs) will get notification of these requests since it relates to the availability of the specimen type.

For all other archival requests, NWBioSpecimen will submit the request to the appropriate SUAC for prioritization of use. For example, this panel evaluates the impact that the research study has on the research field and assigns priority scores to biospecimens that are highly sought after.

Step 5: Developing a Statement of Work (SOW) & Budget Estimate

For clinical trials, this step is omitted due to time sensitivity and since a predetermined study protocol was already provided and approved during Feasibility Assessment.

For all other archival requests, NWBioSpecimen must develop a SOW and budget estimate for approvals by the researcher. A Research Coordinator will work with you to clarify the work that needs to be done (including refining query parameters, case quantities, histology requests, and data requests). The SOW and matching budget estimate will be presented to the researcher for review. The SOW will be signed and returned to NWBioSpecimen if the researcher agrees to the intended work.

Budget estimates are based on internal University of Washington Rates. You will be billed for actual coordinator/technician time so actual costs may be lower or higher than the estimates given, although any costs in excess of estimates require pre-approval. NWBioSpecimen provides services at UW Management Accounting & Analysis (http://f2.washington.edu/fm/maa/recharge) approved rates.

Step 6: Case Request & Pathologist Authorization

If the study approvals require patient consent/authorization, the patient signed consent/authorization must be provided with the case request. Clinical slides and tissue blocks from pathology cases are obtained from on-site storage (recent cases) or off-site archives (older cases). This delivery process can take 2-3 days depending on order size and how quickly our vendor can return the cases to us (1+ week for projects involving large case orders). Once received, each case is organized and scanned for tracking/QC. *Note: materials cannot be pulled/held in advance of an order, and all cases must be returned to the archives within 3 months of pulling (per UWMC loan policy) except for rare occasions with separate approvals in place.*

Cases are then sent to the Pathology CLIA Holder or designee for authorization to use clinical materials for research use. Pathology laboratories are regulated by a federal law called the "Clinical Laboratory Improvement Amendments of 1988" (http://www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf) which is enforced by meeting the requirements of the College of American Pathologists (CAP) and receiving laboratory accreditation and all research use of clinical materials must comply with these regulations as well as hospital and departmental policies such that not all cases requested for a study may be available for research use.

Step 7: Histology and Specimen Distribution

Once all approvals are in place, biospecimens can be submitted to the Histology Lab or the TMA facility for work to be completed. Turn-around-time for Histology depends on the number of research histotechnicians working during a given week. For projects involving IHC, NWBioSpecimen utilizes the clinical IHC staff so turn-around-time is extremely dependent on the higher priority clinical workload.

Step 8: Billing

If a UW budget number is provided, you can expect to be charged on the next billing cycle following project completion (approximately 4-6 weeks). The budget coordinator designated on your NWBioSpecimen Study Registration Form will receive an itemized ISD via email that includes payment instructions from nwbiobus@uw.edu. If invoicing was selected for payment, the timeframe may be increased.