CHILDREN'S ONCOLOGY GROUP

Accessing Legacy COG Biospecimens
Frequently Asked Questions

Contents

Version date: 02/11/2026

Biospecimen Request Overview

Access to Children's Oncology Group (COG) Biospecimens requires COG Biology Committee review and approval. Requests for rare specimens, specimens that have concerns for depletion, requests that make up 50% or more of a single trial arm and/or are for specimens from ≥ 50 patient cases require COG Scientific Council review.

All sample requests will undergo final review by National Cancer Institute's (NCI's) National Clinical Trials Network Core Navigator Correlative Sciences Committee (NCTN Navigator CCSC) or NCI's Cancer Therapy Evaluation Program (CTEP).

Once an approval is received, investigators are required to enter material and or data sharing agreements and submit processing fees. The COG Biobank at the Biopathology Center will distribute biospecimens once all agreements, documentation and fees are collected. Upon receipt of biospecimens, investigators are required to provide updates on project status on a yearly basis. Investigators should consult with COG regarding manuscript publication requirements.

Preparing for Submission

How can I determine what specimens are available to request from the COG Biobank?

The NCTN Biospecimen Catalog provides a searchable, comprehensive listing of NCTN Trial Biospecimens that may be available for secondary use. The Specimen Resource Locator is also available for access to specimens outside of COG.

Investigators are asked to submit a COG pre-inventory request form (PIBRF). Download the pre-inventory request form from the COG Website and submit to specimens@childrensoncologygroup.org. COG will provide availability of biospecimens that can be used to formulate a biospecimen request proposal.

Investigators should know that biospecimen availability is subject to change. Biospecimen and data availability will not be confirmed until after NCI Approval. All investigators should be aware that the Navigator and COG inventory query results are not a guarantee of Biospecimen availability.

What documents are needed to submit a request for biospecimens?

The NCTN Correlative Science Proposal Submission Form, an IRB letter of approval or exemption, and an NIH formatted Biographical sketch should be submitted to specimens@childrensoncologygroup.org. The proposal submission must include a pdf document with letters of support from co-investigators, including a letter from the study's primary statistician.

Where can I access the biospecimen request forms?

All forms are available via https://www.childrensoncologygroup.org/obtainingbiospecimens. Investigators can also request forms via email to specimens@childrensoncologygroup.org.

When should I obtain funding for a proposal?

CTEP pre-review and approval is required for any new grant application planned to support the use of non-Navigator biospecimens. To initiate a CTEP pre-review, please send an email to specimens@childrensoncologygroup.org

For Navigator biospecimens, investigators should complete the COG and NCI review and approval process before applying for funding. Approval of a grant application does not constitute approval for the use of biospecimens.

Supporting Documentation

What IRB documents are needed?

A document of determination of exemption or approval from your Institutional review board or Ethics Committee is required. The document should include the PI's name, title of the project, and a date of acknowledgement that is current (not expired). Annual documentation is required for projects not deemed exempt.

Are multiple IRB documents required for all members of a collaborative team?

IRB documentation is needed for each investigator that intends to receive and work with biospecimens. If two investigators are at the same institution, only one IRB document from the lead investigator is needed. For a request with two or more investigators at separate institutions, an IRB letter should be put in place from each investigator at their institution.

Do I need an IRB letter if I work for an industry Company?

Yes, an IRB letter is needed.

We will utilize a 3rd party commercial lab to help process our samples. Does a commercial lab require an IRB letter?

Commercial labs do not require an IRB as they are working as vendors in a project.

Do I need to submit a biographical sketch?

Lead investigators are required to submit a biographical sketch (or bio sketch). COG will review these documents for an investigator's credibility and experience. See the following link for further guidance: Bio sketch Format Pages, Instructions and Samples | grants.nih.gov

In some instances, a biographical sketch is required for supporting collaborators such as statisticians, pathologists, bioinformaticians, etc.

Do I need a letter of support from my collaborators?

A letter of support from co-investigators and the project statistician will be needed for all NCTN Navigator submissions.

What credentials are needed to submit a biology request?

A CTEP I-AM RCR is needed by the time the request is ready to submit to the NCI for final review. There are not any specific professional credentials required as all investigators are welcome to submit a proposal.

How can I register for a CTEP-IAM/RCR account?

Investigators can go to https://ctepcore.nci.nih.gov/iam/ to create an account. After the CTEP account is created, complete the Registration and Credential Repository (RCR) account at https://ctepcore.nci.nih.gov/rcr/. Investigators should have at least an Associate account for biobank proposals

Do I need to be a COG member to request biospecimens?

No, investigators interested in biospecimens are not required to have a COG membership.

Completing the CCSC Proposal Submission Form

Do I need to list all collaborators as a co—investigator on my project?

Please list the proposed study's co-investigators including the primary proposal statistician. Only those investigators who have had/will have substantive input into the design, development, and/or conduct of your proposed correlative science study should be listed. The proposal submission must include a pdf document with letters of support from co-investigators, including a letter from the study's primary statistician.

What should I include as a response for Section 10: Trial(s) from which biospecimens are being requested

Number of cases where biospecimens were obtained in the trial: If requesting specimens from NCTN Navigator trials, investigators should check the number of cases for the samples of interest in NCTN Navigator.

If requesting biospecimens from trials that are not in NCTN Navigator, include “Not Available”.

Investigators should know that biospecimen availability obtained from Navigator and COG is subject to change. The biospecimen and data availability will not be confirmed until after a proposal is approved. All investigators should be aware that the Navigator and COG inventory query results are not a guarantee of biospecimen availability.

Review Process

The release of biospecimens for secondary use is under the purview of COG and the NCI.

How do I submit my documents for COG review?

Submit all documents to specimens@childrensoncologygroup.org.

What happens during the COG Review?

The application review will take at least 4-6 weeks at each stage of COG review. The projects are approved, disapproved or requested for responses to reviewer comments. If an application receives approval, it will proceed through review by the Scientific Council (if applicable).

Expedited review.

Select applications can be reviewed using an expedited pathway overseen by the specific disease committee. These are generally for exploratory or pilot investigations and involve small numbers of non-rare biospecimens. The definition of which studies are appropriate for expedited review is left to the discretion of the disease committee chair/vice-chair but should be defined a priori. For example, requests for < 50 biospecimens from non-rare patient subsets are considered appropriate for expedited review for neuroblastoma. For other rarer tumor types, this number may be smaller and will be decided by the appropriate biology committee. Expedited requests do not undergo COG Scientific Council review and instead will be submitted for NCI review.

Full disease-specific biology subcommittee review.

The biology chair will circulate applications with the PI bio sketch and any supporting documents to their standing subcommittee for review (with or without external reviewers). It is expected that > 2 primary reviewers will be identified for each application, and that for larger or complex applications an additional review from the disease group statistician be requested. For all application requests that require COG Scientific Council and CTEP review (requests ≥ 50 patient cases in total, biospecimens from ≥ 50% of patient cases from a single trial arm, or for certain rare or difficult to attain biospecimens), the disease group statistician must review the statistical justification for the application and approve of it first. The expected turn-around time for receipt of reviews is approximately 4 weeks.

What are common outcomes for Scientific Council Review?

Approved: the project may move forward to the NCI.

Approved with Stipulations: to be addressed point by point by the PI and resubmitted.
Approved with Recommendations: up to the discretion of the vice Chair of Biology to decide if they must be addressed and resubmitted prior to moving forward. If addressed, the revised application and supporting documentation may be resubmitted to Scientific Council for informational purposes only.
Deferral Notice: the investigator may submit a revised application with the point-by-point response letter.
Disapproved: the project cannot move forward.

How are requests for Tissue Micro Arrays (TMA) considered for review?

COG determined full review based on the number of slides being requested. If >50 slides are being requested, the TMA request will be reviewed by the Scientific Council. On the contrary, the Navigator Core Correlative Sciences committees reviews TMA requests are based on the requested number of patient cases.

What is the National Cancer Institute (NCI) Review Process?

There are two routes of review that projects can undergo for biobank requests:

1. National Clinical Trials Network (NCTN) Navigator clinical trial specimen resource.
2. Cancer Therapy Evaluation Program (CTEP)

What proposals qualify for NCTN Navigator review?

After receiving support from COG, requests for biospecimens collected via randomized phase 2 and phase 3 studies activated after 1995 and other NCTN selected studies are routed through the NCTN Navigator web portal.

The Navigator submission process is outlined by 3 steps: 1) PI submits a letter of intent 2) The Group Concierge completes the feasibility check and 3) PI submits their NCTN Correlative Science Proposal Submission Form for final review. All fully reviewed requests are reviewed by the NCTN Core Correlative Sciences Committee (CCSC).

What if the COG-approved biospecimens I'm seeking aren't accessible via the Navigator website?

If the biospecimens you requested were from patients enrolled on any randomized phase 2/3 or phase 3 clinical trial activated after 1995, and the trial does not appear in Navigator please reach out to specimens@childrensoncologygroup.org.

Who should I reach out to if I have questions about the Navigator website?

A Frequently Asked Question document is available for download on the NCTN Navigator website, Navigator-Login (ctsu.org). All additional inquiries regarding the Navigator portal should be routed to the Navigator Front Door Service via navigatorcontact@imsweb.com.

Do I need to specify data elements I am requesting in my biobank application?

Clinical data tied to biospecimen request proposals should be listed in the NCTN Correlative Science Proposal Submission Form.

Do I need to specify data I am requesting via the Navigator portal?

The investigator should check all boxes corresponding to the clinical data elements being requested in the NCTN Correlative Science Proposal Submission Form. The PI should check the "Other Specify" box to include additional data elements that are not already listed. Any clinical data requested in Navigator must be outlined in the approved COG Application and the NCTN Correlative Science Proposal Submission Form.

What qualifies for expedited Navigator reviews?

If requesting fewer than 50 patient cases and requesting fewer than 50% of the patient cases from each of the included trial arms, with no risk of biospecimen depletion the proposal may be eligible for expedited review. The Expedited NCTN Correlative Science Proposal Submission Form should be used for the proposal submission. Investigators can access the expedited form on the NCTN Navigator Portal. Expedited proposals are reviewed by the NCI's Cancer Therapy Evaluation Program (CTEP) after the request is submitted to the Navigator portal.

How long does it take for Navigator proposals to be reviewed?

Proposals will be scheduled for review at the first available NCTN-CCSC monthly review date that is ≥6 weeks after the proposal is received and accepted by the NCTN-CCSC coordinator.

> Note: Proposals submitted through the pediatric expedited proposal review process will generally be reviewed by NCI CTEP within 4 weeks. For more information about the pediatric expedited proposal review process, see: https://nctnbanks.cancer.gov/index.html#nctngroups

What proposals qualify for CTEP review?

Proposals that do not include Navigator studies qualify for CTEP review. Requests for biospecimens collected via randomized phase 2/3 and 3 studies activated before 1995, phase 2 studies or through APEC14B1/COG biology studies (e.g., AALL08B1, ANBL00B1, AREN03B2) require approval from COG and NCI's Cancer Therapy Evaluation Program (CTEP).

After the COG review is complete, the COG Biobank project coordinator will submit the application packet to CTEP via the Protocols and Information Office email. The application packet includes the NCTN Correlative Science Proposal Submission Form, a Protocol Submission Worksheet and a case list provided by the statistician.

NCI Review Outcomes

Proposals will be reviewed by the NCTN-CCSC for scientific merit, feasibility, and appropriateness of the statistical plan. Proposals may be approved, approved-on-hold, receive revisions requiring a response, disapproved, or not forwarded to Committee. Proposals not forwarded to the Committee are administratively disapproved by CTEP. Reasons for such disapproval may include lack of sufficient information to analyze the science, feasibility, and/or statistical plan, inappropriate use of samples. If/when resubmitted, such proposals will be entertained as de novo submissions. See https://ctep.cancer.gov/initiativesPrograms/nctn_ccsc_proposal_submission.htm for more information.

I received an approval from the NCI, now what?

Investigators that receive approval from the NCI will need to enter into agreements with the Children's Oncology Group (COG) to obtain biospecimens and data (if applicable). The NCI

outcome letter outlines the expectations and required documents that are needed to move forward with distribution.

How long does it take to receive biospecimens after NCI approval has been received?

Timelines will vary depending on the project, processing required, quantity, and other factors. Investigators will receive updates on estimated time of completion on a regular basis.

Agreements

What agreements are needed to receive biospecimens?

If an application is approved, the requestor must agree to sign a *Materials Transfer Agreement (MTA)*, crediting COG in any subsequent publication of the research with COG biospecimens. If correlated clinical outcome data is also requested with biospecimens, then the requestor must also sign a *Data Use Agreement (DUA)*.

A Cooperative Human Tissue Network (CHTN) Agreement for Use of Tissue and Data is also required for the release of biospecimens from the COG Biobank at the BPC.

NCTN Navigator CCSC or CTEP review can take at least 6 weeks or more.

Where can I receive a cost estimate?

For all inquiries, the COG Biobank and Data Project Coordinator can help obtain a cost estimate from the COG Biobank at the BPC.

Policies

How can I access COG Policies?

Policies can be accessed via the COG Members Website under the Administration Drop Down Menu. Please contact specimens@childrensoncologygroup.org if you do not have a COG Membership, and you would like more information on policies.

Publications

What information do I need to provide to COG regarding publications or completed projects?

The use of materials from the COG Biobank at the BPC represents the establishment of collaboration with COG. In general, when samples are provided that are characterized by COG, or when projects require statistical expertise and/or the input of clinical features including patient outcome, we request that appropriate members of the COG be included as co-authors in any manuscripts or abstracts submitted for publication or presentation. When a research and intellectual contribution of COG members is of little consequence in your work, co-authorship is not required but acknowledgment of the collaboration with COG is requested. The first and final draft of all abstracts and manuscripts reporting data obtained from COG must be reviewed by

the Vice-Chairs of the relevant disease biology subcommittee (copied on the correspondence) and by the COG Publications Office (pubs@childrensoncologygroup.org, with a copy to specimens@childrensoncologygroup.org), prior to submission, to ascertain proper authorship and acknowledgments.

Please remember to cite applicable grants as follows:

Use of biospecimens, please cite:
NCTN Operations Center Grant U10CA180886
COG Biospecimen Bank Grant U24CA196173
Pediatric Division CHTN grant UM1CA239754
WWWW Foundation, Inc. (also known as the QuadW Foundation) – if applicable

COG Statistical support provide, please cite:
NCTN Statistics & Data Center \ U10CA180899

Who can I reach out to if I have questions about publications?
Investigators can reach out to COG's publications Office via pubs@childrensoncologygroup.org for guidance on publications.

Common Questions about COG Biospecimens

Where are sample biospecimens housed?
The COG Biobank at the Nationwide Children's Hospital Biopathology Center in Columbus, Ohio.

We would like to replace the samples we received, what do we need to do?
Email specimens@childrensoncologygroup.org with a summary of your request including why you are requesting replacement samples.

Can I return my biospecimens to the COG Biobank?
Biospecimens that are removed from the COG Biobank cannot be returned. Source: FAQs & Funding Opportunities | NCTN | Initiatives/Programs | CTEP (cancer.gov)

Upon receiving approval from the biology committee, I received a Project ID. What is a project ID used for?
A biospecimen request that is approved by the Biology Committee receives a COG project ID number for tracking purposes. This ID number correlates to its respective protocol and is referenced in agreements and correspondence related to the biospecimen proposal.

I am interested in banked Tissue Microarray (TMA) slides. How can I request them?
Complete the TMA table in the PIBRF and specify details in the NCTN Correlative Science Proposal Submission Form.

What if I want to make an amendment to my application?
Requests to amend applications should be routed to specimens@childrensoncologygroup.org.

How can I receive the accompanying clinical data for biospecimens I received?

Once the work with biospecimens has been completed, investigators should reach out to specimens@childrensoncologygroup.org. A fully executed data usage agreement will be required for investigators to receive clinical data.

I need only one sample for research purposes, what do I need to receive this sample?

All COG Biobank requests, regardless of quantity, must go through the biospecimen request process. Requests for biospecimens from less than 50 patient cases may be eligible for expedited review if the request is for non-rare biospecimens, there are no concerns for depletion, and the number of requested specimens do not make up more than 50% of cases on a single trial arm.

I work for an industry company. How does this affect my biospecimen request?

COG is open to collaborations with all institutions and entities. COG Biobank requests from industry will undergo the same review process as a request received from any other institution. There is no difference in the review process based on institution type.

How can I find COG Sponsored Clinical Trials that have banked biospecimens that are available to request?

To find COG sponsored clinical trials, investigators can go to Home | ClinicalTrials.gov and use filters to search for “Children’s Oncology Group” and NCI sponsored studies.

Can I request biospecimens from a clinical trial that is currently active?

Generally, banked biospecimens from active clinical trials are not available to request until the trial is completed. Study data and biospecimens are eligible for secondary use when the study is completed and reported on. If the trial has reached 75% accrual, a discussion can be arranged for potential access.

Digital Image Requests

Digital image requests follow the standard COG Biobank procedures. Please submit the NCTN Correlative Science Proposal Submission Form, IRB letter, and Bio sketch to specimens@childrensoncologygroup.org.

I am interested in obtaining clinical data along with biospecimens. How can I request data?

Outline all variables of interest in section 17, page 5 of NCTN Correlative Science Proposal Submission Form.