Ewing Sarcoma Sample Request

APPLICATION FOR USE OF BANKED BIOSPECIMENS

Investigators continue to need reliable biospecimen collections with linked clinical, treatment, and outcome data crucial for advancing cancer research, validating and bringing biomarkers and tests from the bench to bedside, and enabling personalized medicine in the future. The purpose of the Children’s Oncology Group (COG) biospecimen bank located at the Biopathology Center (BPC)/Nationwide Children’s Hospital in Columbus, OH is to support integrated and integral biomarker studies conducted by the COG, and to maintain a publicly available supply of biospecimens to support research conducted by the childhood cancer research community.

Instructions

The Principal Investigator (PI) responsible for overseeing the project, laboratory and personnel who will receive, use and process the requested biospecimens should complete this application. Each section of this application must be fully completed. The information in these forms is necessary in order to accurately document your request for tissue and other services and to ensure that the COG and BPC operate within the guidelines of the National Cancer Institute (NCI). When submitting a written request for services, note the following:

- A written justification of the need to transfer the materials and benefit to the applicant’s research.
- Copy of the COG Materials Transfer Agreement (COG) signed by the collaborator.
- Documentation of the collaborator’s current IRB approval or exemption unless the collaborator is covered under the IRB approval granted for the project proposed in this application.

The Children’s Oncology Group (COG) and the Biopathology Center (BPC) do not supply samples to specimen banks whose purpose is distribution to third-party researchers; those researchers should be encouraged to apply to the BPC directly.

The information in these forms is necessary in order to accurately document your request for tissue and other services and to ensure that the COG & BPC operates within the guidelines of the National Cancer Institute. When submitting a written request for services, note the following:

1. Please download and fill out the Sample Request Form (see Required Documents section below). Please make sure you have all the required documentation detailed in the Specimen Request Form.
2. If requesting specimens from more than one specific anatomic site or disease, please complete separate copies of the Specimen Request Form as necessary (biospecimen type and preparation details).
3. Patient identity is confidential. Samples and accompanying clinical data will be identified by a unique code and patient-identifying information will not be released under any circumstances.
4. The PI is responsible for remission of processing fees to the BPC, including fees for any additional services performed and any shipping costs not directly billed to the applicant’s courier account. Please contact The Biopathology Center at BPCDist@nationwidechildrens.org for the current fee structure.
5. A current copy of your NIH biosketch must also accompany this application.
6. PIs must obtain human subjects review from their institution in order to receive specimens from the COG/BPC. Full or expedited approval or an exemption for your project can be obtained from your Institutional Review Board (IRB) (Human Use Committee). A COPY OF THE HUMAN SUBJECTS APPROVAL OR REVIEW DOCUMENTATION SHOULD BE RETURNED WITH THIS FORM. Documentation of annual review of non-exempt protocols by the PI’s institution must be forwarded to the BPC in order to maintain eligibility to receive tissue. This is not necessary for exempt protocols. If your institution does not have an internal review, contact the investigator services team at specimens@childrensoncologygroup.org.
7. A Materials Transfer Agreement (MTA) with the COG is included with this application so you may begin the review process with your institutional official while your proposal is under evaluation with the respective COG disease committee. Please note that if your proposal is approved, then the COG MTA is required to be fully executed before any specimens will be distributed.
8. Also required prior to specimen distribution is completion of an Agreement For Use of Tissue and Data Use Agreement between the investigator and the Biopathology Center (BPC)/Collaborative (formerly Cooperative) Human Tissue Network (CHTN). The BPC/Pediatric Division of the CHTN serves as the specimen distribution mechanism for the COG.
9. Each request will be reviewed by the respective COG disease area’s Biology Subcommittee.
10. PIs of studies approved by the COG will be required to submit brief, periodic progress reports to the respective COG disease committee, and once the primary analysis of the study is published, PIs must send specific data sets (i.e., at the patient level) from the correlative study to COG. Any publication of the study should be sent to the respective COG disease committee, for their information, with appropriate acknowledgments.
11. All approved requests for COG specimens will be filed with the NCI Cancer Therapy Evaluation Program (CTEP). Requests for > 100 samples require review and approval by the COG Scientific Council and the NCI Cancer Therapy Evaluation Program (CTEP), in addition to the respective COG Disease Committee’s review. Request for < 100 samples will be sent to the NCI CTEP as file-only studies.
12. For certain diseases/biospecimens, (e.g. rare or difficult to attain biospecimens), full COG review approval may be required for requests of any size. Full COG review includes evaluation by the respective COG Disease Committee and the COG Scientific Council. A fee for statistical effort in generating specimen-associated data-sets and data analyses may apply.
13. If you have any questions about this web application, contact Tanya Tello at the Children’s Oncology Group (ttello@childrensoncologygroup.org or 626-241-1552).

Required Documents & Submission Process

The following documents need to be included at the time of electronic submission:

- Sample Request Form.docx
- Proposal
- Curriculum Vitae of Individual responsible for Data Analysis Plan
- NIH Biographical Sketch
- IRB Chairperson Letter

When all documents listed above are ready to be submitted, please CLICK HERE to be taken to the Electronic Submission site.

You should receive an email within 1-2 hours indicating that your proposal submission has been received.

COLLABORATING PERSONNEL/LABORATORIES

Any transfer of samples, aliquots, derivatives or associated clinical data to collaborating personnel or laboratories outside of your home institution that are not under the direct supervision of the indicated PI requires the following:

- A written justification of the need to transfer the materials and benefit to the applicant’s proposed research.
- Copy of the COG Materials Transfer Agreement (MTA) signed by the collaborator.
- Copy of Agreement For Use of Tissue and Data Use Agreement between the investigator and the BPC/CHTN.
- Documentation of the collaborator’s current IRB approval or exemption unless the collaborator is covered under the IRB approval granted for the project proposed in this application.

This applies to pay-for-service labs that may be used for your project.

DISTRIBUTION TO THIRD-PARTY RESEARCHERS

The COG and BPC do not supply samples to specimen banks whose purpose is distribution to third-party researchers; those researchers should be encouraged to apply to the BPC directly. Transfer of specimens to another bank is strictly prohibited.

CHILDREN’S ONCOLOGY GROUP STATEMENT OF CONFIDENTIALITY

The Children’s Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. The Certificate protects against the involuntary release of information about subjects collected during the course of our covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.