# Translational Research Program (TRP)

**Concepts Requesting Utilization of Existing Alliance Biospecimen Resources**

## Step One: TRP Triage Review

 Study principal investigator (s) complete Triage Review Form and submit the completed form to TRP Director of Translational Research Operations (Yujia Wen, MD/PhD at ywen@bsd.uchicago.edu)

## The TRP Triage Review process will involve:

* Appropriate disease or modality Committee Chair
* Appropriate disease or modality Correlative Science Vice Chair
* Parent study or studies’ principal investigator(s)
* Biorepository Principal Investigator
* TRP Executive Officer
* TRP Director of Translational Research Operations
* TRP Principal Investigator/Program Director

TRP triage review is streamlined through emails coordinated and recorded by TRP project manager. Only concepts with majority approval will move forward to full correlative science protocol development.

After a concept is approved, TRP Director of Translational Research Operations will forward an approval notice to a designated protocol coordinator through email. Designated protocol coordinator will contact study principal investigator(s) with protocol template to initiate the protocol development process.

## Step Two: Protocol Development Process

* 1. Study principle investigator submits a completed Alliance Conflict of Interest Form to TRP Director of Translational Research Operations (Yujia Wen, MD/PhD at ywen@bsd.uchicago.edu )
	2. Study principle investigators complete the first full draft protocol and submit to the designated protocol coordinator.
	3. Protocol Development Process:
* Designated protocol Coordinator is engaged as the point person for duration of protocol development/review process.
* Designated protocol Coordinator determines resource requirements for concept and works with concept Investigator(s), central office, TRP Director of Translational Research Operations, biorepositories, and statistics to ensure there is adequate support.
* TRP Protocol Coordinator provides the Correlative Science Protocol Template, lays out guidance for protocol development review, timelines, and responsibilities to the Investigator, Statistician, and Biorepository Contact
	+ Investigator provides specific protocol content regarding background, purpose, methods, and other elements.
	+ Biorepository Staff to generate actual case inventory to the Statistical Center to generate eligible case specimen list and present an estimated budget.
	+ Assigned protocol statistician develops statistical section and provides a cost budget to the investigator if data set prep and future data analyses will require more than 25 hours of work.
* The study team and necessary stakeholders review completed protocol. Feedback is submitted from their review.
* The Study Chair and TRP EC discuss the planned mechanism for funding and the TRP can write a letter of support for the grant application, etc. (contract agreement manager and/or group chair office may be engaged)

## Step Three: TRP EC Full Review

* 1. Protocol draft submitted to the TRP Executive Committee for final review. Concurrent review by a primary reviewer, a secondary reviewer, and a statistical reviewer is required.
	2. If approved, the TRP Project Manager will contact the study team regarding the approval.
	3. For protocols which are conditionally approved or “tabled” pending revision, the TRP EC will stipulate whether re-submission will require full EC re-review or just TRP PI/Director sign-off only. All TRP EC review comments should be addressed before resubmission.
	4. If disapproved, the TRP PI will write a letter to investigators outlining major concerns and suggestions for resubmission or redirection of the study.

Full Review and Scoring:

TRP will recruit two independent reviewers with the appropriate disease/molecular expertise and one statistical reviewer. The Leukemia panel will oversee the review for the leukemia or other hematologic malignancies banked in the Alliance Leukemia Tissue Bank, while the Solid Tumor panel will review the concepts that will use material banked in the other Alliance biorepositories. Concepts will be given a priority score following initial review by the TRP Executive Committee that will guide allocation of TRP, statistical, and Biorepository resources for the protocol development process. Categories for scoring concepts include:

* + - Scientific and/or clinical impact
		- Overall feasibility
		- Level of innovation
		- Cooperative group relevance
		- Study design

## Step Four: NCI CTEP Review

The final TRP EC approved protocol will be sent to CTEP for approval; this will generally entail submission of a protocol amendment to the parent clinical trial protocol or submission of a stand-alone secondary-use biospecimen study. Considering the operational burden on study sites, stand-alone study protocols are preferred.

## Step Five: Post-NCI CTEP Approval

Following final NCI CTEP approval, several criterion must be addressed prior to protocol activation which include:

* If there is a pending agreement, the study will not be activated until the agreement is finalized
* Specimen recipient lab must submit site IRB approval or exemption according to site institutional policy
* Specimen recipient lab must be registered with Alliance
* Materials Transfer Agreement (MTA) or Memorandum of Understanding (MOU) must be finalized

Following CS study activation, the Study Chair has ongoing responsibilities that include:

* Acquisition and analysis of specimens, images, and/or data
* Coordinates generation of abstract and manuscript, ensuring authorship of publication includes appropriate contributors
* Collaboration with Alliance Publications Committee before presentation or publication of results
* Ensuring Conflict of Interest is current for the lab PI and Study Chair throughout the duration of the study
* Maintains IRB approval/exemption status, including any protocol amendments, according to site institutional policy
* Returning any leftover/unused specimen/derivatives to Alliance Biorepository upon completion of work
* Discuss amendments with Alliance TRP