

Appendix 5: Submission process to access US patient samples

Once (Neo)ALTTO SC grants approval, the research project proposal will also need to be submitted (using the NCTN-CCSC proposal form, Version 1, version date July 15, 2015) to the Alliance group representative at ALTTO@mayo.edu, please also copy: MorenoAspitia.Alvaro@mayo.edu

1. The Alliance representative will submit the proposal to the Protocol Information Office (PIO) at the NCI Cancer Therapy Evaluation Program (CTEP) at pio3@CTEP.NCI.NIH.gov. The proposal should be accompanied by a Cover Letter/Email from the Alliance which states that the proposal is being submitted as a Correlative Science Proposal under the NCTN collaboration with BIG on the ALTTO study.
2. Once NCI grants approval, the investigator will need to submit the proposal to their local IRB for review and approval.

NOTE: If in some institutions it is not a local requirement to submit translational Research Project Proposals to the local IRB, there will need to be review by the Mayo IRB to determine if the proposal can be approved or if it is IRB exempt if the samples to be used in the proposal will include US patient samples stored by the Alliance/Mayo biorepository.

3. Once IRB approval has been granted, the investigator should contact Roxann Neumann at Mayo Clinic in Rochester Minnesota (Neumann.Roxann@mayo.edu).
4. A MUA/MTA will need to be completed. The completed MUA/MTA will need to be reviewed and approved by the Regulatory Affairs Branch at NCI/CTEP (NCICTEPRABDocuments@mail.nih.gov) prior to release of samples from the Alliance/Mayo biorepository.

NOTE: A MUA (Material Use Agreement) is used for academic institutions and a MTA is used for commercial entities (ie. Frontier Science), with the involvement of Mayo Legal.

5. Alliance will send to the investigator to complete 4 separate forms. Once the completed forms are received, approved and **funding is in place** then Roxann can send the samples.

For any other questions regarding this process please contact ALTTO@mayo.edu or Roxann Neumann, Neumann.roxann@mayo.edu

Process to access US BM - Diagram

