RFA-CA-15-022:
Guidance for "Letter(s) of Support" to Access Biospecimens from NCI-sponsored National Clinical Trials Network (NCTN) studies

COMPLETED AND REPORTED STUDIES

Definition:
These are NCTN clinical trials that have completed enrollment, all primary and secondary clinical objectives have been met, and the results reported. All protocol-specified integral and integrated correlative science objectives using the trial biospecimens have been completed.

Access to trial biospecimens requires a written proposal to use the specimens to be developed in collaboration with an NCTN Group (NCTN Group PI/Chair for the NCTN Group Operations Center grant). The NCTN Group must submit the proposal to the NCI NCTN Core Correlative Science Committee for review and recommendation for release of samples. Such proposals, when approved, may also require the review and comment by CTEP's pharmaceutical collaborator(s) (the supplier of the agents(s) used in the study).

Letter of Support:
Interested investigators may request Letters of Support from the NCTN Group (NCTN Group PI/Chair for the NCTN Group Operations Center grant) responsible for the conduct of the clinical trial of interest. This Letter of Support must indicate the willingness of the NCTN Group to participate in the submission of a biospecimen use proposal to the NCI NCTN Core Correlative Science Committee and does not constitute permission for biospecimen release. This letter must be signed by the principal investigator of NCTN Group Operations Center grant (Group Chair).

ONGOING AND PLANNED STUDIES

Definition:
NCTN Group clinical trials that have not yet reached their primary endpoint and are reported, and/or still under oversight of the Data Safety Monitoring Board may be amended to include new integrated correlative science endpoints. This includes studies from initial activation to those that have completed enrollment and have not yet reported out. Studies still under development may have collaborative integrated correlative science endpoints added.

In both cases, such correlative science endpoints must be added through NCTN Group review and agreement, followed by NCI/CTEP review and approval under the NCTN Program. Review and comment by CTEP's pharmaceutical collaborator(s) will also be required when the collaborator(s)' agents are used.

Such amendments for integrated correlative science endpoints require detailed background information, detailed assay information, and focused statistical plans.

Letter of Support:
Interested investigators must request Letters of Support from the NCTN Group (NCTN Group PI/Chair for the NCTN Group Operations Center grant) responsible for the conduct of the clinical trial of interest. This Letter of Support must indicate the willingness of the NCTN Group to submit an amendment for use of the on-going trial's biospecimens for an integrated correlative science study to CTEP and does not constitute permission for biospecimen release. This letter must be signed by the principal investigator of NCTN Group Operations Center grant (Group Chair).