Policy Name: Functions of Biospecimen Repositories	**Policy Number:** 11.1
Section: Biospecimen Repositories and Translational Research – 11	**Date Revised:** November 7, 2013

11 Biospecimen repositories and translational research

11.1 Functions of biospecimen repositories

The Alliance biospecimen repositories perform various functions for the group. The main function of the repositories is to collect, process, store, and distribute the biospecimens associated with Alliance trials. In addition, the repositories provide other services for the group such as: preparation of nucleic acids, preparation of tissues for quality control review by pathologists, preparation of tissue microarrays and performing research for correlative science projects. The Alliance repository management personnel participate in the Group Banking Committee (GBC) and work with that committee to standardize processes across the network groups.

The work to be done by the repositories is specified in each protocol. Correlative science studies that are companions to Alliance treatment protocols are either "embedded" in those protocols, as sub-studies, or written as "stand-alone" companion trials. Some protocols describe only the collection of specimens and in such cases the companion laboratory studies are developed and written at a later date.

Specimens from Alliance-coordinated studies are managed by the Alliance Biospecimen Management System (BioMS), which tracks biospecimens as they are collected, processed, stored and distributed. This system integrates multiple biorepositories from the legacy ACOSOG, CALGB, and NCCTG groups into a single Alliance biorepository system. The specific locations to which biospecimens are sent depends on the protocol through which the biospecimens are collected, the type of biospecimen collected, and any specialized processing requirements.

Biospecimens collected through Alliance trials are sent to one of the five Alliance biospecimen repositories:

- OSU – Alliance Biorepository at The Ohio State University
- HEME – Alliance Hematologic Malignancy Biorepository
- LCTB – Alliance Lung Cancer Tissue Bank
- WUSTL – Alliance Biorepository at Washington University
- MAYO – Alliance Biorepository at Mayo Clinic

The Alliance Biorepository at The Ohio State University (OSU) is a repository for biospecimens associated with solid tumors studies as well as lymphoma studies. OSU receives all types of biospecimens including tissue blocks, tissue slides for central morphology review, and biofluids including serum, plasma, and urine.

The Alliance Hematologic Malignancy Biorepository (HEME) also resides at The Ohio State University and stores specimens from patients with acute or chronic

leukemia, myelodysplastic syndrome, or multiple myeloma who are enrolled on an Alliance protocol. HEME primarily receives blood and bone marrow specimens, and, in some cases, buccal smears.

The Alliance Lung Cancer Tissue Bank (LCTB) is located at the Brigham And Women's Hospital in Boston, MA. The purpose of the LCTB is to collect, catalog and store frozen samples of lung carcinoma and when possible, portions of involved lymph nodes and adjacent uninvolved lung tissue obtained from previously untreated patients. In addition to tissue specimens, blood samples are also collected pre- and post-resection from the patients to provide a source of quality DNA, RNA and protein for molecular studies.

The Alliance Biorepository at Washington University (WUSTL) in St. Louis, MO, is focused on the collection, storage, and distribution of frozen tumor tissue from adjuvant and neoadjuvant trial patients, and their use for integral and integrated genomics-based biomarker studies. As such, WUSTL mainly receives frozen tumor biopsies, surgical resection specimens, and matching serum, plasma, and whole blood.

The Alliance Biorepository at Mayo Clinic (MAYO) in Rochester, MN, and is the repository for biospecimens associated with solid tumors studies, with a particular focus on biospecimens from neuro-oncology studies. MAYO receives all types of biospecimens such as: tissue (FFPE and frozen), serum, plasma, etc.

Most protocols require that specimens collected on Alliance trials be sent from the clinical site to the designated repository. In some instances, due to issues of biospecimen stability or the necessity for rapid turnaround time for an integral biomarker result, it may be required that biospecimens be sent directly to the analysis laboratory of an investigator for a particular study. Such exceptions must be approved by the director of translational research or the principal investigator of the Alliance TRP. If approved, the investigator receiving the specimens must agree to follow the Alliance specimen repository policies and procedures as documented by the completed Alliance Investigator Agreement. If an investigator is interested in establishing a new Alliance biospecimen repository, the approval of the Alliance group chair is required.

The Alliance biorepositories are the intermediaries between the submitting institution and the research investigator. Each Alliance biospecimen repository acts as the Alliance guardian for the specimens.

Policy Name: Policies and Procedures for Alliance Repositories	**Policy Number:** 11.2
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11.2 Policies and procedures for Alliance repositories

As the Alliance steward of specimens, the repository director agrees to procure, store, process and distribute the specimens according to Alliance policy. In addition, if the bank does not comply with Alliance policy, the Alliance can move the biospecimens to another approved Alliance location.

The repository director is responsible for ensuring that the appropriate quality control and quality assurance procedures are in place for specimen handling, processing, storage and distribution.

The repository will undergo periodic audits to ensure compliance with Alliance and NCI policies. Oversight for the audits of the Alliance repositories will be a function of the Translational Research Program Executive Committee.

The Alliance repositories store biospecimens only from patients who are pre-registered or registered on a study coordinated by the Alliance or another cooperative group.

If a registered patient withdraws consent from treatment but agrees to be followed on protocol, biospecimens may be submitted as required by the protocol. If a registered patient withdraws consent for participation in the study or consent for follow-up, biospecimens may not be submitted. If biospecimens have already been submitted but not distributed to investigators at the time when the patient withdraws consent, those biospecimens will be withdrawn from the repository and will be disposed of appropriately – either destroyed or, in the case of paraffin blocks, returned to the submitting institution. Attempts will be made to retrieve any specimens that have been sent from the repository to investigators. However, processed specimens and the research data generated from them will not be rescinded, and may be used in study analyses.

Biopecimens are not released from the repository to investigators until the Alliance statistician assigned to the study or designee confirms the record of patient consent in the Alliance database. If a specimen is present in the repository but does not have the appropriate patient consent, the specimen will be withdrawn from the repository and will be disposed of appropriately – either destroyed or, in the case of a paraffin block, returned to the submitting institution. Disagreement between investigators and statisticians with respect to consent language for specific analyses will be adjudicated and decided by Alliance ethics leadership, statisticians, and the director of translational research.

All biospecimens managed by the repositories are tracked by a database system (the Biospecimen Management System). Each specimen submitted to an Alliance repository is accompanied by the appropriate paperwork, as required by the protocol. Local records are kept in addition to the database. Local records will be secured in a locked cabinet/office at all times and database security will follow that recommended by the Alliance Statistics and Data Center (SDC).

For paraffin block specimens that have been submitted to any Alliance repository, the appropriate representative sections and/or cores will be prepared and the block will remain on file and will be available to the submitting institution for any medical-legal need.

Alliance repositories must maintain the following safeguards to protect patient privacy, confidentiality and medical-legal concerns:

- A unique Alliance biospecimen identification number will be assigned to each biospecimen. Biospecimens must be stored and distributed with this number only. Investigators may not receive any patient identifiers, only the unique specimen bank number.

- Only select bank personnel may have access to match the unique sample ID with the Alliance patient ID number and only select Alliance statisticians may have the ability to link the unique specimen ID number, patient information, and clinical outcome. Exceptions must be approved by the principal investigator of the Translational Research Program and the group statistician for the Alliance.

- Reports (including manuscripts, abstracts, and progress reports) may never list any patient by name or initials. If needed, only unique identification codes may be used.

- Unless indicated in the protocol and performed in a CLIA-certified laboratory, results from correlative science studies may not be provided to the patient or physician. Upon request, information may be made available as aggregate data in the form of abstracts or manuscripts.

- The Alliance maintains Certificates of Confidentiality for each of its repositories from the US Department of Health and Human Services (HHS), which protects against the involuntary release of information collected during the course of the study. The researchers involved in this project may not be forced to identify a patient in any legal proceedings (criminal, civil, administrative, or legislative) at the federal, state, or local level. However, some information may be required by the Federal Food, Drug, and Cosmetic Act, the HSS, or for purposes of program review or audit.

11.3 Patient consent for use of specimens

Patient consent for studies (including those of heritable genes) must be obtained prospectively. Consent forms must include adequate information to assess risks.

It is the Alliance policy that all companion protocols with specimen submission that are embedded in a protocol must be offered to all patients enrolled on the study, although patients may opt not to participate. Therefore, specimen submission, in general, is optional for the patient but not optional for the site. Exceptions to site participation in specific companion studies may be granted by study chair, in consultation with the corresponding correlative sciences vice-chair and the TRP, in circumstances when the requisite resources or other infrastructure are not available at that site. The site must offer companions to patients. There may be rare instances in which specimens are considered a mandatory part of the study (i.e., if there is a primary endpoint that depends on their analysis or if the specimen is required to determine eligibility or study arm stratification). In these rare cases, specimen submission will be mandatory.

In the case of future studies including germ line susceptibility studies (studies of heritable genes), participants are asked to grant broad permission (i.e., it is unknown exactly what tests might be appropriate or performed in the future at the time the specimen is banked). Participants will NOT be re-contacted for each individual study.

Previously banked material that was not originally intended for extensive DNA studies (e.g., whole genome sequencing, whole exome sequencing, and genome-wide association studies) and for which informed consent was not originally obtained may be used for such research, but in these cases a re-consent must be obtained from the participant at the institutional level. For deceased patients, where re-consent is not practicable, a waiver of consent must be obtained at the institutional level.

11.4 Obtaining Alliance specimens

The Alliance encourages the conduct of studies that link basic or translational research with the results of Alliance treatment trials. Investigators performing laboratory studies serve as study chairs of Alliance correlative science companion trials.

Proposals to utilize the specimens collected in a prospective trial ideally should be included in the clinical trial protocol concept at the time it is submitted to the Alliance Study Concept Review Committee. Proposals to study specimens retrospectively should be submitted following the process described below. Each proposal should include an introduction, specific aims, preliminary data, research design, methods, statistical analysis plan, and references. Particular attention should be paid to describing the performance characteristics of the analytical methods to be employed. A template is available on the Alliance website under the 'Clinical Trials' tab.

11.4.1 Submission and approval of a correlative science proposal

A proposal to utilize biospecimens and resources of the Alliance will be reviewed in the following manner.

The concept should be based on an innovative idea, built around a strong biologic hypothesis, be scientifically valid and have significant clinical relevance. The investigator must demonstrate expertise, both technical and scientific, relevant to the work proposed. Therefore, previous publications in the area and/or preliminary data are required. Preliminary data are also required to evaluate the scientific rationale and logistics of the concept, the performance characteristics of the assay(s) to be employed (including accuracy compared to a gold standard, reproducibility, variability, and/or other available analytic validation), and to demonstrate clinical relevance. The study must be feasible to be performed in and require a cooperative group setting; a study that can be performed in a single institution is not appropriate. Also evaluated is the use of and impact on Alliance resources, including the repositories, the SDC, the Central Protocol Operations Program, and if the investigator has financial support for the study.

The concept review and approval process consists of two steps, which includes a triage review followed by full review. The triage review's goal is to rapidly identify concepts that will be disapproved due to fundamental flaws or lack of feasibility (such as proposals for inappropriate use of Alliance specimens, requests for specimens which are not available, or concepts with significant scientific flaws including overlap with pre-existing, approved projects). This process involves the appropriate disease

or modality (e.g., Leukemia Correlative Science) committee chair and/or vice-chair, study principal investigator(s), and biorepository staff. For all parties involved, providing investigators early feedback regarding critical flaws will provide an opportunity for them to identify other sources of tissue and/or revise their project to better align with resources and policies of the Alliance. Projects without critical flaws should move forward to full review. It is anticipated that investigators requesting a letter of support from the Alliance as part of a grant application provide a concept sheet for triage review prior to obtaining a letter of support.

The full review's goal is a rigorous assessment of the scientific merits of the concept to facilitate prioritization within the TRP and disease or modality committee and the allocation of Alliance resources. Full review begins when concepts successfully complete triage review. Full review will model that of the Study Concept Review Committee with two independent reviewers with the appropriate disease/molecular expertise and a statistical reviewer for each concept who will be recruited by the TRP Executive Committee on an ad hoc basis. Additional investigators have been engaged to participate in the TRP Executive Committee to support concept review. Upon completion of review; the concept will be given a priority score that will guide allocation of TRP, statistical, and biorepository resources. Specific allocation of resources will be based upon discussions between TRP administrative core and the appropriate disease or modality committee.

As evaluation of concepts for solid tumors and leukemia may require different expertise, both the triage and full reviews will be overseen by two different panels of experts (i.e., solid tumors and leukemia). 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.

While there are no official timeline guidelines for this process, the goal is to complete review and prioritization within six months of concept submission. The TRP will track all concepts and help with project management for approved concepts. The submission and approval process is as follows:

1. Investigators must complete the Translational Research Program Triage Review Form, available on the Alliance website.
2. TRP will obtain comments from correlative science vice chair, disease committee chair(s), study principal investigators, and the biorepositories.
3. The TRP Executive Committee will review and vote go / no-go. Minimum number of votes needed: at least half of the members or

Leukemia Correlative Science Review Committee, depending on the nature of the concept, must vote for voting to be considered complete. Majority vote is the decision.

4. Concepts with adequate number of go's and equal or greater go versus no-go votes move forward to full review.
5. Concepts moving to full review require:
    a. Investigator must complete a full correlative science protocol template with all required elements.
    b. Central Protocol Operations Program's concept review staff will be engaged (ideally a protocol coordinator specifically focused on biospecimen-use only concepts).
    c. Biorepository staff provides specific information regarding the number and condition of samples available for the concept.
    d. Disease or modality committee statisticians review and/or develop statistical section for Alliance investigator-initiated studies, or review protocol and confirm availability of requested clinical/outcome data and eligible sample size for industry-initiated and non-Alliance sponsored studies.
    e. Disease or modality committee chair(s) and Correlative Science vice chairs review concept and sign off. The disease or modality committee chair will submit the concept to the SCRC for concept review just as they do trial concepts.
    f. The Alliance Foundation and/or the Office of the Group Chair's contracts specialists will be contacted to initiate budget development, memorandum of understanding, and contract.
    g. TRP will determine resource requirements for concepts and works with concept investigator(s), Central Protocol Operations Program, biorepositories, and statistics to ensure there is adequate support.
6. Concepts will be presented to the TRP Executive Committee for final approval and prioritization using the SCRC scoring categories listed below.
    a. Scientific and/or clinical impact
    b. Overall feasibility
    c. Level of innovation
    d. Network group relevance
    e. Relative importance

Each individual project submitted for final approval will contain a statistical section, written and/or approved by an Alliance statistician, detailing the hypothesis and the estimated sample size required for the proposed analyses. The group statistician must approve exceptions to this policy.

- Final Alliance-approved protocols 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.

- Once CTEP approval is obtained, IRB approval will be obtained from the IRB affiliated with the laboratory receiving and performing studies on Alliance biospecimens.

- Contracts and memorandum of understanding will be executed for approved concepts.

- For protocols which are conditionally approved or "tabled" pending revision, full committee re-review, or the director of translational research or principal investigator of TRP sign-off only, will be stipulated by the TRP Executive Committee as required for approval after resubmission.

- If not approved or disapproved, the principal investigator of TRP will write a letter to concept investigator(s) outlining major concerns and suggestions for resubmission or redirection of the proposed study.

All studies utilizing specimens must be submitted to NCI/CTEP. For studies embedded in a clinical trial, reviews of the correlative sciences components will be included in the review of the clinical study. Any separate, correlative science study that uses ≥100 biological specimens from group trials (or ≥100 patients for a separate, non-treatment adjunct study) must undergo CTEP review. Any separate, correlative science study that uses <100 biologic specimens from group trials (or <100 patients for a separate adjunct study) must be submitted to CTEP for tracking purposes ("File Only") but does not undergo formal review. For correlative science proposals seeking to use specimens from intergroup trials, CTEP review can be substituted by review by an intergroup correlative sciences committee according to an agreement between the particular intergroup and CTEP.

11.4.2 Procedures following approval

All correlative science investigators must agree to use the specimens for only the Alliance-approved research project and to follow Alliance policies and procedures. Here are some specific guidelines:

- Once the project is approved, the investigator will be responsible for ensuring that his/her research is conducted under the rules governing their individual institution, as well as those set forth by the Alliance.

- If the investigator is not a participant in the Alliance but is based within an Alliance member institution, the investigator should contact the Alliance principal investigator at the institution in order to become a participant and have the investigator's name entered in the Alliance database.

- If the investigator is not a participant in the Alliance and is not at an Alliance institution, the chair of the responsible scientific committee, in consultation with the investigator, may appoint an Alliance participant as the co-chair of the proposed study. The person serving as the Alliance co-chair will assist with study logistics and will present a synopsis of the status of the study at Alliance meetings if the non-Alliance investigator is unable to attend.

- Samples are furnished to the investigator by the appropriate Alliance specimen repository for the purpose of the project as approved. Research must be limited to that described in the approved protocol.

- Investigator must not share any portion of specimen or derivative specimen with another investigator or lab without permission of the director of translational research or the principal investigator of the TRP and the relevant scientific oversight committee.

- Investigators must discuss return of all unused specimens to the Alliance specimen repository at the completion of their correlative study. This includes RNA, DNA, urine, plasma, serum, tissue, slides, unstained sections, etc. Investigators are prohibited from using Alliance specimens or specimen derivatives for purposes other than those approved by the Alliance.

- Data from all laboratory tests performed on samples from any Alliance repository will be submitted to the Alliance SDC, usually via electronic means. The analysis of the data will be conducted by the responsible Alliance statistician or designee with the necessary expertise. The designee must be approved by the principal investigator of the TRP and the group statistician. The group statistician must approve any exception to this rule.

- All publications must be reviewed and approved by the Alliance, following guidelines in the Alliance Policies and Procedures. The support of the appropriate Alliance repository will be acknowledged in publications.

The following documentation must be on file with the Alliance Chicago Office before samples can be distributed to an investigator:

- Documentation of approval of the scientific proposal by the SCRC or the TRP Executive Committee and NCI/CTEP and/or the relevant intergroup correlative sciences review committee when appropriate.

- Documentation of IRB approval from the investigator's institutional review board.

- The investigator must sign an Alliance memorandum of understanding and agree to follow all other Alliance Policies and Procedures.

- A study-specific Financial Disclosure Form must be completed by the investigator and is subject to review by the Conflict of Interest Committee.

- Registration of the laboratory performing the research with the Alliance Chicago Office.

- Documentation of CLIA and/or CAP certification of the laboratory, if applicable.

The above-mentioned documents are available for download on the Alliance website under the 'Clinical Trials' tab. Once all documents are on file, the director of translational research will notify the appropriate Alliance specimen repository of project approval.

Policy Name: Sending Specimens to the Alliance Repositories	**Policy Number:** 11.5
Section: Biospecimen Repositories and Translational Research – 11	**Date Revised:** March 15, 2013

11.5 Sending specimens to the Alliance repositories

Each protocol document must specify how to collect, prepare and ship specimens to the Alliance repository. Questions regarding the collection and/or shipment of the materials should be directed to the repository where the specimen is being sent.

The Alliance has instituted special considerations for the small percentage of institutions whose policies prohibit the release of tissue blocks. If, due to institutional policy, a block may not be sent, an institution must contact the appropriate Alliance repository to obtain a protocol for submission of representative tissue.

If an Alliance study requires slide submission for histopathology review, those slides must be received at the appropriate repository within 60 days of patient registration unless otherwise specified in the protocol.

All specimens shipped to Alliance repositories must have patient consent and be accompanied by the appropriate paperwork (forms, path report, etc.).

All items should be handled using universal precautions. Each institution has training available in universal precautions.

For more details, please see Translational Research Program Biospecimen Collection, Processing, and Submission – Manual of Standard Operating Procedures.

Policy Name: Oversight of the Alliance Repositories	**Policy Number:** 11.6
Section: Biospecimen Repositories and Translational Research – 11	**Date Revised:** March 15, 2013

11.6 Oversight of the Alliance repositories

Oversight of the Alliance repositories is primarily the responsibility of the Translational Research Program. The relevant TRP committee, the individual disease committees, and the vice-chair of the disease in charge of translational research are responsible for (1) determining which biospecimens should be collected on the trials and what the appropriate methods are for collection and processing of those biospecimens, (2) ensuring that the repositories have the appropriate quality control and quality assurance procedures in place for biospecimen handling, processing, storage and distribution, (3) providing central histologic/cytologic review for quality control of patient eligibility and confirmation of response, and (4) histologic review of tissues for correlative science projects to ensure that representative tissue is being distributed for laboratory assays.

Central histopathology review is limited to:

- Diagnoses that have traditionally shown significant discordance rates between local pathologists and central pathology review, such as those for lymphomas and leukemias.
- Studies that require expert or special histologic assessment.

The TRP Executive Committee is primarily responsible for oversight of compliance of the Alliance repositories with Alliance and NCI policies regarding specimen collection and distribution. In addition, this committee is responsible for ensuring that the repositories follow the NCI guidance document "Best Practices for Biospecimen Resources" that was published and updated in 2011. The Alliance repositories will undergo periodic audits to ensure compliance with the NCI Best Practices (http://biospecimens.cancer.gov/practices) and oversight for the audits will be a function of the TRP Executive Committee.

11.6.1 Role of pathology in discrepancies in diagnosis

In any case involving an apparent significant discrepancy between an observation made by an Alliance study pathologist and a diagnosis rendered at the submitting institution, the Alliance pathologist takes the following steps to determine the nature of the problem:

- The study pathologist notifies the biospecimen repository regarding the diagnostic discrepancy in the case. The repository checks the case identifiers. If the problem is clerical (e.g., wrong specimen), the repository rectifies the problem directly with the submitting institution through Alliance institutional personnel (e.g., the institutional clinical research professional).

- If the repository determines that all case identifiers are correct, the Alliance study pathologist contacts the institutional clinical research professional (CRP) and, if necessary, arranges to contact the submitting pathologist. The Alliance study pathologist requests that the case be re-reviewed by the submitting pathologist. The Alliance study pathologist discusses with the responsible institutional CRP or pathologist whether other/additional pathologic materials from that case exist that might explain a discrepancy. Any problems related to case identification, specimen selection, or additional diagnostic information or materials are discussed and resolved, if possible, by this direct communication, and the nature of the resolution is communicated to the repository by the study pathologist.

- If an apparent discrepancy still exists, the appropriate Pathology Committee leader and at least one other committee member review the case to confirm the diagnostic discrepancy.

- If the discrepancy is confirmed, the chair of the Pathology Committee immediately reports the correct diagnosis to the responsible data coordinator. The data coordinator reports the correct diagnosis to the clinical research professional at the submitting institution. It is the responsibility of the clinical research professional to notify the submitting pathologist and the physician who registered the patient that there is a difference in diagnosis. The Alliance SDC considers the discrepancy in the final analysis of the study.

Policy Name: Research Support for Correlative Science Projects	**Policy Number:** 11.7
Section: Biospecimen Repositories and Translational Research – 11	**Date Revised:** March 15, 2013

11.7 Research support for correlative science projects

Correlative science investigators are required to have funding for their projects prior to receiving specimens.

In order to facilitate the successful application for funding, the Alliance will review concepts without established funding. For this review, investigators must provide the information requested for a preliminary concept review. In order to receive a letter of support from the Alliance, interested investigators must provide a preliminary concept submission for triage review at least six weeks prior to the grant deadline. Exceptions to this rule have to be approved by the principal investigator of the Translational Research Program.

Approved preliminary concepts, must include a description of the collaboration with the Alliance in their proposal submission and they must comply with the Alliance guidelines, which have been written to ensure scientific integrity, patient confidentiality, specimen protection, and support of the Alliance infrastructure resources.

Any collaboration with the Alliance impacts on Alliance resources, including protocol development, data management, statistical analysis, and specimen banking. In addition to funds to support laboratory science (supplies, equipment, personnel, etc.), investigators seeking funding from any agency must also establish subcontracts with the different resource offices of the Alliance being used, including the following:

- Translational Research Program – Alliance Chicago Office
- Statistics and Data Center (for data management and statistical support)
- Any relevant repository (for sample preparation and distribution, etc.)

Subcontract arrangements must be performed in accordance with Alliance policy and submitted in advance of the grant deadline to ensure appropriate time is given for review and sign-off. A final copy of the grant must be submitted to and approved by the Alliance before submission to the granting agency.

11.8 Industry relations

The Alliance commercial policy in place for clinical studies also applies to studies that involve correlative sciences (for complete policy see section 13). Specific guidelines related to correlative science projects include:

- The Translational Research Program and the Alliance will negotiate contracts with industry, not investigators.

- It is prohibited for an investigator to obtain and use kits, instrumentation, etc. on behalf of the Alliance.

- Investigators must contact the director of translational research and the principal investigator of the Translational Research Program regarding all correlative science industry interactions.

- All proposed collaborations involving Alliance data and/or specimens, including secondary use of tissue from Alliance biorepositories, require approval by the principal investigator of the Translational Research Program and the Alliance group chair. Please include the director of translational research and the TRP executive officer in all communications.

- All data resulting from Alliance studies, including those resulting from collaborations with commercial diagnostic firms, are under the guardianship of the Alliance.

- Data from all laboratory tests performed on samples from any Alliance repository will be submitted to the Alliance SDC. An Alliance statistician will conduct the analysis of the data. The principal investigator of the Translational Research Program and the Alliance group statistician must approve any exception to this rule. Requests to share existing data (data sharing) and provision of data to industry are addressed in section 13.