The Cancer Institute of New Jersey
Guidelines for Access to Biospecimen Resources by Outside Investigators

The Biospecimen Repository Service (BRS) is under the administrative control of The Cancer Institute of New Jersey (CINJ). The Prostate Biospecimen/Data Repository will be a part of the BRS. The BRS operates with the assistance of an internal Shared Resource Advisory Committee, which meets regularly to develop and review policies for specimen procurement and distribution, and fees for services.

Biospecimen resources will be made available to any investigator(s) working in cancer research, following formal application and review.

Prioritization of access to biospecimen resources:
CINJ investigators will receive priority access.
Outside investigators with current peer-reviewed funded research will receive priority over outside investigators without current peer reviewed funded research.

Procedures for applying to access biospecimen resources:
Outside researchers are to initially contact the BRS Director to discuss the rationale, feasibility and the appropriateness of the biospecimen resources for the proposed research. If deemed to be appropriate, the applicant will then be asked to submit a formal application request that includes the following:

1. PI Name and Contact Information
2. Project Title
3. Background and justification of the proposed research
4. Hypotheses and aims
5. Feasibility of the work, including design, statistical power, access to key technologies, experience of the host laboratory, and available staff and funding to support the work
6. Indicate why the work would benefit from the use of CINJ BRS biospecimens
7. Justification for the number and type of samples requested in the context of the proposed research
8. Indicate whether obtaining samples in batches is feasible and whether there is merit in sending part of the requested material to gain feedback on progress before the complete number of samples is sent
9. Indicate the number, amount, and type of sample (e.g. germ line DNA, tumor DNA, frozen tumor RNA, blocks, slides), and what data is required (clinical, epidemiological, genomic or other) (This will be used to assess the impact of the request on the resource, and the workload required to access the material/data
10. Provide documentation of appropriate IRB approval from host institution. And, if request involves a research project with investigators from multiple institutions, documentation of IRB approvals from each participating institution must be provided
11. Submit the host institution's IRB application and approval to UMDNJ IRB for formal review
12. To assist in assessing the merit of the science proposed it is useful know if the work has been peer-reviewed and has successfully obtained grant funding. If so, provide evidence of peer-reviewed success of the proposed research
13. NIH Biographical Sketch of the PI and all co-investigators
14. Indicate if the research project includes collaborations with commercial organizations. If so, provide a list of the collaborating commercial organizations

Application Review:
Applications will be reviewed by the CINJ Scientific Review Board (SRB) to assess whether the application comprises a scientifically justifiable, feasible, and high priority use of the available material and/or data.

The SRB consists of clinical, basic, and population scientists as well as an ethicist and representative of the patient advocacy community.

The SRB may suggest mechanisms and timescales for the delivery of the requested samples and/or data as

well as the costs involved. They may also suggest changes to the proposed application and try to facilitate communication and collaboration between groups working on similar topics. The applicant may be asked to respond to SRB reviewers' comments in writing.

Applications will be scored and ranked on the basis of standard criteria including the novelty, significance and feasibility of the project and the track record of the investigators.

Reasons will be given for refusal of all or part of the proposed use of biospecimen resources. Conditions on, or restrictions to, use of material or data may be made.

Applications by outside investigators that are approved by the SRB will then be submitted to the UMDNJ IRB. The SRB will provide the UMDNJ IRB documentation of its approval.

Approved Requests:
Upon signed and written agreement by the applicant, and evidence of IRB approvals, the project can proceed according to the agreed protocol. Any significant deviations from the agreed protocol must be sent by the applicant in writing for approval before proceeding. Samples will be shipped and data transferred according to the agreed protocol. Material and data will be supplied as soon as possible after a request is approved.

CINJ BRS will charge the outside researcher for the preparation and shipping of biological materials and for extracting and preparing data. Charges are to recover reasonable costs associated with operation of the biospecimen resource.

Annual progress reports will be required by CINJ BRS, and CINJ BRS reserves the right to withhold the supply of further material and/or withdraw data if the rate of progress and level of reporting is unacceptable.

Outside investigator's responsibilities:
The outside investigator agrees:

- to sign Materials Transfer Agreements issued by UMDNJ;
- to pay for the agreed upon costs of preparing and shipping biological materials;
- to pay for the agreed upon costs of extracting or preparing data from the CINJ BRS databases;
- to propose a timeline for the project and to submit annual progress reports. If the project has not been completed within 1 year of the planned completion date, the CINJ SRB reserves the right to terminate the project and recover any outstanding data and biospecimens;
- not to distribute materials or data to investigators or institutions who are not named in the approved application;
- not to use CINJ BRS data and/or materials for purposes other than those agreed to in the approved protocol and signed Material Transfer Agreement (MTA);
  to acknowledge the funding bodies and collaborators that have contributed to CINJ BRS on all publications of research findings that resulted from use of the CINJ BRS (the appropriate acknowledgment wording will be provided by CINJ);
- to return the data and/or any unused materials to CINJ BRS.

Possible Barriers and plans to work around:
Note: Because of the finite nature of the resource, CINJ BRS is unlikely to ship large batches of biological material at one time but will instead ask each applicant to suggest how the material may best be processed. This may include suggestions of batch sizes and milestones by which CINJ BRS can monitor progress – for example the publication of reporting of intermediate results. Because of the difficulties of shipping frozen material, more stable reagents - such as RNA, rather than frozen tissue - will be supplied whenever possible.