Appendix 3. Governance Plan

This governance plan is provided as an example to biospecimen resources to help with planning the resource and defining the authorities, processes, and procedures that are needed to guide key operational decisions. The governance plan should become part of the resource's documents and be available if requested. (Please see Section C.1 of the *NCI Best Practices* for more information and additional recommendations related to custodianship.)

Principal Investigator:
Grant Number:
Project Title:
Project Period:
Name of the Biospecimen Resource (if different than the project):

A. Name of the Custodian:

B. Summary of the Project:

C. Governance Structure of the Project (See Section C.1.):

1. Outline the resource's management structure and discuss the roles and responsibilities of each management or oversight body.
2. Outline the resource's protocols and procedures that guide its operations and discuss whether the protocols are documented and approved by the institutional review board and/or a project oversight committee.

D. Integrity of Biospecimens and Data (See Sections C.1.5. and C.3.):

1. Describe the resource's protocols to ensure the physical integrity of collected biospecimens.
2. Describe the resource's protocols to ensure the integrity of the human research participants' data that accompany the biospecimens.

E. Access to Biospecimens and Data (See Sections C.3. and C.4.):

1. Outline the resource's protocols and procedures for the distribution of samples to investigators. Describe how the scientific merit, prioritization of access requests, and proposed research use are assessed and by what review group.
2. Describe whether samples will be accompanied by data and the type of data. Outline the safeguards that are in place to ensure that confidentiality of the data is not compromised.

F. Release of Research Results (See Section C.2.3.7.):

1. Outline the protocols that are in place for publication and dissemination of research results from biospecimen research. Describe the process for handling results that are potentially stigmatizing to groups.
2. Outline any process to provide educational materials to the public such as brochures, literature, meetings, or public Web sites.

G. Legacy and Contingency Plans (See Section C.1.2.):

1. Outline the resource's plans for the handling and disposition of biospecimens and associated data when reaching any of the following points: (a) End of the budget period of the grant, (b) loss of management or termination of funding, (c) accomplishment of the specific research objectives of the study, (d) depletion of biospecimens, or (e) achievement of critical data end points.

H. Retention of Biospecimens, Data, and Records (See Sections C.1.3. and C.2.3.1.):

1. Outline the resource's protocols for the handling and disposition of biospecimens and associated data sets following the discontinuation of participation by a human research participant.
2. Outline the resource's protocols for the retention of biospecimens, data, and records pertaining to informed consent and the identity of human research participants.

I. Sharing of Resources (See Sections C.1.6. and C.5):

1. Outline the resource's protocols and procedures for the sharing of research data and tools generated from biospecimen research consistent with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing/) and the NIH Research Tools Policy (https://www.ott.nih.gov/sites/default/files/documents/pdfs/Ferguson-AUTM-TTPM-3rd-ed-vol-4-Research-Tools.pdf) .
2. Outline the resource's protocols for communicating information to human research participants regarding the general type of research performed on biospecimens and the sharing of biospecimens with other researchers, when practicable.

J. Conflict of Interests (COIs) (See Sections C.1.4. and C.6.):

1. Describe the protocols for managing and limiting any potential COIs for the resource's staff consistent with 42 CFR Part 50 Subpart F, as well as applicable NIH COI policies.