# NHLBI Biospecimen Collection Questionnaire

The Questionnaire is designed to assist with the assessment of the potential scientific value and the quality of an NHLBI funded biospecimen collection. The elements related to the quality of the biospecimens follow current best practices at

<http://biospecimens.cancer.gov/bestpractices/> and <http://www.isber.org>

Questionnaires are reviewed following the process described in Chapter 6 of the BioLINCC handbook at <https://biolincc.nhlbi.nih.gov/media/guidelines/handbook.pdf>

**Name of Clinical Study:** Click here to enter text.

**Clinical Study Program Official(s):** Click here to enter text.

**Grant/Contract Number:** Click here to enter text.

**Grant/Contract funding period:** Click here to enter text.

**Date Clinical Study completed:** Click here to enter text.

**Date Primary Results Published**
**or Submitted for Publication:** Click here to enter text.

**Complete Sections A through H if requesting to transfer the collection to the NHLBI Biorepository, otherwise complete Sections B through H**

## Eligibility to Transfer Biospecimens to the NHLBI

* 1. Has an Institutional Review Board reviewed and verified that submission of the collection to the Biorepository for subsequent sharing with non-Study investigators for research purposes is consistent with the informed consent of study participants?

Yes [ ]
No [ ]

* 1. Can the Study provide electronically a SAS or Excel/CSV data file of the current biospecimen inventory with the variables described in Section H, Q.5?

Yes [ ]
No [ ]

* 1. Is the Study prepared to sign a NHLBI Material Transfer Agreement for Biospecimens prior to shipment of vials/samples to the NHLBI Biorepository?

Yes [ ]
No [ ]

* 1. Does the Study acknowledge that Collections in the NHLBI Repository are subject to periodic utilization assessments and possible reduction?

Yes [ ]
No [ ]

*If “No” is answered for any question, the Study should contact their NHLBI Program Official to discuss the application requirements. The Material Transfer Agreement may be viewed at*[*https://biolincc.nhlbi.nih.gov/media/NHLBI\_Biospecimen\_MTA\_Template.pdf*](https://biolincc.nhlbi.nih.gov/media/NHLBI_Biospecimen_MTA_Template.pdf)

## Clinical Study Background and Future Scientific Use

* 1. Provide a synopsis of the clinical study protocol using the following format: objectives, background, subjects enrolled, study design, and conclusions.

Click here to enter text.

* 1. Describe the original intent of the biospecimen collection (e.g. what were the research questions that the collection would address).

Click here to enter text.

* 1. Describe the clinical study results and the evidence that this biospecimen and data collection has facilitated scientific progress. (E.g. provide details including publications and ancillary studies; were hypothesis generated that could lead (or have led) to future studies using these or other samples).

Click here to enter text.

* 1. Describe the uniqueness of the collection:
		1. *What other similar collections in a similar population are publically available?*

Click here to enter text.

* + 1. *How does this collection differ from other publically available collections?*

Click here to enter text.

* 1. What audience would you target for the promotion of this collection?

Click here to enter text.

* 1. Describe at least three scientific questions that could be explored by non-Study investigators in the next three to five years using this collection. Describe the benefit, value, significance, and potential impact of this research and the specimens that could be used to address each research question.

Click here to enter text.

* 1. Has this collection been used for ‘omics and/or other multiplexed assays (e.g., GWAS, sequencing, proteomics, large-scale chip assays)? If so, please specify and indicate pass rate or other quality control metrics.

Click here to enter text.

## Informed Consent

* 1. Does the Study informed consent document include restrictions on the use of the biospecimens?

Yes [ ]
No [ ]

* + 1. If Yes, provide a list of restrictions.

Click here to enter text.

*Note: Submit a document summarizing the Study and/or site changes to the Study informed consent template regarding the use and storage of biospecimens with the Questionnaire.*

## Procedures Used To Collect, Process, Track and Store Biospecimens

* 1. Was a single set of standardized procedures used build the collection
	(e.g., collect, process, track, ship and store)?

Yes [ ]
No [ ]

* + 1. *If No, describe the Study procedures used:*

Click here to enter text.

* 1. Were the biospecimens processed and stored centrally?

Yes [ ]
No [ ]

* + 1. *If No, describe the Study procedures:*

Click here to enter text.

* 1. Were study specific worksheets/forms developed to document the collection, processing and storage (including shipping) information?

Yes [ ]
No [ ]

* + 1. *If No, describe the Study procedures:*

Click here to enter text.

* 1. Is the volume, cell count or concentration for each sample measured (i.e., a default option was not used, and the actual volume, cell count or concentration for each vial was captured in the data system)?

Yes [ ]
No [ ]

* + 1. *If No, provide information related to vial content:*

Click here to enter text.

* 1. Are all biospecimens stored using containers/vials that have been rated for the applicable material type and storage temperature?

Yes [ ]
No [ ]

* + 1. *If No, provide information related to storage containers*

Click here to enter text.

* 1. For each of the key biospecimen parameters listed below indicate if the parameter is 1) captured electronically in the study data files; 2) documented in the study manuals or procedures (e.g. processing initiated within 24 hours of collection); or 3) not documented or captured.

| **Key Biospecimen Parameters** | **Yes,** **captured electronically** | **Yes,** **documented in Study manuals** | **Not****documented or captured** |
| --- | --- | --- | --- |
| *Date of specimen collection* |[ ] [ ] [ ]
| *Time of specimen collection* |[ ] [ ] [ ]
| *Collection tube type* |[ ] [ ] [ ]
| *Preservative used* |[ ] [ ] [ ]
| *Storage temperature between collection and processing* |[ ] [ ] [ ]
| *Date processing initiated* |[ ] [ ] [ ]
| *Time processing initiated* |[ ] [ ] [ ]
| *Date specimen frozen*   |[ ] [ ] [ ]
| *Time specimen frozen* |[ ] [ ] [ ]
| *Vial comments (e.g., sample condition, indications of hemolysis, etc.)* |[ ] [ ] [ ]

## Specimen Labels

* 1. Is each biospecimen sample labeled with a bar coded identifier unique to each biospecimen (in both scanner and eye readable format) with no additional identifiers or handwritten information?

Yes [ ]
No [ ]

* + 1. *If No, provide information related to label content and how individual samples are identified.*

Click here to enter text.

* 1. Describe the label on all the types and sizes of the vials/containers.   Describe all of the information which is included on the labels in detail (for example, participant identifier, draw/visit identifier, type of specimen, etc.) and specify whether that information is included in a barcode, is pre-printed on the label, is hand-written or is some combination.

Click here to enter text.

* 1. Describe how the labels were assigned and how the sample label ID links to the participant ID in the Study dataset.  Include the Study document sections that describe the labels, labelling procedures and label tracking with the submitted Questionnaire.

Click here to enter text.

* 1. Describe any deviations from the labelling summary provided above which may exist among specimens within the proposed collection to be transferred and how these deviations are tracked.

Click here to enter text.

* 1. Is there documentation indicating that the label stock will adhere to the vials and be legible over time?

Yes [ ]
No [ ]

* + 1. *If No, describe the label stock and its limitations*

Click here to enter text.

* 1. Provide a picture(s) of labelled samples. Include all label formats and all types and sizes of storage vials/containers that were used. This will assist in determining the resource requirements needed to acquire and maintain the collection.

Right click in the boxes below to paste the image file(s).

|  |
| --- |
|  |
|  |

## Biospecimen and Data QA/QC Program

* 1. Briefly summarize the Study’s biospecimen and data Quality Assurance/Quality Control program.

*General information on QA/QC programs and their components may be found at* <http://biospecimens.cancer.gov/bestpractices/to/qac.asp>

Click here to enter text.

## Assay Data and Laboratory Methods

* 1. Is detailed information on the laboratory assays that were performed as part of the Study protocol included in the dataset and documentation?

Yes [ ]
No [ ]

* + 1. *If No, provide a brief summary of how this information will be provided.*

Click here to enter text.

## Biospecimen Collection Information

This information is used to estimate the resource requirements needed to maintain the collection.

* 1. Has the inventory been consolidated (i.e., the majority of boxes are full and all non-consented/Study-retained vials have been removed)?

Yes [ ]
No [ ]

* + 1. *If No, describe the plans to consolidate the collection prior to transfer.*

Click here to enter text.

* 1. Are funds available to pay for the transfer or maintenance of the collection?

Yes [ ]
No [ ]

* + 1. *If yes, describe the funding plan*

Click here to enter text.

* 1. Briefly describe the current storage equipment being used. Include the number and types of freezers (e.g. mechanical upright or chest; -20 or -80; Liquid Nitrogen Tank) being used, who owns the freezers and whether or not the freezers will be transferred with the collection.

Click here to enter text.

* 1. Provide the Study biospecimen collection schema, including all types of biospecimens collected (e.g., serum, plasma, DNA, etc.) and the visit or collection time points. Right click in the box below to paste your biospecimen collection schema, or provide it as a separate document.

|  |
| --- |
|  |

* 1. Provide separately a SAS or Excel/CVS data file and data dictionary that includes the variables listed below. The data file should be structured to list one observation for each individual biospecimen sample in the inventory and include all the samples that the Study proposes to send. The data dictionary should include a description of the variables and their formats. For variables that are not captured electronically, the data dictionary should indicate if this information is captured non-electronically and, if it is, where and what data are captured.
* **Subject ID** – the Study participant ID that links the biospecimen sample to the Study data
* **Subject Type**, ***if applicable*** – e.g. Case/Control, Donor/Recipient, Study Arm
* **Study ID of Associated Subject**, ***if applicable*** – e.g. if this is a case/control study, the subject ID of the paired case/control would go here.
* **Laboratory ID, *if applicable*** – an ID specific to the biospecimen draw, assigned by the laboratory
* **Sample Label ID**– the identifier on the sample vial/container. If each sample does not have a unique ID then describe how each individual sample is identified in Section E, Q #1
* **Study Visit, *if applicable*** – either a visit number (e.g. visit 1, visit 2, etc.), a coded visit (e.g. 1 = baseline, 2 = 1 year follow-up), or an actual visit name (e.g. Screening, 3 Week, 6 Month, 4 Year). The visit numbers should reflect the collection schedule provided in Section H, Q4.
* **Material Type –** plasma, serum, whole blood, DNA etc.
* **Volume or Quantity –** if the actual volume/quantity is unknown this must be documented in Section D, Q#5
* **Volume or Quantity Unit** – (e.g. ml, cells, ug)
* **Number of Thaws** – number of freeze/thaw cycles the sample has undergone
* **Sample Storage Temperature**
* **Storage Box ID** – the current storage location of the sample
* **Box Row ID** – the current storage location of the sample
* **Box Column ID** – the current storage location of the sample
* **Vial/Sample Comments –** e.g., sample condition, indications of hemolysis, etc.
* **Informed consent for sample use by non-Study investigators** – Yes/No
* **Informed Consent Restrictions *if applicable* –** if there are no restrictions record none in the data dictionary. Of note, only biospecimens that can be shared with non-Study investigators will be accepted. Restrictions noted in Section C, Q#1a of the Biospecimen collection Questionnaire should be included.
	1. Provide the following study documents and information:
* Study protocol (most current version)
* Study informed consent template and a document summarizing the Study and/or site changes to the Study informed consent template regarding the use and storage of biospecimens
* Study procedures related to data and biospecimen acquisition including the Study Manual of Procedures, the procedures used to collect, label, ship, process, aliquot, store, track and assay biospecimens, and the biospecimen QA/QC program
* The names and contact information for Study (data coordinating center and laboratory) staff essential to the maintenance of the collection.

**Date questionnaire completed:** Click here to enter a date.

**Questionnaire contact person:**  Click here to enter text.

**Comments (Optional):**

Click here to enter text.