NRG ONCOLOGY

*Advancing Research. Improving Lives.™*

# Biospecimen Access (Non-Navigator) Letter of Intent

**Date Submitted:** _____

**Title** *(must include the clinical trial number[s] from which biospecimens are being requested)***:**

_____

## INVESTIGATOR INFORMATION

**Principal Investigator:** _____

**Institution**: _____

**Position/Department**: _____

**Mailing Address**: _____

**Email:** _____

**Phone:** _____

## BIOSPECIMENS REQUESTED

1. **Disease Site** *(check all that apply)*

☐ Breast, specify: _____ ☐ Lung, specify: _____

☐ GI, specify: _____ ☐ Melanoma, specify: _____

☐ GU, specify: _____ ☐ Brain, specify: _____

☐ GYN, specify: _____ ☐ Sarcoma, specify: _____

☐ Head&Neck, specify: _____ ☐ Other, specify: _____

2. **Disease Characteristics** *(if applicable – e.g., HER2+ breast cancer, squamous cell lung cancer, etc.)***:**

_____

3. **Disease Stage** *(e.g., I, II, III, IV, any)***:** _____

4. **Biospecimen Requirements** *(check all that apply)*

4.1 **TISSUE**

4.1.1 **Tissue Type**

☐ Metastatic Tumor ☐ Primary Tumor

☐ Normal Tissue ☐ Recurrent Tumor

☐ Persistent Tumor ☐ Other Tissue Type, specify: _____

☐ Pre-Malignant

4.1.2 **Formalin-Fixed, Paraffin-Embedded Tissue** *(specify quantity – e.g., ten 5µm slides, two 2mm cores, one 20 µm curl)*

☐ Core (Punch); quantity: _____ ☐ Unstained Slides (Charged); quantity: _____

☐ Curl (Scroll) ; quantity: _____ ☐ Unstained Slides (Uncharged); quantity: _____

☐ Stained Slides; specify stain: _____ ☐ Unstained TMA Slides; quantity: _____

4.1.3 **Frozen Tissue** *(specify quantity – e.g., 0.2g, ten 5µm slides)*

☐ Snap-Frozen; quantity: _____ ☐ OCT-Embedded; quantity: _____

4.1.4 **Other Tissue Preparation**

☐ Other Preparation, specify: _____; quantity: _____

4.2 **BLOOD / BLOOD PRODUCTS** *(specify quantity – e.g., 500µL, 1x10$^6$ cells)*

☐ Serum; quantity: _____ ☐ Plasma; quantity: _____

☐ Whole blood; quantity: _____ ☐ Buffy Coats; quantity: _____

☐ Peripheral Blood Mononuclear Cells (PBMCs); quantity: _____

4.3 **BODY FLUIDS / OTHER BIOSPECIMENS** *(specify quantity – e.g., 500µL, 5g)*

☐ Bone Marrow; quantity: _____ ☐ Saliva; quantity: _____

☐ Peritoneal Fluid; quantity: _____ ☐ Urine; quantity: _____

☐ Peritoneal Wash; quantity: _____ ☐ Stool; quantity: _____

☐ Other Body Fluid/Biospecimen, specify: _____; quantity: _____

4.4 **NUCLEIC ACIDS** *(specify quantity – e.g., 50ng)*

4.4.1 Extracted from FFPE Tumor

☐ DNA; quantity: _____ ☐ RNA; quantity: _____

4.4.2 Extracted from Frozen Tumor

☐ DNA; quantity: _____ ☐ RNA; quantity: _____

4.4.3 Extracted from Non-Malignant Tissue

☐ DNA; quantity: _____ ☐ RNA; quantity: _____

4.4.4 Extracted from Peripheral Whole Blood

☐ DNA; quantity: _____ ☐ RNA; quantity: _____

4.4.5 Other Source/Preparation

☐ Other, specify: _____; quantity: _____

5. **Patient Population** *(e.g., stage I, high grade, recurrent, tissues from patients treated with paclitaxel, paired primary/metastatic, etc.)***:**

_____

6. **Number of Cases Requested** *(e.g., formal statistical justification is not required; however, a summary statement supporting the number of cases requested is required for review)***:**

_____

7. **Other Biospecimen Resources** *(include a brief summary of any plans to pool the provided biospecimens with biospecimens from other studies, including studies from other NCTN Groups and/or NCI biospecimen resources)***:**

_____

## CLINICAL DATA REQUESTED / STATISTICAL CONSIDERATIONS

8. **Clinical Data** (*check all that apply*)

☐ Age ☐ Gender ☐ Race/Ethnicity ☐ Stage ☐ Grade

☐ Arm Assignment ☐ Response ☐ Overall Survival ☐ PFS/RFS

☐ Other, specify: _____

9. **Statistical Analysis** *(indicate the extent to which the NRG Oncology Statistical and Data Management Center [SDMC] will be involved in the analysis.)*

☐ **NRG SDMC – Full Collaboration**
NRG SDMC has lead responsibility for all statistical analysis even if there is an external collaborating statistician*. NRG SDMC will assist with proposal development, receive biomarker data, and assist with manuscript preparation.

☐ **NRG SDMC – Joint Collaboration**
External collaborating statistician* has lead responsibility for the analysis but there is a collaborating NRG SDMC statistician. NRG SDMC will assist with proposal development, answer study-related questions, and review analysis reports, abstracts, presentations, and manuscripts.

☐ **NRG SDMC – Limited Collaboration**
NRG SDMC will provide requested clinical data only. Proposal development, analysis, and manuscript preparation is to be done by external collaborating statistician*.

**The current CV and contact information for the external collaborating statistician must be provided with this LOI. Additionally, the external collaborating statistician must provide a brief description of the analytic plan.*

## PROJECT SUMMARY

10. **Hypothesis** *(90 words or less)***:**

13. **Background / Preliminary Data** *(500 words or less)***:**

14. **Specific Aims** *(list no more than 3; total of 120 words or less)***:**

15. **Planned Assays** *(check all that apply)*

☐ Comparative Genomic Hybridization (CGH) ☐ Cytotoxic Assay
☐ ELISA ☐ ELISPOT ☐ Flow Cytometry
☐ DNA *in situ* Hybridization (FISH) ☐ Genotyping (SNP) Array
☐ Gene Expression Microarray ☐ Immunohistochemistry (IHC)
☐ RNA *in situ* Hybridization ☐ Ligand Binding Assay
☐ Mass Spectrometry ☐ Microscopy/Imaging ☐ PCR ☐ RT-PCR
☐ Proliferation Assay ☐ Protein Activity Assay ☐ Sequencing-NGS Whole Genome
☐ Sequencing-NGS Whole Exome ☐ Sequencing-NGS Targeted/Deep
☐ Serum Extracellular Domain (ECD) Test ☐ Western Blot (Immunoblot)

☐ Other, specify: _____

15.1 **Assay Status** *(if more than one assay will be used, include the status for each assay)***:**

☐ Assay within a clinical laboratory; specify assay(s) and laboratory(ies) to be used:

_____

☐ New laboratory-based assay, published; specify assay(s) and laboratory(ies) to be used:

_____

☐ New laboratory-based assay, not published; specify assay(s) and laboratory(ies) to be used:

_____

☐ Laboratory-based assay within CLIA environment, published; specify assay(s) and laboratory(ies) to be used:

_____

☐ Laboratory-based assay within CLIA environment, not published; specify assay(s) and laboratory(ies) to be used:

_____

15.2 **Assay Validation**

15.2.1 Number of human specimens used for assay validation *(include number for each assay)*:

_____

15.2.2 The assay(s) has(have) been applied to the biospecimen type being requested.

☐ Yes, specify: _____ ☐ No, specify: _____

15.2.3 From which clinical trial(s), if applicable, has(have) biospecimens been used *(for a listing of trials, refer to www.clinicaltrials.gov)*:

_____

☐ Unknown

15.3 **Assay Publication(s)** *(if assay has been published, specify assay and include reference)***:**

_____

16. **Funding**

16.1 **Source**

☐ Academic ☐ Industry ☐ Other, specify: _____

16.2 **Status**

☐ Extramural, non-NIH funding
☐ Funding proposal under review
☐ NIH funded
☐ Funding proposal in development
☐ Institutional funding
☐ Not funded

17. **NCTN Group(s) with which you have a Membership Affiliation**

☐ Alliance ☐ CCTG ☐ ECOG-ACRIN
☐ COG ☐ NRG Oncology ☐ SWOG

18. **Additional Comments:**