VTR Request Form

10/30/2024

I. STUDY INFORMATION All fields required.

Study Title				
Cancer Site(s)				

Section A. Principal Investigator and Laboratory

1. Principal Investigator Information

Name		Institution			
Institutional Email					
Address 1					
Address 2					
City		State		ZIP Code	
Phone 1		Phone 2			

2. Recipient Laboratory Contact Information Provide the names and contact information for two people at the lab receiving the study materials.

Laboratory Contact 1

Name		Institution			
Institutional Email					
Address 1					
Address 2					
City		State		ZIP Code	
Phone 1		Phone 2			

Laboratory Contact 2

Name			
Institutional Email		Phone	

3. Recipient Clinical Data Contact Information Provide the name and contact information for the person receiving the clinical data.

Name		Institution			
Institutional Email					
Address 1					
Address 2					
City		State		ZIP Code	
Phone 1		Phone 2			

Section B. Project Information and Regulatory Documentation

What types of data, tissue, or other services are being requested? *(select all that apply)*	☐ Formalin-fixed, paraffin-embedded (FFPE) tissue acquisition & processing ☐ Pathology report deidentification ☐ Pathologist review or tissue selection ☐ Digital whole slide imaging ☐ VTR Program Standard Dataset ☐ Custom clinical data collection
Since the meeting with the registry, have the project objectives, subject eligibility criteria, and/or tissue or data requirements changed? *If Yes, please submit a new Study Information Form.*	☐ Yes ☐ No
Type of IRB Review & Approval. Investigators will be required to submit documentation of IRB review and approval. Identify the type of IRB documentation you expect to provide.	☐ Full Board ☐ Expedited ☐ Exempt from review

IRB Number *(if applicable)*		IRB Determination Date *(if applicable)*		IRB Expiration Date *(if applicable)*	

Does this project involve sequencing of nucleic acids or proteins extracted from requested specimens? *If Yes, an Institutional Certification must be submitted.* *(For further details, refer to https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications)*	☐ Yes ☐ No

Section C. Funding Information

A funding support letter is required to show proof of grant or other funding. If the project is funded by NIH, then a data sharing plan is required. For further details, refer to *NIH Data Management and Sharing Policy*.

Is the study funded? *If Yes or Pending, complete Table 1.*	☐ Yes ☐ No ☐ Pending
If currently unfunded, what are the planned sources of funding?	

Table 1: Sources of Funding

Information Requested	**Funding Source #1**	**Funding Source #2** *(if not applicable, leave this column blank)*
Funding Status	☐ Pending ☐ Received	☐ Pending ☐ Received
Name Source		
Is this project funded by NIH?	☐ Yes ☐ No	☐ Yes ☐ No
Grant Number		
Grant Start Date		
Grant End Date		

II. CASE ELIGIBILITY CRITERIA

Complete the case eligibility criteria in Table 2. Index cases are the primary group being studied. If data, whole slide images (WSIs), and/or tissue are being requested for a comparison group, complete that column. For example, in a study comparing cancer cases among Black individuals with cancer cases among White people, the Black cases are the index cases, and the White cases are the comparison group cases. If there is no comparison group, leave that column blank.

Table 2: Case Selection Eligibility

Eligibility Criteria	Index Cases		Comparison Group Cases *(complete column if applicable)*	
What is the target case count?				
Sex	☐ Male ☐ Female ☐ Unknown ☐ All	Counts _____ _____ _____ _____	☐ Male ☐ Female ☐ Unknown ☐ All	Counts _____ _____ _____ _____
Race	☐ White ☐ Black ☐ Other ☐ Unknown	Counts _____ _____ _____ _____	☐ White ☐ Black ☐ Other ☐ Unknown	Counts _____ _____ _____ _____
Ethnicity	☐ Hispanic or Latinx ☐ Not Hispanic or Latinx ☐ All	Counts _____ _____ _____	☐ Hispanic or Latinx ☐ Not Hispanic or Latinx ☐ All	Counts _____ _____ _____
Minimum Age *(years)*				
Maximum Age *(years)*				
Stage at Diagnosis *(select all that apply)*	☐ In Situ ☐ Localized ☐ Regional ☐ Distant ☐ Benign borderline ☐ Unknown		☐ In Situ ☐ Localized ☐ Regional ☐ Distant ☐ Benign borderline ☐ Unknown	
Maximum Survival Time *(months)*	_____ or ☐ Any		_____ or ☐ Any	
Minimum Survival Time *(months)*	_____ or ☐ Any		_____ or ☐ Any	
Earliest Year of Diagnosis *(YYYY)* No later than 9 years prior	_____ ☐ Any		_____ ☐ Any	
Most Recent Year of Diagnosis *(YYYY)* No earlier than 1 year prior	_____ ☐ Any		_____ ☐ Any	
Only Include First Primary Cancer	☐ Yes ☐ No ☐ Uncertain		☐ Yes ☐ No ☐ Uncertain	
Allow Synchronous Multiple Primaries	☐ Yes ☐ No ☐ Uncertain		☐ Yes ☐ No ☐ Uncertain	
Allow Metachronous Multiple Primaries	☐ Yes ☐ No ☐ Uncertain		☐ Yes ☐ No ☐ Uncertain	
Allow Neoadjuvant Treatment	☐ Yes ☐ No ☐ Uncertain		☐ Yes ☐ No ☐ Uncertain	
Types of Neoadjuvant Treatment Allowed *(check all that apply)*	☐ Chemotherapy ☐ Immunotherapy ☐ Hormone therapy ☐ Radiation therapy ☐ Other *(specify)* _____ ☐ Uncertain		☐ Chemotherapy ☐ Immunotherapy ☐ Hormone therapy ☐ Radiation therapy ☐ Other *(specify)* _____ ☐ Uncertain	

Table 2: Case Selection Eligibility Continued		
Eligibility Criteria	**Index Cases**	**Comparison Group Cases** *(complete column if applicable)*
Procedure Types Allowed *(check all that apply)*	☐ Biopsy ☐ Surgery ☐ Autopsy ☐ Uncertain	☐ Biopsy ☐ Surgery ☐ Autopsy ☐ Uncertain
Allow Cases With Only Biopsy Tissue	☐ Yes ☐ No ☐ Uncertain	☐ Yes ☐ No ☐ Uncertain
ICD-O-3 Topography Code(s)* *(Found starting on p 42 of this document: https://iris.who.int/bitstream/handle/10665/96612/9789241548496_eng.pdf[1])*		
ICD-O-3.2 Morphology Code(s) Included* *(Found at http://www.iacr.com.fr/index.php?option=com_content&view=category&layout=blog&id=100&Itemid=577[2])*		
ICD-O-3.2 Morphology Code(s) Excluded*	☐ None ☐ All others _____	☐ None ☐ All others _____
Biomarker Restrictions *(ex: triple negative breast cancers)* *For a list of biomarkers captured by SEER, refer to https://apps.naaccr.org/ssdi/list/*		

III. SPECIMEN SELECTION AND PROCESSING

Specimen Type(s) Requested *(Complete Table 3 if you are requesting tissue processing and/or whole slide imaging)*: Note that the slide scanners used for the VTR Program are Leica/Aperio scanners and produce .svs WSIs. WSIs will be sent to requestors via encrypted external hard drives. The drive size and associated cost will depend on the total data size of the WSI collection. Requestors will be responsible for the cost of the external hard drive.

Table 3: Study Tissue Selection and Processing Requirements			
Requirement	**Primary Tumor**	**Non-Tumor** *(complete column if applicable)*	**Metastasis** *(complete column if applicable)*
Tissue Requirements			
Requirement	☐ Required ☐ If available ☐ Not required	☐ Required ☐ If available ☐ Not required	☐ Required ☐ If available ☐ Not required
Preferred Specimen Site Term(s) *(ex: lymph node, breast, etc.)*			
Total Amount of Tissue Needed *(microns)*			
Number of Blocks Needed			
Specimen Selection			
Minimum Tumor Cellularity (%)			
Maximum Tumor Necrosis			

[1] Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin L, Parkin DM, Whelan S. *International Classification of Diseases for Oncology*, Third Edition, First Revision. World Health Organization, 2013. Accessed August 19, 2024. https://iris.who.int/bitstream/handle/10665/96612/9789241548496_eng.pdf

[2] International Association of Cancer Registries. *International Classification of Diseases for Oncology* (ICD-O), Third Edition, Second Revision Morphology. Accessed August 19, 2024. http://www.iacr.com.fr/index.php?option=com_content&view=category&layout=blog&id=100&Itemid=577

*Please separate each code with a semicolon. Provide codes only, without terms

Table 3: Study Tissue Selection and Processing Requirements Continued			
Requirement	**Primary Tumor**	**Non-Tumor** *(complete column if applicable)*	**Metastasis** *(complete column if applicable)*
Specimen Processing Tissue processing requested			
☐ **Unstained Slides** *(if checked, answer below)*			
a. Unstained slides number *(per block/total)*			
b. Unstained slides thickness *(microns)*			
☐ **H&E-Stained Slides** *(if checked, answer below)*			
c. H&E-stained slides number *(per block/total)*			
d. H&E-stained slides thickness *(microns)*			
e. H&E-stained slides level ratio *(number of unstained slides to each H&E-stained slide)*			
☐ **Scrolls in Tube(s)** *(if checked, answer below)*			
f. Scrolls number *(per block/total)*			
g. Scrolls thickness *(microns)*			
☐ **Ribbons** *(if checked, answer below)*			
h. Number of sections *(per block/total)*			
i. Ribbons thickness *(microns)*			
Whole Slide Imaging (.svs images generated via Leica/Aperio scanners)			
Scanning Magnification	☐ 20x ☐ 40x ☐ Unknown	☐ 20x ☐ 40x ☐ Unknown	☐ 20x ☐ 40x ☐ Unknown
Maximum Number of H&E-Stained Slides per Case to Scan	_____ ☐ All available	_____ ☐ All available	_____ ☐ All available
Pathologist Prescreening and Selection	☐ Yes ☐ No ☐ Uncertain	☐ Yes ☐ No ☐ Uncertain	☐ Yes ☐ No ☐ Uncertain

IV. SEER DATA AND CUSTOM CLINICAL DATA COLLECTION REQUESTS

Section A. Pathology Report Deidentification *(Complete if you are requesting deidentified pathology reports)*	
What types of specimens do you want deidentified pathology reports of?	☐ Initial biopsy ☐ Surgical resection ☐ Metastasis ☐ Recurrence biopsy
Section B. Custom Clinical Data *(Complete if you are requesting custom clinical data collection in addition to the VTR Program Standard Dataset. For a list of these standard data items, visit the VTR Program Website.)*	
Briefly describe the types of data being requested *(Please limit to 150 words)*	
Will a codebook or data dictionary be provided?	☐ Yes ☐ No