

## CCR Resource Utilization Form

### STUDY IDENTIFICATION

Branch / Lab: \_\_\_\_\_ PI: \_\_\_\_\_  
Study Title: \_\_\_\_\_

**1. Is there a CRADA/CTA/other Technology Transfer agreement involved?**       Yes    No

*If yes, please identify source of the CRADA/CTA/other agreement and the current status.*

*If yes, please name your tech transfer contact:*

**2. Are there any funding/resources that will be requested from external sources?**       Yes    No

*Please identify who is or may be providing funding/resources and identify the current status (signed agreement, currently in process, not initiated).*

**3. Are you requesting additional CCR money to support your correlative studies (e.g. assays)?**       Yes    No

*List the type of S&S and specific costs requested. Please note that you will also need to place a request in the RRS system for this request to be formally approved.*

**4. What is the source of your drug supply (list the manufacturer(s))?**       N/A

**5. Does the study require an IND to be held by the CCR?**       Yes    No

**6. Will the CCR be the coordinating center for a multi-institutional study?**       Yes    No  
If yes, approximately how many sites? \_\_\_\_\_

**7. What database will this study be using?**

- C3D                                       Rave (CTEP)  
 Labmatrix                                 Outside Sponsor  
 Other: (please specify: \_\_\_\_\_)

**8. Will this study be using the ClinOmics platform?**       Yes    No

**9. Will this study be using the Figg Lab in any capacity?**       Yes    No

**10. Does this study involve radiation therapy?**       Yes    No

**11. Does this study involve the Molecular Imaging Program?**       Yes    No

**12. Are you using a sterile or non-sterile product that will require additional manufacturing (e.g. synthesized, repackaged, reformulated for research use and administered or dispensed by the NIH)?**       Yes    No

*If yes, complete the sterile & non-sterile products for human administration (SPHA) request form.*

**13. Will you be using the Laboratory of Pathology for any testing beyond standard confirmation of diagnosis utilizing H& E stains?**       Yes    No

*If yes, complete the laboratory of pathology worksheet.*

## Protocol Pathology Worksheet

Complete if you selected "Laboratory of Pathology" on Question 12 and/or Question 15

### STUDY INFORMATION

Branch / Lab: \_\_\_\_\_ PI: \_\_\_\_\_

Study Title: \_\_\_\_\_

Designated Pathologist and/or Associate investigator: \_\_\_\_\_

Anticipated Enrollment:

Adults \_\_\_\_\_ Pediatric \_\_\_\_\_ Both \_\_\_\_\_

### PATHOLOGY RELATED PROTOCOL REQUIREMENTS

**1. Does the study require any pathology related protocol **pre-entry** requirements?**     Yes     No

If **YES**, please identify specific requirements

<input type="checkbox"/>	Required tumor type(s) Specify: _____
<input type="checkbox"/>	Other required pathology Specify: _____
<input type="checkbox"/>	Required biomarkers Specify: _____
<input type="checkbox"/>	Required Genetics Specify: _____
<input type="checkbox"/>	Other Specify: _____

**2. Does the study require any pathology related protocol **post-entry** requirements?**     Yes     No

If **YES**, please identify specific requirements

<input type="checkbox"/>	Anticipated surgical procedures / biopsies Specify: _____
<input type="checkbox"/>	Anticipated fine needle aspiration biopsies Specify: _____
<input type="checkbox"/>	Anticipated body fluid or cell preparation evaluations Specify: _____
<input type="checkbox"/>	Anticipated blood or bone marrow evaluation (flow, molecular, cytogenetics) Specify: _____
<input type="checkbox"/>	Anticipated autopsy evaluations Specify: _____
<input type="checkbox"/>	Biomarker evaluation Specify: _____
<input type="checkbox"/>	Tissue procurement Specify: _____
<input type="checkbox"/>	Other Specify: _____

**3. Summary of Pathology Service Requirements:**

	Estimated # of Patients	Notes (including routines/patient requirements)
Required Flow Cytometry		
Required Cytogenetics (G bands)		
Required Cytogenetics (FISH)		
Required Molecular Testing Specify: _____		
Required FISH (on paraffin tissue sections)		
Routine Light Microscopy		
Cytopathology – FNA services		
Cytopathology – Other fluids or cell preparations		
Required IHC Tests Specify: _____		
Required EM Examination		
Other Requirements Specify: _____		

**4. Please add any additional comments regarding pathology resource requirements for this study**

## Sterile & Non-sterile Products for Human Administration (SPHA) Request Form

Précis:

Product Needed

Units Needed (total):

# of patients to be studied:

Proposed and alternate sources for product, if known:

IC Funds for project identified?  Yes  No

Urgency (within 1 month, 3 months, 6 months, longer):

Please route the completed form to your Scientific Director for approval to proceed to identify a source and obtain a quote

\_\_\_\_\_  
Scientific Director

\_\_\_\_\_  
Date

*Scientific Director:*

*Please forward to Dr. Michael Gottesman ([GottesmM@mail.nih.gov](mailto:GottesmM@mail.nih.gov)), Chair, SPHA Committee*