

CCR Resource Utilization Form

STUDY IDENTIFICATION

Branch / Lab: _____ PI: _____

Study Title: _____

1. Was disease community engagement used in the design for this study? Yes No

If yes, please describe the process for engaging the disease community/research subject perspectives.

If no, please explain why no process for disease community engagement was used.

2. Is there a CRADA/CTA/other Technology Transfer agreements involved? Yes No

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

If yes, please name your tech transfer contract:

3. 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).

4. 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.

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

6. Does the study require an IND be held by the CCR? Yes No

7. Will the CCR be the coordinating center for a multi-institutional study? Yes No

If yes, approximately how many sites? _____

8. What database will this study be using?

- | | |
|---|--|
| <input type="checkbox"/> C3D | <input type="checkbox"/> Rave (CTEP) |
| <input type="checkbox"/> Labmatrix | <input type="checkbox"/> Outside Sponsor |
| <input type="checkbox"/> Other: (please specify: _____) | |

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

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

11. Does this study involve radiation therapy? Yes No

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

13. 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.

14. 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), Chair, SPHA Committee