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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?

☐ C3D ☐ Rave (CTEP)

☐ Labmatrix ☐ Outside Sponsor

☐ 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.

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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

- ☐ Required tumor type(s) **Note 1**
  Specify: _____
- ☐ Other required pathology **Note 2**
  Specify: _____
- ☐ Required biomarkers **Note 3**
  Specify: _____
- ☐ Required Genetics **Note 4**
  Specify: _____
- ☐ Other
  Specify: _____

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

If **YES**, please identify specific requirements **Note 5**

- ☐ Anticipated surgical procedures / biopsies
  Specify: _____
- ☐ Anticipated fine needle aspiration biopsies
  Specify: _____
- ☐ Anticipated body fluid or cell preparation evaluations
  Specify: _____
- ☐ Anticipated blood or bone marrow evaluation (flow, molecular, cytogenetics)
  Specify: _____
- ☐ Anticipated autopsy evaluations
  Specify: _____
- ☐ Biomarker evaluation **Note 6**
  Specify: _____
- ☐ Tissue procurement **Note 7**
  Specify: _____
- ☐ Other
  Specify: _____

3. Summary of Pathology Service Requirements: **Note 8**

	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

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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

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