**PVAMC PATH & LAB NEW STUDY QUESTIONNAIRE**

**\*\*NOTE\*\* In all communications, please include your study ACRONYM & IRB# in the subject line.**

1. Full study name, as well as **a very short (no more than 5 or 6 letters) acronym or word that reflects your study** to help the lab more quickly respond to any questions or issues.
2. 4-digit protocol ID (include in the subject line, along with the “short” name for your study, of all your communications with the lab)
3. Principal Investigator’s name and contact info. (include phone and pager #s & email address(s))
4. Research Coordinator’s name and contact info. (include phone and pager #s & email address(s))
5. Research Assistant(s) name(s) and contact info. (include phone and pager #s & email address(s))
6. If lab orders will be entered under the patient’s name**, it is a requirement** that all orders placed in CPRS be done so through a **Study-Specific Research Clinic**.
7. Have you contacted R&D about setting up your clinic?
8. If so, do you know your study clinic name?
9. Will the tests be ordered under patient’s name or de-identified/blinded?
10. Patient names may be ordered in CPRS in a study-specific research clinic (see #6).
11. De-identified must be ordered in the VISTA “research” file following a specific naming format.
12. Send a “*short*” **study abstract** or **summary** that includes a description about how the VA lab is involved. For example, will the VA be running the tests or just collecting the samples?

**\*\* Include info regarding Pathology specimens (cytology or tissue) \*\***

1. Will you be escorting the patient to the draw room or sending them alone?
2. Could they show up on a non-visit day for collection?
3. If they show up on a non-visit day, and there are no orders, who can we call?
4. What tests does your study need?

a). List tests to be performed by the VA Clinical Laboratory (in-house):

**Note: If you will be using the VA Pathology department (tissue/cytology), see # 18.**

b). List blood/urine **collections only** (specimens to be taken or picked up by a study representative and stored or analyzed elsewhere) = Draw & Hold Tests:

**\*\* Your study will be responsible for supplying the collection tubes/containers for these specimens\*\***

1. Provide name(s) and contact information of person(s) needing to be contacted to pick specimens up from the lab after collection (if appropriate to your study).
2. What kind of processing and/or storage requirements are needed for specimens that the VA lab will NOT be performing?

**\*\* We may, or may not, be able to help you with processing, depending on the complexity. \*\***

1. Study’s funding source.

Call the R&D service to determine if you will need a financial MOU with lab.

1. Study’s estimated start date?
2. Estimated length of study?
3. Estimated number of study participants (specify: VA or non-VA patients).

**\*\* NOTE: The VA lab draw room is not open on off-shifts, weekends or holidays. Therefore,**

**Patients may only be seen for specimen collection 7:00AM – 5:00PM Monday through Friday. \*\***

1. **If you intend to collect tissue or cytology specimens, or use the VA Pathology department in any way, you must:**
2. All tissue/pathology requests must approved by Dr. David Cohen, Associate Chief of Staff/Research & Development Service, before contacting the Pathology department.

**Below is what I used to have. I’m not sure what the steps are after you approve it. What happens after you discuss it with Bryan & Olga and get their approval?**

a) Contact the Chief of Pathology & Laboratory Medicine Service to discuss exactly what your study is expecting from the VA Pathology department. Be very specific.

1. What kind of specimen(s) will be collected, when and how.

2. What are you expecting the pathology dept. to do: Cut slides from tissue? Stain slides? Make cytology slides? Send slides/specimens/reports to outside entities?, etc.

b) Establish a signed agreement between the Chief of Path & Lab and your study’s PI outlining specifically what the VA Pathology dept. agrees to do for your study. This will be coordinated through the Lab Research Coordinator.

c) Obtain estimated costs for use of the VA Pathology dept. through the Lab Research Coordinator.

d) Include the Lab Research Coordinator in all communications with the pathology department regarding your study.