SUBJECT: VA Ann Arbor Healthcare System (VAAAHS) Instructions for Utilizing Pathology Services for Research

1. **PURPOSE:**

   This guidance document outlines the process for using VA Ann Arbor Healthcare System Pathology Service for research purposes.

2. **DEFINITIONS:**

   AAROW: The electronic regulatory software used by the VA Ann Arbor Research Service for reviewing research applications and monitoring approved projects and protocols.

   ADPAC: Automated Data Processing Application Coordinator.

   Clinical Impact Form: A form used by VA Ann Arbor Research Service to assess the burden of clinic use by a research project prior to gaining approval for the research project.

   Human Subject: A human subject is a living individual about whom an investigator (whether professional or student) conducts research, and:
   (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
   (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

   Research: Research is the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. It is a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalized knowledge.

   VISTA/CPRS: Electronic medical records systems used by the Veterans Health Administration.

3. **Requirements for Receiving Approval to Use Pathology Services:**

   a) While completing a protocol application for human subjects research in AAROW, you will be required to complete a Clinical Impact Form. This form must be completed by the study team and signed by the Chief of Pathology Services.

   b) In order to complete the Clinical Impact Form, you will need guidance on cost of services. Contact the Chief of Pathology or the Laboratory Supervisor to discuss price guidelines and to receive approval for use of services.

      a. Some projects may be exempt from costs associated with pathology services provided. In this case, a Clinical Impact Form must still be completed in AAROW indicating the cost of services is $0.00 for phlebotomy or other process.

   c) The Clinical Impact Form will be evaluated by IRB (local or CIRB) prior to protocol approval.

   d) Approval for your project from the RDC will be granted only after your project application returns to the RDC. The Committee meets once per month (1st Wednesday of the month). If

utilizing human specimens, you must also complete the Safety Application in AAROW to assure all safety concerns have been addressed with the Subcommittee on Research Safety.

4. <u>**Instructions for Ordering Pathology Services in AAROW:**</u>

a) To use the phlebotomy services from pathology, an order must be placed in CPRS. Please note that the study coordinator or other study staff must escort the participant to the laboratory to obtain the blood draw even if pathology is providing the collection kit.

b) The following are the steps for ordering a research phlebotomy service in CPRS:

    a. Log into CPRS
    b. Choose the 'Orders' tab
        i. From the Lab Menu, select 'Outpt Orders'
        ii. For provider, choose the Principal Investigator
    c. Navigate to the 'New Visit Tab'
        i. Enter the date of visit (future date or today)
        ii. IMPORTANT: Be sure check the box for 'Historical Visit: a visit that occurred at some time in the past or at some other location (possibly non-VA) but is not used for workload credit' so the participant is not charged for this service.
    d. Select 'OK' to proceed
    e. Select 'Non-Quick Order labs' from the options listed
        i. Type in 'Research sample collection'
        ii. Select the collection date (future date or today)
    f. Enter Order Comment in the specified area
        i. The comment must include what supplies are needed, the staff member's name who will accompany the participant and contact information at minimum.
            1. Comment Template: "Research staff will provide collection kit. If the patient shows up to lab alone, please contact [Staff Name], [Staff pager or phone #]. DO NOT PERFORM BLOOD DRAW UNTIL SPEAKING WITH RESEARCH STAFF unless given prior instructions. [Billable/Non-billable] to [Name of Study & IRB Protocol #]."
                a. Choose billable vs. non-billable based on agreement with pathology service.
    g. Choose 'Accept Order' to proceed.
    h. Close both dialogue boxes
    i. Right click on the order you entered
        i. Navigate to the 'Action Menu'
        ii. Select 'Sign on Chart'
            1. Right click the order once more
            2. Choose 'OK'

c) Your order is now pending and will be visible to phlebotomy staff.

5. <u>**Tracking for Reimbursement to Pathology (if required):**</u>

a) As indicated, investigators must receive approval from Pathology Service prior to utilizing the "Research Sample Collection". Most of the time, the protocol will be required to compensate Pathology for services rendered. The study team is responsible for tracking these services and requesting a cost transfer from their study budget to Pathology Service.

b) If a protocol is required to pay for pathology services, study teams must use the "Quarterly Report of Pathology Services Usage for Payment by Research Service" form attached to the end of this document to report Pathology services used to the Research Budget Analyst. The form must be submitted to the Research Budget Analyst **prior to the end of each financial quarter** to initiate the cost transfer to Pathology Service. VERAM managed studies will be invoiced by the Research Budget Analyst according to these reports. If your funds are managed by an outside facility, a subcontract must be established with VERAM. In that case, contact the VERAM director before utilizing VA services.

6. <u>**VISTA Menus for Placing and Signing Orders in VISTA/CPRS:**</u>

a) Placing and singing orders in CPRS requires a special VISTA menu and key be assigned to staff if this permission is not automatically given to the staff during orientation (more common for clinical roles). The ADPAC for the staff member can assign this menu.

    a. The ADPAC can assist in determining the most appropriate key but the research service often uses the 'OREMAS' or the 'ORELSE' keys.

    b. If staff plan to place orders using VISTA instead of CPRS, the LRZ ORDER LAB TESTS will also be required.

7. <u>**CONTACTS:**</u>

Permissions for pathology services:
        Stephen Chensue, Chief of Pathology at 734-845-3425
        Elizabeth Carriger, Pathology Supervisor at 734-845-5254

Tracking orders & compensating pathology:
        Vicky Burrell, Research Budget Analyst at 734-845-5604
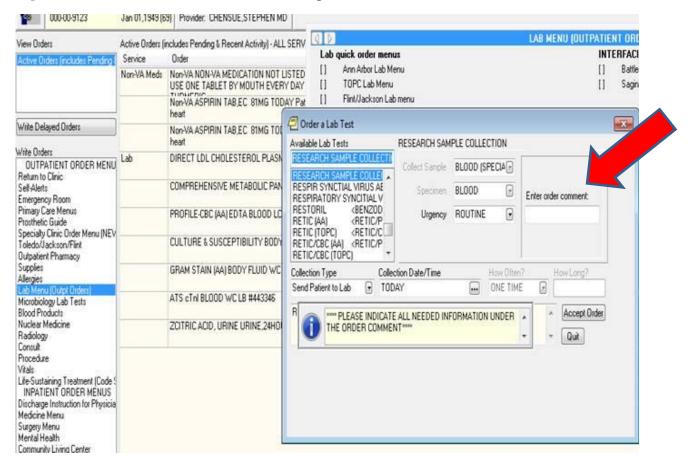
ADPAC for Research Service:
        Christopher Robinson, Program Support Assistant, at 734-845-5600

8. <u>**FOLLOW-UP RESPONSIBILITY:**</u> Clinical Research Center Program Manager

9. <u>**ATTACHMENTS:**</u>

Figure 1 – Comment Section for "Research sample collection" in CPRS
Document 1 – Quarterly Report of Pathology Services Usage for Payment by Research Service

Figure 1. Comment Section for "Research sample collection" in CPRS

Document 1. Quarterly Report of Pathology Services Usage for Payment by Research Service

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<u>Quarterly Report of Pathology Services Usage for Payment by Research Service</u>

Purpose: Investigators must receive approval from Pathology Service, generally during initial study approval prior to utilizing the "Research Sample Collection". The Clinical Impact Form must reflect this approval and agreed upon costs of services. The study team will be required to compensate Pathology for services rendered, although there are rare exceptions. The study team is responsible for tracking these services and requesting a cost transfer from their study budget to Pathology Service. If a protocol is required to pay for pathology service, this form is to be used to submit the total number of phlebotomy blood draws performed by the Pathology Service on behalf of the protocol on a quarterly basis.

Instructions: The study team should track all phlebotomy services performed by the Pathology Service at the VA Ann Arbor or affiliated outpatient clinic using a tracking form. This tracking spreadsheet should be kept by the study team as part of protocol records. Information from the study team's tracking form should be used to complete this usage form. This usage form must be submitted to the Research Budget Analyst **prior to the end of each financial quarter** to initiate the cost transfer to Pathology Service. VERAM-managed studies will be invoiced by the Research Budget Analyst according to these reports.

Study PI:	
Study Title:	
Study Coordinator:	**Study Coordinator Email:**
RMS Account # (assigned by Research Budget Analyst)**:**	
Funds Managed By*: *circle one*	Research Service VERAM
Fiscal Year (begins 10/1)**:**	**Fiscal Quarter:** *circle one* Q1 Q2 Q3 Q4
Date Submitted to Research Service:	

Total number of Phlebotomy Procedures Performed this Quarter:	
Costs per Phlebotomy Procedure (per clinical impact form):	$
Total Amount to Transfer to Pathology this Quarter	$

For Research Office Use Only	
Date Costs Transferred to Pathology Service:	
Signature of Authorizing Official:	

*If your funds are managed by an outside facility, a subcontract must be established with VERAM. Contact the VERAM director before utilizing VA services.