

LOUIS STOKES CLEVELAND  
VA MEDICAL CENTER  
10701 EAST BOULEVARD  
CLEVELAND, OHIO 44106

MEDICAL CENTER POLICY 151-010  
July 1, 2007

## RESEARCH PROTOCOL ORDER SET

1. **PURPOSE.** To establish a policy that will allow orders and tests required as part of a research study to be ordered by Research Coordinators.

2. **POLICY.** Research Coordinators will order specified orders and tests according to VA Approved Research Protocols as outlined in a "Research Protocol Order Set" through the Computerized Patient Record System (CPRS).

### 3. DEFINITIONS

a. **Research Coordinator** is defined as a registered nurse, physician assistant, registered pharmacist, or registered dietician that has responsibility for coordination and management of a research study. The Research Coordinator is employed to perform/ensure that study procedures of research protocols are carried out at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC).

b. **VA Approved Research Protocols** are protocols that have been approved by the Institutional Review Board (IRB), Research and Development Committee (R&D), and if applicable the Pharmacy and Therapeutics (P&T) Committee.

c. **Research Protocol Order Set** is a predetermined set of patient orders specific to a research protocol that can be accessed through CPRS.

d. **Research Clinical Study Coordinator** is defined as the individual within Medical Research Service (MRS) responsible for coordination of Clinical Study Coordinators.

### 4. RESPONSIBILITIES:

a. **Associate Chief of Staff for Research will:**

(1) Review and approve all requests for access to research protocol order set, assuring that individuals requesting access are working on VA Approved Research Protocols.

(2) Review and approve "Research Protocol Order Set" yearly. This order set will be comprised of research related orders (i.e. blood tests, collection of samples, etc.) that pertain to current approved research protocols.

b. **Principal investigators** are responsible for reviewing the study related order set with the Research Coordinator and ensuring that labs ordered are required as part of the research study.

c. **Research Coordinator** is responsible for placing orders only as part of the research study.

d. **Research Clinical Study Coordinator** will have responsibility for finalizing research protocol order set requests.

#### **4. PROCEDURES**

a. Principal Investigator and Research Coordinator will submit a detailed protocol order set for orders specific to the research study and submit it to the MRS Clinical Study Coordinator.

b. The MRS Clinical Study Coordinator will request through QUIMS, Clinical Coordinator that the Research Coordinator be given access to orders listed under protocol

c. Documentation of request and approval will be kept in Medical Research Service.

**5. REFERENCE:** None

**6. RESCISSION:** Medical Center Policy 151-010 dated July 1, 2004 has been rescinded. The review date of this policy is July 1, 2010.

**7. FOLLOW UP RESPONSIBILITY:** Associate Chief of Staff for Research.

WILLIAM D. MONTAGUE  
Medical Center Director

Attachments

**RESEARCH PROTOCOL ORDER SET REQUEST**

**Request authorization for** [redacted]

**VA approved research protocol** [redacted]

**IRB #** [redacted]

**to have access to orders detailed below:**

1. [redacted]

On this date [redacted] we have reviewed our research protocol and agree to use this process only for orders required by this study.

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**Principal Investigator**

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**Research Study Coordinator**

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For Office Use Only

**This request has been reviewed and approved by:**

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**Associate Chief of Staff/Research**

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**Date**

**PROCEDURE FOR REQUESTING ORDERS FOR A SPECIFIC PATIENT**

1. In CPRS Select a **New Patient**
2. On the patient's chart select the **ORDERS TAB**
3. From the **WRITE ORDERS MENU** Select **ADD NEW ORDERS**
  - a. In **ENCOUNTER PROVIDER** enter the name of the Principal Investigator
  - b. Select **APPOINTMENTS** or **NEW VIST** (as applicable) and complete required detail.
4. From the **ADD NEW ORDER MENU**
  - a. Choose the specific order you need
  - b. Complete required detail of the order (i.e. time /date/ etc. .)
  - c. Select **ACCEPT** the order
5. Select the order you just requested it will be *highlighted in blue*.
  - a. Select '**release without MD signature**'
  - b. Select '**policy**'