

**Yale University School of Medicine / Yale New Haven Hospital
General Clinical Research Center (GCRC)
Standard Operating Policies and Procedures**

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| TITLE: Policy for Verification of Licensed Medical Coverage for GCRC Research Protocols | | Source: Research Subject Advocates |
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| EXECUTIVE COMMITTEE: Robert S. Sherwin, M.D. GCRC Program Director | | GAC COMMITTEE: David Coleman, M.D. GCRC GAC Chairman |

I. Purpose

To outline the policy for licensed medical coverage for inpatient admissions and outpatient visits for GCRC research protocols.

II. Background

Verification of the availability of licensed medical coverage for all inpatient GCRC admissions and outpatient visits (where required) is an essential element of the planning process. To ensure the safety of the research subject and the appropriate performance of the research, there must be verification of the availability of the responsible licensed physician or alternate responsible licensed physician.

III. Policy Statement

A. Inpatient Admissions

- Admitting orders for the research admission submitted to the GCRC staff must list the name and contact information (home/office/cell phones, and beeper) of the responsible physician. Standing orders must provide around the clock contact information for each protocol's responsible physician and alternate physician.
- The responsible physician information will be transferred to the research subject's bedside flow sheet to provide information in the event an emergency arises.
- An appropriate alternate licensed physician(s) must be named in the admitting orders and on the flow sheet in the event that the responsible physician is unavailable. The around the clock contact information (home/office/cell phones, and beeper) for the alternate physician must also be provided.
- Upon admission of the research subject, the designated responsible physician listed in the admitting orders will be contacted. It is expected that the responsible physician will respond in a timely manner. No research will begin on the subject until there is verification of the availability of the responsible physician.

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- Admission history and physical examination notes as well as the admission orders must be signed by the responsible physician within 24 hours.

B. Outpatient Visits

- For all outpatient visits, the responsible and alternate physician contact information will be noted on the nurse's protocol flow sheet.
- Outpatient visit protocols in which procedures require the presence of a physician will require verification of the availability of a responsible or alternate physician prior to the onset of the research.
- For outpatient visits in which the physician is not required, the responsible physician or alternate must be available for contact in case an emergency arises.