

**(56) Marsha D Hopwood, John C Mabry, and William L Sibley (1981)**

***The Role of General Clinical Research Centers in Clinical Trials: a characterization with recommendations***

**Prepared for the National Institutes of Health, R-2669-NIH, November 1980**

**Santa Monica, California: RAND Corporation**

### ***Preamble***

This report documents the findings of the second year of a 2-year project entitled *Evaluation of the role of clinical research centers in clinical trials, with emphasis on information processing*. The project was sponsored by the General Clinical Research Centers (GCRC) program of the Division of Research Resources of the National Institutes of Health. The goals for the project were: first to develop a broad understanding of clinical trials, their organizational, administrative, operational, and information processing problems, and potential solutions, and secondly, to develop a detailed understanding of the role of the GCRC program in clinical trials, and to recommend methods for facilitating trials that make use of the resources it supports. A companion Rand report, *A First-Order Characterization of Clinical Trials*, R-2653-HIH, September 1980, addresses the first of these goals (Preface, page iii). This report is available online (<https://www.rand.org/pubs/reports/R2669.html>) but the companion report is not.

### ***Aims***

*The present report summarizes information gathered by the authors about clinical trials that make use of GCRC program resources and recommends changes to those resources to facilitate clinical trials. The information was obtained from structured interviews with approximately 150 clinical investigators and from informal interviews with approximately 75 support staff members. The recommendations presented are based on the interview results and their interpretation, as well as on previous Rand reports concerning GCRC program resources and the research activities of the investigators who use them. The information in this report should be of interest to the GCRC program and to those who participate in its deliberations regarding future resource development and allocation. The report should also be of interest to other government, university, and private individuals involved in funding, supervising, or planning resources for clinical trials; and to information scientists and others providing resources to support clinical trials (Preface, page iii).*

### ***Contents (xi + 51 pages)***

[Sub-sub-headings omitted]

Preface

Summary

Acknowledgments

Figures and Tables

1. Introduction

GCRC program background

Project methods

Sources of information for this report

An information processing view of clinical trials

2. Characteristics of the typical clinical trials investigator

Background and training

Research support

Attitudes toward clinical trials

Involvement in clinical trials

- Use of computers for clinical trials
  - Use of statistics for clinical trials
  - Impediments to clinical trials
  - Resources for clinical trials
  - 3. Characteristics of the clinical trial that uses GCRC resources
    - Trial organization
    - Trial design and reporting
    - Trial size and potential GCRC load
    - Data volume
    - Required personnel and facilities
    - Personnel involvement during particular trial stages
    - Staff stability and continuity
    - Personal workload
  - 4. Characteristics of the GCRC environment
    - The director's view
    - Views expressed by other GCRC staff
    - CLINFO and clinical trials
  - 5. Recommendations
    - Context for GCRC support for clinical trials
    - Information processing topics for further exploration
    - Models for GCRC support of clinical trials
    - Recommendations about personnel
    - Recommendations about computer system support
    - Recommendations about developing investigator expertise
- References

***Authors***

The report does not contain any details of the authors' backgrounds.