

VOLUME 7

National Institute on Alcohol Abuse and Alcoholism

PROJECT  
**MATCH**  
MONOGRAPH  
SERIES

# STRATEGIES FOR FACILITATING PROTOCOL COMPLIANCE IN ALCOHOLISM TREATMENT RESEARCH

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
National Institutes of Health

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**National Institute on Alcohol Abuse and Alcoholism  
Project MATCH Monograph Series  
Volume 7**

# **Strategies for Facilitating Protocol Compliance in Alcoholism Treatment Research**

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Public Health Service  
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Project MATCH is supported by grants under a cooperative agreement funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and implemented by nine clinical research units and a coordinating center. The project was initiated and is administered by the Treatment Research Branch, NIAAA.

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# Acknowledgments

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While the authors of this monograph were intimately involved in designing the methods and procedures described here for facilitating compliance with research protocols, the issues and content represent the combined wisdom of the investigators and support staff involved in Project MATCH. We have drawn upon their knowledge and expertise in presenting the compliance strategies found to be effective in that study. We also wish to express our appreciation to Carolyn Kott Washburne, whose assistance with planning, organizing, and editing was enormously helpful. Special thanks to Cathy Nelson for her hard work and dedication in helping to pull together the final draft.

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# Preface

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Clinical trials typically require attention to two aspects of subject compliance: (1) compliance with the intervention being tested, for example, attending psychotherapy sessions and taking medications, and (2) compliance with the requirements of the research protocol, that is, attending data collection sessions and completing questions, providing biological specimens, and naming collaterals. Maximizing subject followup rates and completeness of the data base is essential to the internal validity of a trial. Volume 6 of the Project MATCH Monograph Series, *Improving Compliance With Alcoholism Treatment*, provides strategies for enhancing client compliance with psychosocial treatments, as well as therapist compliance with treatment protocols. This monograph describes methods for facilitating research compliance in a multisite clinical trial. Practical strategies are offered for retaining participants in trials and for gathering accurate data in a timely manner. Specific examples from Project MATCH are used to illustrate methods of enhancing research compliance.

The monograph begins with Zweben's discussion of how our experience with Project MATCH prompted us to write a volume on compliance with research. Then Carty, Rice, and Barrett discuss, in detail, practical strategies that have been used effectively to address common sources of noncompliance in alcoholism treatment outcome research. Such difficulties might be related to resource needs of clients (e.g., lack of transportation) or pressures that interfere with continuing with followup assessments and related matters (e.g., relapse). Also, this section examines how staff are trained to address compliance issues such as identifying early warning signs of noncompliance.

Barrett and Morse focus on developing a customized compliance strategy to deal with the individualized needs of participants. They discuss the different circumstances and needs of participants who require special handling. Particular focus is placed on how the worker can tip the decisional balance in favor of continued participation.

Next, Morse and Barrett address methods for maintaining collaterals in the research protocol. This is an important issue in alco-

holism treatment research since these data are necessary to validate self-report data on alcohol use and related measures.

Rice, Freda, and Lawson deal with setting up and maintaining an electronic data base for monitoring activities of participants. At issue is how to use these data to enhance compliance with the protocol. For example, they demonstrate ways to flag certain events that might be indicative of potential compliance problems, such as death in the family, marital separation, or loss of a job.

McRee discusses the role of the coordinating center in the organization of the trial. Emphasis is placed on how the training and supervisory activities of the MATCH Coordinating Center helped to maintain boundaries between data collection and therapy in Project MATCH. Specific examples from Project MATCH demonstrate how coordinating activities directly and indirectly promoted compliance with the research protocol and facilitated the accuracy of research reporting,

This volume is aimed at a wide audience of clinical researchers, including individuals planning to become investigators and those already involved in conducting clinical trials, research assistants, and practitioners in general. We recognize that the strategies presented in this monograph may be familiar to researchers especially those having extensive experience in conducting outcome research. What is new is the organizing framework for addressing compliance problems, the detailed description of the compliance strategies, and the systematic way in which these strategies are delivered. The authors hope this volume will be useful as a reference guide for researchers dedicated to enhancing research compliance in a problem-drinker population.