

## The Cras Guide To Monitoring Clinical Research

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Medical Research for Hire  
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Elizabeth Weeks-Rowe  
British Museum  
Rebecca Daniels  
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the cra s guide to monitoring clinical research now in its third edition continues to be a key resource for both novice and experienced cras seeking to learn more about the field of monitoring or to better understand their roles and responsibilities as the industry becomes more global and technologically focused with helpful tips and strategies checklists personal experiences key takeaways and exercises plus new chapters on clinical trial roles and responsibilities monitoring for device and biologic trials globalization of studies edc and more the cra s guide is a must have training and educational tool that you ll refer to again and again topics include a comprehensive review of cra roles and responsibilities understanding regulations and gcps study initiation and monitoring plans recruiting and retaining study subjects the informed consent process conducting adverse event and safety monitoring preparing for audits and detecting fraud the future outlook job descriptions and current academic programs devices and biologics managing multi national trials irbs and data safety monitoring boards exercises with answers recommended for novice and experienced cras health professionals interested in pursuing a career as a study monitor instructors conducting training and educational programs

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today more than 75 percent of pharmaceutical drug trials in the united states are being conducted in the private sector once the sole province of academic researchers these important studies are now being outsourced to non academic physicians according to jill a fisher this major change in the way medical research is performed is the outcome of two problems in u s health care decreasing revenue for physicians and decreasing access to treatment for patients as physicians report diminishing income due to restrictive relationships with insurers increasing malpractice insurance premiums and inflated overhead costs to operate private practices they are attracted to pharmaceutical contract research for its lucrative return clinical trials also provide limited medical access to individuals who have no or inadequate health insurance because they offer free doctors visits diagnostic tests and medications to participants focusing on the professional roles of those involved as well as key research practices fisher assesses the risks and advantages for physicians and patients alike when pharmaceutical drug studies are used as an alternative to standard medical care a volume in the critical issues in health and medicine series edited by rima d apple and janet golden

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