Re-engineering the Clinical Research Enterprise
Clinical Research Policy Analysis and Coordination

The Re-engineering the Clinical Research Enterprise Roadmap set of initiatives is also addressing the difficulties clinical researchers confront in satisfying the multiple requirements of diverse regulatory and policy agencies. Clinical researchers must understand and fulfill these varying requirements that often overlap and may even contradict one another. NIH aims to take a leadership role in working with other agencies, institutional review boards, and other organizations to develop better processes and to standardize requirements for reporting adverse events, human subjects protections, privacy and conflict-of-interest policies, and standards for electronic data submission. Harmonizing policies and reporting requirements will help minimize unnecessary burdens that slow research, while at the same time enhancing patient protections.

As a step toward realizing these goals, NIH has created a Clinical Research Policy Analysis and Coordination (CRpac) Program to serve as a focal point for the ongoing coordination, streamlining, and optimization of policies and requirements concerning the conduct and oversight of clinical research. In its capacity as the primary Federal agency for the support of clinical research, NIH has a responsibility to promote the efficiency and effectiveness of the clinical research enterprise, in part through the promotion of policies that facilitate compliance and oversight, uphold the highest standards of human subjects protections, and promote public trust in research.

The CRpac Program, housed within the Office of Science Policy in the Office of the NIH Director, works on an array of issues and activities on behalf of all NIH components. The program's ultimate objective is to develop and implement coordinated policies and practices reflective of the needs and points of view of NIH's varied organizational components and stakeholders. CRpac staff work closely with other Federal agencies and offices that have responsibilities concerning the oversight of clinical research, including the Office of Human Research Protections, the Food and Drug Administration, the Department of the Veterans Administration, the Department of Defense, and other Federal agencies that have adopted the Common Rule.

Some specific foci for this effort include:

- Harmonizing diverse adverse event reporting requirements;
- Clarifying the respective roles and responsibilities of Data Safety and Monitoring Boards (DSMBs) and other review mechanisms;

- Reconciling various requirements for auditing and monitoring of clinical trials;
- Developing standards for electronic submission of safety and clinical research information;
- Providing guidance on the applicability of privacy requirements and HIPAA to clinical research;
- Clarifying policy where variability in the interpretation of the human subjects regulations exists;
- Examining the characteristics and features of central versus local IRB review and considering the best model of review for various forms of research;
- Studying various approaches to providing informed consent and sharing best practices;
- Creating dialogue on promoting science, safety, and ethics through clinical trial design.

The URL for the NIH Roadmap web site is nihroadmap.nih.gov. For more information on the Re-engineering the Clinical Research Enterprise Clinical Research Policy Analysis and Coordination Program, contact Kelly T. Fennnington, Office of Science Policy, Office of the NIH Director, (301) 594-5598, fenningk@od.nih.gov or Allan C. Shipp, Office of Science Policy, Office of the NIH Director, (301) 435-2152, shippa@mail.nih.gov. Further information about NIH can be found at its Web site: www.nih.gov.

NIH welcomes comments on the CRpac Program's activities; please send comments to CRpac@od.nih.gov.