



*An Association of Research Institutions*

January 23, 2023

VIA EMAIL TO: [emergencyclinicaltrials@ostp.eop.gov](mailto:emergencyclinicaltrials@ostp.eop.gov)

**RE: Response to Emergency Clinical Trials RFI**

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. One area of significant interest and expertise among COGR member institutions is the ethical conduct of clinical research involving human participants and the beneficial impact that findings from such research have on understanding and mitigating threats to public health. We write today to submit comments in response to the [White House Office of Science and Technology Policy's issuance of the "Request for Information; Clinical Research Infrastructure and Emergency Clinical Trials" \(87 F.R. 64821, Oct. 26, 2022\)](#), hereafter the "RFI."

The COVID-19 pandemic made clear the need for government agencies, research institutions, health care institutions, and pharmaceutical manufacturers to quickly launch clinical research during public health emergencies, as well as to broadly share and analyze the results of such research. COGR member institutions were on the front lines of many COVID-19 research efforts, and lessons learned from that experience can help inform preparations for future clinical research being conducted in similar emergency circumstances (hereafter "Emergency Clinical Research" or "ECR"). These lessons include the need to consider research from the patient/participant perspective, recognition of the fact that research can happen anywhere (patient home, community clinic, pharmacy), and that flexibility on the part of institutions and regulators is essential to ensuring that research can quickly "pivot" to address changing circumstances. COGR appreciates OSTP's issuance of the RFI to collect information for use in developing an Emergency Master Agreement framework to facilitate the conduct of Emergency Clinical Research, and we offer here responses regarding each of the broad topics set forth in the RFI.

**1. *Governance for emergency clinical trials response.***

As events during the COVID-19 pandemic illustrated, scientific progress toward understanding the virus and developing vaccines and treatments depended on the joint efforts of government, corporate, and non-profit entities. To address each of the items listed under this topic, COGR encourages OSTP to convene working groups that involve members from research funding agencies, clinical research regulatory agencies (e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP)), pharmaceutical companies, contract research organizations (CRO), research institutions, institutional review boards (IRBs), public health agencies, hospitals and other health care institutions (e.g., home health care organizations, pharmacies), and groups that represent the interests of clinical trial participants. In the heat of an emergency, research-intensive institutions may be more likely to take on research projects, but clinical entities may be so overwhelmed by the emergency that they are unable to engage in anything other than core clinical activities, and many also lack experience in conducting research and/or trained research personnel. Yet, emergency circumstances demand that clinical options be tested and deployed rapidly.

Accordingly, working groups should develop process maps that identify logistical and regulatory “choke points” and potential solutions that facilitate ECR across all types of institutions. Additionally, the groups should pinpoint factors that prevent sites and individuals from participating in clinical research, including financial and legal issues, such as subject injury costs or site liability/insurance issues. Non-traditional research sites that lack research-related compliance, risk management, and trial management infrastructure will be unable to address these issues amid a public health emergency, and, thus, to expand the site base, these items must be addressed before the next public health emergency. Analysis of these sticking points should identify existing regulatory flexibilities, as well as flexibilities that agencies can extend in emergency circumstances that can be leveraged to mitigate issues, and when such flexibilities are inadequate, regulatory changes should be considered.

**2. *Identifying and Incentivizing Research Institutions and Networks; Building Diversity and Equity, Subsections***

COGR supports OSTP’s efforts to solicit recommendations on how to improve the diversity of both the sites that conduct ECR and the participants in that research, and we believe that certain existing projects and networks can be leveraged in this regard. For example, National Center for Advancing Translational Sciences (NCATS) supported Clinical Translational Science Awards (CTSA) program sites often have established relationships with the communities and patients that they serve. These relationships are particularly important in communities whose culture or history have engendered distrust of medical research. Research intensive institutions may be able to build on these relationships by facilitating the ability of other community health providers (e.g., community hospitals and clinics) to participate in ECR through a hub and spoke system, that

leverages the research institutions' expertise and infrastructure, while increasing outreach and broadening the participant base.

To promote these relationships, ECR participation roadblocks must be identified and eliminated, particularly for non-traditional research sites. For example, home health care agencies and pharmacies are often reluctant to participate in federally sponsored research activities if they must execute a Federalwide Assurance document or have staff undergo training in good clinical practices (GCP). Such requirements can limit participation in the best of circumstances, let alone in time critical research conducted during the height of a public health emergency, and their costs and benefits should be carefully considered in the ECR context, particularly when the activities being performed are substantially similar to clinical activities. We recommend that HHS work with OHRP to tailor the requirement for a Federalwide Assurance to the level of participation and engagement of community sites in emergency research.<sup>1</sup> Thought also should be given to whether additional flexibility is required regarding the application of the single IRB requirement in the context of ECR, where there may be tangible benefit to using local IRBs working directly in their communities.

In terms of incentives, we note that the RFI does not specifically discuss or seek information regarding funding needs. We respect this approach, as cost and budget considerations typically are handled on a project basis. However, COGR believes that it is critical for federal agencies to (a) identify areas in which the federal government can provide standing support that sites can tap to perform necessary functions in the ECR scenario; and (b) consider initiatives that will ensure the availability of appropriate clinical trial infrastructure in the event of a public health emergency. For example, the federal government's development, and on-going financial support, of a government maintained ECR data repository with associated electronic data collection tools would facilitate data collection and sharing, while eliminating a significant cost for sites and streamlining their trial budgeting. Government support for the development of technology for collecting data directly from electronic health records would also help build infrastructure that will facilitate participation by diverse sites in ECR.

### 3. ***“Warm Base” Research***

There are basic skills that cut across clinical research, no matter what type of disease/condition is being targeted: knowledge of applicable regulatory and GCP requirements; establishment of clinical investigations systems and processes; and data collection, analysis, and reporting. A warm base research approach must foster the development of these skills at potential ECR research sites and provide continuing support so that bases don't “cool.” A program that utilizes the aforementioned “hub and spoke” approach could be developed to support experienced principal

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<sup>1</sup> For additional discussion on the issue of “engagement” in research see COGR's July 8, 2022 letter to the Office of Human Research Protections (OHRP) and Secretary's Advisory Committee on Human Research Protections (SACHRP) in the record of the July 20-21, 2022 SACHRP meeting at <https://www.regulations.gov/document/HHS-OASH-2022-0013-0016>.

investigators and research coordinators at mature research sites in providing initial and continuing training to a core of research personnel at developing research sites to facilitate a state of readiness. Similarly, once an ECR protocol is initiated, seasoned investigators could be available for consultation with (or if the emergency is regional, perhaps deployment to) other research sites to assist with protocol-specific training and quickly bringing sites online.

A demonstration project would be an important first step in establishing a warm base research network, and perhaps leveraging existing networks such as the [Community Oncology Research Program](#) would provide an excellent avenue for such a project. COGR believes that agency funding of such a project is critical, but as it has done in the research security arena, OSTP should take the necessary steps to ensure that all involved federal agencies remain consistent in their award requirements. To do otherwise will undercut efforts to streamline ECR research and to promote diverse participation.

#### **4. *Emergency Master Agreement***

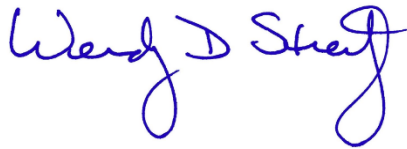
A user-friendly clinical trial master agreement that is acceptable to all research sponsors and sites without the need for multiple modifications has long been the “Holy Grail” of the clinical trial world. Fundamental differences in how public, private, for-profit, and non-profit entities can address complex issues such as data use, intellectual property rights, indemnification, and compensation for subject injury pose significant difficulties in the development of a one-size-fits-all contract. Nonetheless, certain groups have made great strides along these lines by developing contract templates that might be leveraged for use in ECR. For example, the FDP has developed a [fixed rate clinical trial subaward template](#) and [associated guidance document](#) with which many sites are familiar. In another effort, the [Accelerated Research Agreements Initiative](#), organized working groups with representatives from research institutions and pharmaceutical companies and developed model clinical trial agreement forms including the Accelerated Confidential Disclosure Agreement, Accelerated Clinical Trial Agreement, and the CTSA Data Transfer & Use Agreement.

In developing a master agreement, consideration must also be given to the fact that non-U.S. institutions and companies may need to be involved for the ECR research to be fruitful. Global and political circumstances may make research institutions of all types reluctant to work with certain international partners, yet their information, data, and expertise may be essential to addressing the emergency. In such circumstances, OSTP and U.S. government agencies must be prepared to provide clear direction on any prohibited collaborations. Further, the development of mechanisms to foster rapid government-to-government communications regarding the emergency and ways to facilitate global ECR (e.g., international regulatory flexibilities) are essential.

**Conclusion**

COGR applauds OSTP's efforts to improve the nation's capacity to undertake ECR and to build on lessons learned from the COVID-19 pandemic. This will undoubtedly be difficult work, but COGR and its member institutions stand ready to assist in these efforts. We once again thank OSTP for this opportunity to provide our comments, and we hope that they will prove helpful. Should OSTP have any questions regarding this transmittal, please contact Kris West, COGR's Director for Research Compliance and Ethics at [kwest@cogr.edu](mailto:kwest@cogr.edu).

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is written in a cursive style with a large, looping initial "W" and a long, sweeping tail on the "t".

Wendy D. Streit  
President