



May 14, 2024

Submitted electronically to: [VRDCRFI@cms.hhs.gov](mailto:VRDCRFI@cms.hhs.gov)

**RE: Response to Centers for Medicare & Medicaid Services February 2024 Request for Information on Research Data Request and Access Policy Changes – Updated March 1, 2024**

To Whom It May Concern:

We write to offer comments in response to the [Centers for Medicare and Medicaid Services \(CMS\) Request for Information \(RFI\) on Research Data Request and Access Policy Changes](#) (“CMS RFI”) first published on the CMS website in February 2024, and updated on March 1, 2024. COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. We focus on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens.

COGR and its member institutions recognize the importance of conducting research involving the use of CMS data in a safe and secure manner, and we support the need for federal requirements aimed at achieving this goal. We support CMS’ solicitation of public input before implementing changes in the process for accessing such data for research, and we appreciate the opportunity to provide comments.

The CMS RFI sets forth a series of study-related questions that are directed to researchers who will be impacted by the policy changes. COGR has encouraged its member institutions to alert investigators who use CMS data to the RFI so that they can provide study specific comments. COGR’s comments here focus on the broader implications of proposed policy changes and their institutional impact. Our primary concerns with the policy changes outlined in the CMS RFI are as follows:

- Confining the conduct of research using CMS Research Identifiable File data (“RIF Data”) to the CMS Chronic Conditions Warehouse Virtual Research Data Center (CCW VRDC)

will severely curtail how research using RIF Data can be conducted because it limits researchers' ability to link data and use analytical tools.

- The proposed pricing structure for the access to the CCW VRDC and RIF Data will create a substantial cost burden for all institutions and significantly impede the ability of emerging research institutions and early-stage researchers to conduct research using RIF Data.

### ***Confining Research Using RFI Data to the CCW VRDC will Limit the Types of Research Conducted***

The current CMS system permits researchers to obtain physical data extracts for use on institutional systems that meet CMS prescribed data security standards. This system affords researchers the flexibility to link RFI Data with other data sets and to use the wide variety of analytical tools and programs that are available at institutions. The proposed policy changes eliminating physical data extracts restrict researchers' ability to link data and access these tools, thus impeding the conduct of on-going federally funded research that was developed in reliance on the continuing ability to access these extracts for use in institutional environments. Additionally, the development of new research projects using RFI Data will be hampered by the requirement to use the heavily constrained CMS VRDC environment.

CMS' proposed prohibition on the transfer of physical data extracts to institutions also fails to recognize that institutions have successfully established data enclaves in which research using RFI Data can be conducted securely. COGR member institutions are well acquainted with the security risks associated with collection, analysis, and storage of human subject data for research purposes. They have worked diligently to develop secure data enclaves that conform to the [CMS Requirements and Guidance for Security and Privacy Controls](#)<sup>1</sup> that are required per the terms of CMS Data Use Agreements (DUA) that data users must enter to gain access to RFI Data. Institutions have demonstrated that these enclaves can effectively protect RFI Data, while enabling researchers to link RFI Data to other data sets and to use analytical tools that are not available in the CCW VRDC environment.

The [National COVID Cohort Collaborative | National Center for Advancing Translational Sciences \(nih.gov\)](#) and [PCORnet®, The National Patient-Centered Clinical Research Network | PCORI](#) are two successful examples of federally funded data enclaves that obtain CMS data exports and use privacy-preserving technology (such as encrypted hash tokens) to link the CMS data with other clinical datasets and produce research findings that would not be possible absent these linkages. The National COVID Cohort Collaborative brings together data from more than 60 large health systems and has generated hundreds of critical research findings, papers, and presentations. PCORnet combines real time clinical data from some 40 health systems with CMS data to perform critical patient outcome focused research.

These research programs (and many more) will be devastated by the proposed changes abolishing physical data transfer. The proposed changes to these and research programs will prevent data linkages and analysis with tools that are unavailable in the CMS VRDC environment. As discussed, RFI Data is frequently linked to other research or proprietary data such as patient cohort

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<sup>1</sup> As set forth in CMS' Data Management Plan Self-Attestation Questionnaire.

information, and health outcomes data. This linked data is often subject to restrictions on its movement or transfer (e.g., Institutional Review Board approval, subject consent), and therefore, can only be used in institutional data enclaves that were established to meet these requirements. Prohibiting the use of RFI Data in such environments will preclude the data linkages that drive the power, accuracy, and reliability of real-world clinical research data. Moreover, taxpayers will be unable to realize the full benefits of the hundreds of millions of federal dollars invested in these research programs and lose opportunities for improved health outcomes.

**COGR respectfully requests that CMS reconsider the requirement that all CMS data remain within the CMS VRDC environment and instead maintain current policy, which permits institutions that can satisfy the CMS DUA requirements to continue to receive physical data extracts.** The abrupt changes proposed by the CMS RFI will cut-off RFI Data access to on-going, federally funded research that is key to improving patient outcomes and lowering healthcare costs. Requiring federally funded researchers to work solely within the CMS VRDC environment would also discard the considerable investment that federal agencies and institutions have already made in creating secure data enclaves such as the COVID Cohort Collaborative and PCORnet.

***If CMS cannot continue with the current RFI data policy, we recommend that that it consider an alternate approach per which it permits the release of RFI Data to data enclaves that meet a high degree of security such as that represented by FedRAMP certification, or another similar security certification (for example, compliance with the Cybersecurity Maturity Model Certification program).*** Some institutions may choose to create these enclaves themselves, or there may be opportunities to build consortia that develop and operate enclaves, or for partnership with research institutions that have established enclaves. Amending the proposed policy changes to offer this option would support the continuing conduct of projects that rely on institutional data linkages and tools and enable the continued developed of research that incorporates these features.

We note, however, that the creation of such data enclaves will come at considerable cost to institutions. Under 2 CFR Part 200 (the Office of Management and Budget's "Uniform Guidance"),<sup>2</sup> costs for institutional information technology (IT) infrastructure are generally classified as part of the facilities and administrative (F&A) cost rate. Normally, such rates are negotiated with an institution's cognizant agency every two to three years, and the administrative portion (where IT infrastructure costs normally reside) has been capped since 1991. Institutions already under-recover the full costs of performing federally funded research, and any additional IT infrastructure costs will further perpetuate this cost imbalance and potentially limit the conduct of research using RFI Data to only extremely well-funded institutions. **Accordingly, we firmly believe that the best course of action is for CMS to withdraw the proposed policy changes, keep the current RFI data transfer policy in place, and, as necessary, continue to work with the research community to explore alternate mechanisms to address any data security concerns.**

***CMS' Proposed Costing Structure Burdens Institutions and will Curtail the Ability of Emerging Research Institutions and Early-Stage Researchers to Participate in Research using***

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<sup>2</sup> 2 C.F.R. Part 200.

## **RFI Data**

The [CMS Fee Information for CMS Research Identifiable Data](#) includes the following three fee schedules: 1) Physical Access to Data (which will be phased out in 2025 per the proposed policy changes), 2) VRDC (Researcher), and 3) VRDC (Innovator). The CMS RFI notes that CMS will institute price increases for physical delivery of research files (until that access method is phased out), including a new initial project fee of \$20,000 for the first year of a project and a project renewal fee of \$10,000/year thereafter.<sup>3</sup> The imposition of this new project fee will negatively impact on-going research projects that do not have the budget capacity to absorb this substantial additional cost, as well as the ability of institutions, particularly emerging research institutions to initiate new projects.

The VRDC fee lists includes “seat” fees for researchers that range from \$20,000 to \$22,000 per user/per year for the first year of a project and renewal fees of \$13,000 to \$15,000 per user/per year thereafter.<sup>4</sup> In addition to these user fees, CMS assesses a VRDC project fee per DUA/per year that ranges from \$15,000 to \$35,000 for the first year of the project, and project renewal fees of \$10,000 to \$25,000 per year thereafter.

Although the CMS RFI does not include changes to the VRDC fees, institutions can expect dramatically increased costs under the proposed policy changes because each individual researcher that uses the VRDC is required to pay a seat fee and seats cannot be shared.<sup>5</sup> Accordingly, institutions will be required to either incur substantial additional costs to ensure that all members of a research team can have access to the RFI Data within the VRDC, or, alternatively, face the prospect of reducing the number of researchers with access to RFI Data. Smaller and emerging research institutions without the resources to support seat fees for multiple researchers, may disproportionately bear the burden of these cost increases or simply determine that research using RFI Data is cost prohibitive. Similarly, limited project budgets may force study teams to limit seats, an impact that may fall most heavily on early-stage researchers and trainees.

Notably, these high fees last through the duration of a project, including periods of time when the data is not being actively manipulated, but is stored as part of required data retention and sharing. COGR notes that the NIH’s guidance<sup>6</sup> on the allowability of such costs when data is stored in a repository must be incurred within the exiting budget period. Thus, many researchers with approved research grants will be unable to pay the costs under the proposed CMS model within their existing grant budgets. Further, new research grants will be required to spend more of their funding to support data access costs, thus reducing funding available to support the research involving that data. **We urge CMS to enter into discussions with federal research funding agencies as to how these charges will be assessed to awards and their impact on project budgets.**

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<sup>3</sup> CMS, [Fee List for RIFs: Physical Research Data Request](#) (Feb. 12, 2024).

<sup>4</sup> Quarterly renewals are permitted if a full year’s access is not required.

<sup>5</sup> [CMS Virtual Research Data Center \(VRDC\) FAQs](#) (Jan. 1, 2020)

<sup>6</sup> [Budgeting for Data Management & Sharing | Data Sharing \(nih.gov\)](#)

**Conclusion:**

COGR and its member institutions believe that the proposed policy changes will severely impair the ability of institutions and researchers, **particularly emerging research institutions and early-stage researchers and trainees**, to access the CMS RFI data that is vital to the conduct of epidemiological and health policy research. In short, the proposed policy changes will ultimately result in far fewer researchers being able to access this data to conduct federally funded research. **Accordingly, we urge CMS to either withdraw the proposed policy changes and maintain the current system of data distribution, or, at a minimum, delay the proposed changes, including the assessment of new project fees for physical data extracts, to allow additional time to further engage with the research community, federal research funding agencies, and the Office of Management and Budget (OMB)<sup>7</sup> to determine an appropriate distribution and costing model that can address data security concerns and while continuing to foster equitable and effective data access.**

We thank CMS for the opportunity to offer comments on this RFI. Please do not hesitate to contact me at [mowens@cogr.edu](mailto:mowens@cogr.edu) or Kristin West, COGR's Director for Research Ethics & Compliance at [kwest@cogr.edu](mailto:kwest@cogr.edu) if you have any questions regarding this transmittal.

Sincerely,



Matt Owens  
President

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<sup>7</sup> [OMB Circular A-130, Managing Information as a Strategic Resource](#), (rev. Jul. 28, 2016) at Sec. 5.e.2)(a)-(c) (OMB rules for agencies regarding access to public information call for agencies to provide public information in a manner that promotes analysis and reuse for a wide range of purposes and to avoid charging fees that exceed the cost of dissemination or establishing unnecessary restrictions on dissemination.).