November 27, 2024

Submitted electronically to: https://www.regulations.gov
U.S. Department of Justice
National Security Division
Foreign Investment Review Section
175 N Street, N.E., 12th Floor
Washington, D.C. 20002

RE: Comments Submitted in Response to Notice of Proposed Rulemaking - Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons (Docket No. NSD 104; RIN 1124-AA01)

To Whom It May Concern:

We write to offer comments in response to the U.S. Department of Justice National Security Division's (DOJ) notice of proposed rulemaking (NPRM) "Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons" ("Proposed Rule") that was published in the Federal Register on October 29, 2024.[1] COGR is the national authority on federal policies and regulations affecting U.S. research institutions. We provide a unified voice for over 220 research universities and affiliated academic medical centers and research institutes. Our work strengthens the research partnership between the federal government and research institutions and furthers the frontiers of science, technology, and knowledge. We advocate for effective and efficient research policies and regulations that maximize and safeguard research investments and minimize administrative and cost burdens.

COGR appreciates DOJ's solicitation of public input on the NPRM and the opportunity to provide these comments. We also appreciate DOJ's outreach efforts to educate stakeholders about the Proposed Rule and solicit questions and feedback.

GENERAL COMMENTS

The Proposed Rule sets forth a complex and pervasive regulatory framework that will have significant impact on a wide swath of U.S. business operations and activities. Our comments here, will focus on Proposed Rule's impact on the research mission and research-related operations of

[1] 89 F.R. 86116.

our members – the United States's leading academic research institutions and their affiliated academic medical centers and research institutes. Our overarching concern with the Proposed Rule is its failure to include an exemption to permit the conduct of non-federally funded research[2] activities that do not qualify for exemption under §202.510 or §202.511 and to enter into related vendor and employment agreements that are necessary for the conduct of that research.

Although §202.510 and §202.511 set forth exemptions for certain data transactions associated with clinical investigations that support obtaining or maintaining medical product regulatory authorizations, they do not encompass non-federally funded research. This lack of an exemption for non-federally funded, non-clinical research will significantly impede research institutions' ability to conduct important epidemiologic and other public health research involving Countries of Concern (COCs) and Covered Persons. In our interconnected world, emerging diseases and health threats cannot be walled-off at their point of origin. Rather, these threats quickly become global in nature and require scientists in **all** countries to share data and specimens to conduct the foundational and public health research that is necessary to understand threat mechanisms and track threat patterns. Such research lays the groundwork for the development of the clinical research necessary for the approval and surveillance of medical interventions (e.g., drugs, devices, biologics).

U.S. academic research institutions have long been global leaders in the conduct of public health and foundational research, but the Proposed Rule may force them to curtail their efforts in the international arena **because global health and environmental threats, by their very nature, affect the U.S., its allies, and COCs, and they require cross-border cooperation among scientists in all countries to understand the threats and develop solutions**. The United States government's funding for science is being cut, or at best staying flat.[3] Thus, federal research funding is not the sole source of support for these research activities,[4] and because federal support does not cover the entire project cost, many, if not most, federally funded projects also receive private support from the participating research institution(s) (and sometimes third parties).[5] In our comments on the ANPRM for the Proposed Rule we provided examples of vital, privately funded, multi-national public health research that included research sites within COCs and required researchers at all locations to share genomic data and/or biospecimens.

In short, global public health and foundational research are funded by multiple private and non-U.S. governmental sources. Reliance on these non-federal funding sources will increase whenever

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[2] In this letter, we use the term "federally funded research" to refer to research funded by a component of the United States federal government.
[3] "Final U.S. spending bills offer gloomy outlook for science," *Science* (Mar. 4, 2024) at https://www.science.org/content/article/final-u-s-spending-bills-offer-gloomy-outlook-science.
[4] Although federal dollars constitute a major source of research funding, there is also significant investment in research funding from private industry, academic and research institutions, and private foundations and associations. *See, e.g.,* Congressional Research Service, Federal Research Funding and Development (R&D) Funding: FY2024 (May 19, 2023) at p. 6; Research America, U.S. Investments in Medical and Health Research and Development 2016-2020 (Jan. 2022).
[5] *See*, 2 C.F.R.. §§ 200.2 & 200.306.

U.S. federal scientific funding decreases. These types of research frequently require scientists in all nations to exchange and analyze large data sets containing personal health data, human genomic data, and/or biospecimens. The Proposed Rule provides exemptions for federally funded and certain clinical research, yet it fails to provide any type of exemption for non-federally funded, non-clinical research that is similarly vital to supporting America's scientific prominence. **U.S. participation in global scientific efforts funded by federal and/or non-federal funds is critical to ensure that the U.S. has continuing access to both the raw data and international analyses of that data that are necessary to combat global health and environmental threats, including the detection and tracking of emerging diseases, at their earliest stages. The U.S. cannot isolate itself from the global conduct of science and expect to remain preeminent.** Further, the fast pace at which science must proceed in the face of emerging health threats simply cannot be accommodated by the lengthy, time-consuming process of applying for and obtaining a specific license to engage in a particular transaction.

We once again urge DOJ to include within the final rule an exemption to permit Covered Data Transactions associated with non-federally funded research projects. We recommend that DOJ pattern this exemption after the exemption for transactions conducted pursuant to a grant, contract, or other agreement entered into with the United States Government under §202.504. Specifically, we believe that the transactions detailed in Example 1 for that section should be permitted for both federally funded and non-federally funded research. At the very least, we recommend that DOJ craft a general license for non-federally funded research because the proposed specific license process proceeds too slowly.[6]

The remainder of this letter sets forth specific comments on provisions of the Proposed Rule and items in the NPRM's Preamble for which DOJ requested comments.

SPECIFIC COMMENTS

Comments in this section are organized under the provision of the NPRM's Preamble and/or section of the Proposed Rule to which they pertain.

NPRM Preamble, Section IV.A, Subpart C-Prohibited Transactions and Related Activities, Subsection 10 - Other Human 'Omnic Data [NPRM at p. 86124-25]

This section of the Preamble states that DOJ is considering regulating as a prohibited or restricted transaction "certain transactions in which a U.S. person provides a country of concern (or covered person) with access to bulk human 'omic data, other than human genomic data, as defined in §202.224."[7] Specifically, DOJ proposes to regulate the following types of data for which it

[6] NPRM at §202.802(g)("The Department shall endeavor to respond to any request for a specific license within 45 days after receipt of the request and of any requested additional information and documents.")
[7] NPRM at p. 86124-25.

provides proposed definitions: epigenomic data, glycomic data, lipidomic data, metabolomic data, meta-multiomic data, microbiomics data, phenomic data, proteomic data, and transcriptomic data.[8]

These various categories of 'omic data encompass a wide set of measurements related to human physiological, pathological, or genetic measurements that are used to help understand basic mechanisms or functions of human health states and that do not contain identifiable information. Importantly, the NPRM fails to describe how these types of 'omic data pose national security risks. **Prior to taking further regulatory action concerning 'omic data, we urge DOJ to appoint an advisory panel that includes representatives from government agencies, industry, and academic research institutions to consider the questions set forth in the NPRM Preamble on the advisability and parameters of regulations in this space.**

Interplay between Section 202.211 - Covered Person, Section 202.221 – Foreign Person, and Section 202.238 – Person, and Section 202.256 – United States Person or U.S. Person

The definition of "Covered Person" is built on the definitions of the terms "Person," "Foreign Person," and "U.S. Person." Yet the examples associated with these definitions do not align. Specifically, §202.238 defines a "Person" as "an individual or entity." Section 202.221 defines a "foreign person" as "any person that is not a U.S. person." Section 202.256 defines a "United States person or U.S. person" to include "any person in the United States." Section 202.211 defines "Covered Persons" as certain types of "foreign persons," or persons determined by the U.S. Attorney General to meet certain criteria, regardless of location.

The definition of "Foreign Person" excludes "any Person that is a U.S. Person" and the term "Person" includes both individuals and entities. Accordingly, under the definition of "Person," any individual **or** entity that is in the United States should be considered a "U.S. Person." Example 2 under §202.211 bears this interpretation out when it states that "Chinese or Russian citizens located in the United States would be treated as U.S. persons and would not be covered persons (except to the extent individually designated)." However, this interpretation is inconsistent with Example 7 under §202.256, which states if a company organized under the laws of a COC has a branch in the United States, then "[t]he company, including the U.S. branch, is considered a foreign person." If the term "person" is defined to include both persons and entities, why under the foregoing examples are individual citizens of COCs considered to be U.S. persons when located in the U.S., but the same designation is not afforded to corporate entities located in the U.S.? **We urge DOJ to ensure that the definitions align and treat entities and individuals alike, or, alternatively, modify the definitions to make clear how individuals and entities are treated differently.**

[8] *Id.*

Section 202.211- Covered Person and Associated NPRM Preamble Text [NPRM at p. 86148]

As noted in the discussion above, entities located within the U.S. are not considered to be U.S. Persons solely by virtue of their location. Accordingly, U.S. institutions will be required to vet all persons and entities – whether located in the U.S., COCs, or other foreign countries – to determine if they meet the definition of Covered Person by virtue of their location, primary residence, citizenship, ownership (direct or indirect), principal place of business, and/or listing by DOJ. **We urge DOJ to modify the Proposed Rule to provide that a U.S. Person may rely on certifications and supporting documentation provided by persons/entities to establish their status as non-Covered Persons. We also encourage DOJ to consider how it can help U.S. persons effectively and efficiently meet the Proposed Rule's requirement to identify Covered Persons, such as by providing resources and tools that can be used to identify persons that DOJ has determined to be either Covered Persons or U.S. Persons.**

Section 202.214 – Data Brokerage

We strongly recommend that DOJ amend this provision to clarify the meaning of the phrase "licensing of access to data, or similar commercial transactions involving the transfer." For example, if as part of an unfunded research project a U.S. person transfers a large data set containing human genomic data to a researcher in a COC and requires that researcher to sign a data use agreement limiting the manner in which the data can be used and establishing data security requirements but conferring no rights to use the data for commercial purposes, would the data use agreement be considered "licensing of access to data"? Such data use agreements are a common practice for sharing research data.

During a November 18, 2024 DOJ presentation on the NPRM attended by COGR representatives ("DOJ Presentation"), DOJ representatives advised that the term "commercial" did not apply to the purpose or nature of the transaction being evaluated or the parties engaged in the transaction (i.e., for-profit v. non-profit), but rather that any transfer of covered data in exchange for any type of consideration would be considered to be "commercial." This interpretation is not obvious from the plain language of the provision. **We recommend that DOJ add text to the definition of "Data Brokerage" that makes its interpretation clear.**

Further, we encourage DOJ to include an explicit definition of "consideration" with illustrative examples. For example, does a transaction in which a U.S. scientist transfers 100 deidentified biospecimens over the course of 12 months to a researcher in a COC relating to a topic of mutual scientific interest, and not as part of a research project (whether funded or unfunded), constitute a "similar commercial transaction"? Would the mere possibility of a future collaboration on a scientific research project or serving as a co-author on a paper related to that project be deemed "consideration" for purposes of the Proposed Rule? Such informal and uncompensated interactions between researchers are common in the scientific community. Given the potential

consequences for violating the rule, we urge DOJ to be explicit about what behavior is permitted or prohibited in the international research arena.

Section 202.217 – Employment Agreement

We urge DOJ to clearly state what constitutes "other consideration" with respect to employment arrangements or provide a separate definition of this term. For example, would unpaid service on a volunteer board be considered "employment"?

Section 202.249 – Sensitive Personal Data

This provision states that the following data is excluded from definition of "Sensitive Personal Data":

> Data that is, at the time of the transaction, lawfully available to the public from a Federal, State, or local government record (such as court records) or in widely distributed media (such as sources that are generally available to the public through unrestricted and open-access repositories).

The Office of Science and Technology Policy (OSTP) charged federal funding agencies with updating their public access policies by "no later than December 31, 2025, to make publications and their supporting data resulting from federally funded research publicly accessible without an embargo on their free and public release" and to coordinate with OSTP "to ensure equitable delivery of federally funded research results and data."[9] Agencies are implementing this policy,[10] for various types of scientific data, including the sharing of genomic data[11] with researchers inside and outside the U.S. who meet specified information security standards for maintaining the data. Additionally, scientific journals frequently require that authors deposit the data underlying their publications, including genomic and other 'omic data in publicly accessible repositories that are available internationally.[12] These requirements promote research integrity and reproducibility.

We urge DOJ to include within this definition an example that makes clear that data covered under the Proposed Rule that is placed in and obtained from such repositories per the requirements of federal funding agencies or scientific publishers, as well as any subsequent sharing of that data in accordance with those requirements, is explicitly excluded from the

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[9] A. Nelson, OSTP Memorandum on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research (Aug. 25, 2022).
[10] *See, e.g.,* Request for Information on the NIH Draft Public Access Policy (89 F.R. 51537) (Jun. 18, 2024).
[11] NIH, Office of Extramural Research, Updates to Data Management and Access Practices Under the NIH Genomic Data Sharing Policy (Sept. 23, 2024) (providing an overview of existing requirements for U.S. and non-U.S. researchers to gain access to NIH data repositories into which researchers are required to deposit genomic research data resulting from NIH-funded research in accordance with the NIH Genomic Data Sharing Policy and updates to data management and access practices under that policy).
[12] *See, e.g.,* Nature, *Scientific Data Journal*, Data Repository Guidance (accessed Nov. 20, 2024); PLOS Recommended Repositories (accessed Nov. 20, 2024).

definition of Sensitive Personal Data. Alternatively, DOJ should consider developing a specific exemption covering the deposit, use, and sharing of data that is required to be stored and maintained in accordance with federal public access and/or scientific publication requirements.

Section 202.302 – Other Prohibited Data-Brokerage Transactions Involving Potential Onward Transfer to Countries of Concern or Covered Persons and Associated NPRM Preamble Text [NPRM at p. 86130] and their Relation to Section 202.1001 -- Due Diligence for Restricted Transactions

The Preamble text regarding §202.302 states that the Department "expects U.S. persons engaged in these kinds of data brokerage transactions to take reasonable steps to evaluate whether their foreign counterparties are complying with the contractual provision as part of risk-based compliance programs under the proposed rule" and that "failure to conduct adequate due diligence may subject the U.S. person to enforcement actions if that failure would constitute an evasion of the regulations . . ."[13] However, unlike §202.1001, which outlines due diligence requirements for restricted transactions, §202.302 contains no reference to due diligence requirements for "onward transactions" with foreign persons that are not covered persons. **We strongly encourage DOJ to modify §202.302 to explicitly state the expectation that U.S. persons exercise due diligence for onward transactions and to specify those due diligence requirements. Additionally, we recommend that any specified due diligence requirements** incorporate the concept expressed in the Preamble statement on the definition of "Knowingly":

> [T]he 'knowingly' language is also not intended to require U.S. persons, in engaging in vendor agreements and other classes of data transactions with foreign persons, to conduct due diligence on the employment practices of those foreign persons to determine whether the foreign persons' employees qualify as covered persons.[14]

The Preamble also seeks comments on the specific language used to contractually require "that the foreign person refrain from engaging in a subsequent covered data transaction involving data brokerage of the same data with a country of concern or covered person."[15] We urge DOJ to insert the word "knowingly" before the word "engaging." It is unreasonable to expect any person or entity to refrain from entering into transactions that they did not actually know, and had no reason to know, were in violation of the contractual provision.

NPRM Preamble Text Regarding "Other Exemptions" [NPRM at p. 86140]

The Preamble seeks comments on "whether it is necessary or appropriate to adopt a tailored exemption that would permit covered data transactions involving the export to countries of concern

[13] NPRM at p. 86130
[14] NPRM at p. 86132.
[15] NPRM at p. 86130.

or transfer or sale to covered persons of certain human biospecimens, like blood plasma, intended for direct medical use that the proposed rule would other prohibit." **As previously stated, we urge DOJ to adopt an exemption that would permit the transfer of sensitive personal data, including biospecimens, to COCs and Covered Persons for use in non-federally funded research activities. We also urge DOJ to adopt a tailored exception for the export of products falling under the definition of biospecimens for use in medical and humanitarian missions in COCs in which U.S. persons participate or assist.**[16]

Section 202.504 – Exempt Transactions - Official Business of the United States Government

COGR fully supports this exemption and its coverage of research activities conducted "pursuant to a grant, contract, or other agreement entered into with the United States government."[17] However, we were puzzled by statements from DOJ representatives during the DOJ Presentation to the effect that in the case of research funded by both federal and private funds, only the activities covered by federal funds would be subject to this exemption. This approach ignores the fact that virtually all federally funded research conducted by U.S. universities, academic medical centers, and research institutes is supported with cost-sharing[18] by those entities, as described in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.[19] The vast majority of research projects are not completely funded by federal dollars, and the federal government relies on U.S. academic research institutions to pay an ever-increasing portion of total project cost through voluntary cost-sharing, including unbudgeted academic year salaries and unreimbursed facilities and administrative (F&A) costs.[20] Private third-party entities such as non-profit foundations may also provide funding for research projects. It would be nearly impossible for academic research institutions to track which covered data flows, or portions of covered data flows, were paid for by the federal government under a research grant and which were paid for by the university or other sources. Similarly, the federally supported research would suffer if it were governed by two separate sets of rules. **Accordingly, we urge DOJ to make clear that all components and aspects of a research project conducted pursuant to a federal grant or contract are covered by this exemption, even if federal funding does not support all costs associated with the project.**

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[16] Our comments do not address commercial exports of blood and blood products, but we note that in 2023 there were $5.42 billion in U.S. exports to China of human or animal blood, antisera, and other blood fractions, vaccines, and toxins. [Trading Economics at https://tradingeconomics.com/united-states/exports/china/human-blood-animal-blood-antisera-vaccines (accessed Nov. 10, 2024); cited source - United Nations COMTRADE database on international trade].

[17] NPRM at p. 86134.

[18] 2 C.F.R. §200.1 ["*Cost sharing* means the portion of project costs not paid by Federal funds or contributions (unless authorized by Federal statute). This term includes *matching*, which refers to required levels of cost share that must be provided. *See* §200.306."].

[19] 2 C.F.R. Part 200.

[20] American Association of Universities (AAU), Frequently Asked Questions about Facilities and Administrative (F&A) Costs of Federally Sponsored University Research Fact Sheet (Sept. 26, 2024)(Question 3 – "Behind the federal government, universities are the second leading sponsor of the academic research and development (R&D) that take place on their campuses. Federal data show that colleges and universities pay for more than 25% of total academic R&D funding from their own funds. This university contribution amounted to $22 billion in FY20, including $5.7 billion in unreimbursed F&A costs.")

Section 202.510 – Exempt Transactions - Drug, Biological Product, and Medical Device Authorizations; Section 202.511 – Exempt Transactions – Other Clinical Investigations and Post-Marketing Surveillance and Associated NPRM Preamble Text [NPRM at p. 86137-86139].

These two exemptions are related, so we discuss them together here. The provision at §202.510 exempts from the Proposed Rule's prohibitions "certain data transactions necessary to obtain and maintain regulatory approval to market a drug, biological product, medical device, or combination product in a country of concern."[21] The provision at §202.511 exempts data transactions to the extent that they are "ordinarily incident to and part of clinical investigations" that (a) are regulated by the FDA; or (b) "support applications to the FDA for research or marketing permits for drugs, biological products, devices, combination products, or infant formula"; or (c) "ordinarily incident to and part of the collection or processing of clinical care data indicating real-world performance or safety of products, or the collection or processing of post-marketing surveillance data . . . and necessary to support or maintain authorization by the FDA, provided the data is deidentified."

We have four main concerns about these exemptions. First, as previously discussed, limiting research exemptions to clinical research for the support of medical product regulatory approval by the FDA or a COC will cause tremendous damage to United States research institutions' ability to lead and participate in multi-national public health and foundational research. **Thus, we once again urge DOJ to include an exemption for non-federally funded research. Second, as there are multiple standards for deidentification, we encourage DOJ to provide a definition for this term**. **Third, we recommend that DOJ clarify that these exemptions encompass all data transactions associated with the approval, review, and conduct of research that generates the data to support medical product authorization in a COC or in the U.S. Finally, we also recommend that DOJ expand these exemptions to include vendor and employment agreements so that institutions can obtain necessary in-country expertise to prepare documentation related to the approval and conduct of the research and submissions to regulatory authorities for product approval.** Additional discussion of our third and fourth concerns follows.

Recommendation that Exemptions Encompass Data Transactions Associated with Approval, Review, and Conduct of the Research: Neither the exemption at §202.510 or §202.511 explicitly encompass data transactions that are necessary for in-country institutional review board (IRB)/ethics committee review and approval of studies conducted in a COC to generate the data for authorization applications. For example, similar to the U.S., China requires that an in-country institutional review board (IRB)/ethics committee grant initial approval and provide continuing review for human subject research studies.[22] Further, both China and the U.S. require researchers

[21] NPRM at p. 86137.
[22] Compare, ethical review requirements set forth in 45 C.F.R. Part 46 and 21 C.F.R. Part 56 to review requirements set forth in the Decree of the National Health and Family Planning Commission of the People's Republic of China ("Decree")(Oct. 12, 2016).

to report certain serious adverse reactions or events to the research sponsor and to the IRB/ethics committee for review and action to protect the safety, health, and welfare of research subjects.[23] For multi-site trials, adverse events must be considered across all sites to accurately evaluate their severity and rate of occurrence and to determine if there is any genetic or population-based attributes that may affect frequency or severity. Although most adverse event reports can be deidentified, in some cases genomic or identifiable health data may be required to properly assess the event and its impact on the overall study population. In many cases, studies may require data safety monitoring committees (composed of experts on the disease or condition being studied) to review study data and report to the research sponsor and the IRB/ethics committee.[24] Similarly, sponsors and IRB/ethics committee members may require access to study data to ensure that the study is being conducted in accordance with all applicable ethical standards and laws. **At a minimum, we urge DOJ to clarify that the exemptions at §202.510 and §202.511 encompass all covered data transactions required for initial/continuing approval and monitoring by in-country IRBs/ethics committees and research sponsors.**

Recommendation that Exemptions Encompass Associated Vendor and Employment Agreements: As the Preamble notes, the exemption at §202.510 is "limited to transactions that are necessary to obtain or maintain regulatory approval in the country of concern" and does not "exempt a vendor or employment agreement with a covered person to prepare data for submission to a country of concern's regulatory entity because the Department does not currently believe that such transactions are necessary to obtain regulatory approval."[25] Similarly, in its discussion of §202.511, the Preamble makes clear that this exemption does not extend to vendor and employment agreements that include the transfer of bulk Sensitive Personal Data to Covered Persons in a COC as part of activities associated with a clinical investigation conducted for FDA product authorization.[26]

COGR fundamentally disagrees with DOJ's assessment that working with local, in-country experts in such situations is unnecessary. Indeed, the assistance of local experts (e.g., contract research organizations, consultants, attorneys) is often the key to successfully preparing research protocols and medical product regulatory submissions both in the U.S. and other countries. For example, in-country expertise (e.g., collaborating researchers, consultants, attorneys) is essential to the preparation of documentation that must submitted to IRBs/ethics committees. Such expertise is particularly important when addressing the local context of the research (e.g., applicable laws and local standards, local community, and subject populations considerations), a practice that is fundamental to establishing meaningful informed consent. Similarly, local consultants, contract

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[23] *See,* FDA, Guidance for Clinical Investigators, Sponsors, and IRBs – Adverse Event Reporting to IRBs – Improving Human Subject Protection (Jan. 2009); Decree at Articles 26 & 27.
[24] *See, generally*, NIH Data and Safety Monitoring webpage at https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/policies-and-regulations/data-safety (last updated Aug. 16, 2024) for a overview of data and safety monitoring requirements.
[25] NPRM at p. 86137.
[26] NPRM at p. 86139.

research organizations, and attorneys are key players in preparing regulatory submissions for product approval and navigating the approval process.

Accordingly, we urge DOJ to extend the application of these exemptions to encompass vendor and employment agreements that are required to obtain the in-country expertise necessary to: (a) gain IRB/ethics committees and medical product regulators' approval for the conduct of research necessary to generate data to support medical product marketing authorizations; and (b) to obtain and maintain marketing authorization from medical product regulators, including preparation of marketing applications. To address DOJ concerns about unnecessarily sharing data in these contexts, the exemption could be limited to the sharing of data that is:

- Required by applicable laws;
- Reasonably necessary to developing materials required for initial and continuing ethical review and approval of the research by an IRB/ethics committee; or
- Reasonably necessary for the preparation and submission of regulatory documentation necessary to gain medical product authorization from appropriate government regulatory bodies.

Further, DOJ could require the information to be deidentified to the greatest extent possible under applicable laws and standards. (As previously noted, we recommend that DOJ include a definition of "deidentified within the Proposed Rule.)

Implementation of the Proposed Rule and Subpart J – Due Diligence and Audit Requirements

The Proposed Rule is so complex that it will take all research institutions (particularly institutions with little or no classified or export-controlled research) a tremendous amount of time to thoroughly review and understand the final rule; identify and diagram covered data flows; vet research collaborators/vendors/contractors/employees to determine if they are Covered Persons; determine the applicability of exemptions; revise/terminate existing contracts, subawards, vendor and employment agreements that are impacted by the rule; and develop the policies, procedures, processes, and compliance programs necessary to implement the final rule and carry out required due diligence. **We urge DOJ to recognize both the fiscal and administrative burden that the new rule will generate and to provide an effective date of at least 18 months after the final rule is published.**

In the same vein, we hope that DOJ will be proactive in developing guidance, materials, tools, and training to assist institutions in complying with the final rule. While we appreciate the fact that DOJ will issue advisory opinions, that process does not address institutions' immediate need for assistance in understanding the rule as a whole and their responsibilities under it, as well as how to assess the rule's impact on their operations.

Conclusion

The Proposed Rule will bring a sea change to all activities that involve the transfer of the specified categories of data to COCs, Covered Persons, and foreign persons. The conduct of fundamental research in the public health and biomedical arenas rely heavily on the ability to exchange personal health and genomic data (including biospecimens) with researchers in **all countries**, and the ability to rapidly and freely exchange data across borders is essential for the U.S. to maintain its leadership role in tracking and developing solutions for new global health threats. We firmly believe that the recommendations we offer in this letter will serve to improve the Proposed Rule and help ensure that U.S. research institutions can maintain their preeminence in biomedical and public health research. Without these changes, we fear that U.S. science and technology efforts will suffer. Accordingly, we urge DOJ to adopt our recommendations in the final rule.

Please feel free to contact me at mowens@cogr.edu or COGR's Director of Research Ethics and Compliance, Kristin West at kwest@cogr.edu if you have any questions regarding this transmittal.

Sincerely,

Matt Owens
President