



April 17, 2024

Submitted Electronically to: <https://www.regulations.gov>

U.S. Department of Justice
National Security Division
Foreign Investment Review Section
175 N St., N.E., 12th Floor
Washington, DC 20002

RE: Response to Advance Notice of Proposed Rulemaking – “Provisions Regarding Access to Americans’ Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern” (Docket No. NSD 104)

To Whom It May Concern:

We write to offer comments in response to the U.S. Department of Justice National Security Division’s (DOJ) advance notice of proposed rulemaking “[Provisions Regarding Access to Americans’ Bulk Sensitive Personal Data and Government Related Data by Countries of Concern](#)” (ANPRM)¹ that was published in the Federal Register on March 5, 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 that ever-changing global threats to U.S. security interests require vigilance in protecting research data, particularly sensitive data received from individual research participants. We support the DOJ’s development of regulations that protect U.S. sensitive personal data from possible exploitation by countries of concern, while ensuring that appropriate mechanisms exist to permit the conduct of important federally funded international research collaborations that are critical to supporting U.S. scientific and technological advances and global health initiatives. We also appreciate DOJ’s solicitation of public input on the ANPRM and the opportunity to provide these comments.

GENERAL COMMENTS

The ANPRM is a lengthy and complex document that outlines a proposed regulatory regime that

¹ 89 FR 15780

has the potential to impact day-to-day operations of research universities that involve “bulk sensitive personal data” and “countries of concern” (CoCs), or “covered persons” associated with CoCs, as those terms are defined in the ANPRM. We are encouraging our member institutions to review the ANPRM with respect to its impact on their operations, but our comments here are limited to the ANPRM’s impact on our members’ research activities.

With respect to the ANPRM’s effect on research activities, we fully support the ANPRM’s potential “official business” exemption, which encompasses grantees and contractors of federal departments and agencies, including those that carry out federally funded research activities. This exemption leaves regulatory decisions in this area to research funding agencies and avoids dual regulation by DOJ. This approach supports the conduct of important federally funded international research activities.

However, we are greatly concerned that the ANPRM provides no similar exemption for non-federally funded international research, innovation, and development activities in which academic research institutions are frequently involved. These activities are funded by non-governmental, non-profit foundations, and similar organizations, as well as by commercial entities such as pharmaceutical companies. Such privately funded international research is equally important to achieving global health and scientific advancement, and it often augments funding from federal agencies, which does not fully cover research costs.

Although there may be bright economic and political dividing lines when it comes to CoCs, such is not the case when it comes to international biomedical, public health, and environmental concerns that are unconstrained by geographic boundaries. Accordingly, research on these issues frequently requires the exchange of genomic data, personal health data, and/or biospecimens among scientists in *all* countries to develop effective solutions to large-scale international problems and threats. Restraints on data exchanges that effectively prohibit academic research institutions’ ability to conduct or participate in international research with investigators in CoCs will damage the United States’ ability to combat global health and environmental threats and potentially limit U.S. citizens’ access to new drugs, devices, or medical interventions that are first developed in CoCs.² We discuss these issues more fully below in our specific comments.

The remainder of our comments in this letter address specific questions from the ANPRM that we believe will impact non-federally funded research activities. Comments are organized by the section heading and question number to which they refer.

² See, generally, [Zheng, L., et. al., “Targeted drug approvals in 2023: breakthroughs by the FDA and NMPA,” 9 *Signal Transduct Target Ther.* 46 \(Feb. 20, 2024\)](#) (discussing drugs approved by both the U.S. Food and Drug Administration (FDA) and the Chinese National Medicines and Pharmaceutical Administration (NMPA) in 2023 and citing the FDA’s approval of the Chinese innovative drug toripalimab as the “first FDA-approved drug for the treatment of nasopharyngeal cancer”).

SPECIFIC COMMENTS

Section B. Bulk U.S. Sensitive Personal Data

- 2. Should the Department of Justice treat data that is anonymized, pseudonymized, de-identified, or encrypted differently? If so, why?***

Yes. Anonymization, pseudonymization, de-identification, and encryption can dramatically lower the risk of individual identification and associated risks to individuals. Accordingly, most systems of privacy regulation (e.g., the U.S. HIPAA Privacy Rule,³ the European Union General Data Protection Act [GDPR]⁴) exclude some or all of these categories of data (as they are defined under applicable laws) from the scope of general and/or specific regulation. The DOJ should adopt similar principles in this ANPRM, with the level of de-identification, pseudonymization, or encryption being tied to the sensitivity of the data category at issue.

- 5. The Executive order directs a report and recommendation assessing the risks and benefits of regulating transactions involving other specified types of human ‘omic data. Should data transactions involving these other types of human ‘omic data be regulated? If so, which types of human ‘omic data? What risks, scientific, value, and economic costs should be considered?***

The term human “omic data,” encapsulates a wide-ranging set of the measurements related to human physiological, pathological, or genetic measurements many of which are used to help understand the basic mechanisms or functions of human health states and contain no identifiable information. We agree that identifiable genetic information is sensitive and warrants enhanced protection. However, the majority of the other human “omic data does not fall into this category.

We encourage DOJ to consult with other federal agencies (e.g., FDA, NIH, Office for Human Research Protections) that use and/or regulate the use of such data, as well as external subject matter experts, in developing any regulations in this area, including possible regulation of future “omic” data that is unforeseen today. One approach to obtaining this necessary expertise may be to appoint an advisory panel to consider these questions.

- 6. What, if any possible unintended consequences could result from the definition (including the bulk thresholds) under consideration? In particular, to what extent would the approach contemplated here affect individuals’ rights to share their own biospecimens and health, genomic, and other data?***

The ANPRM’s proposed threshold for human genomic data ranges from a low of 101 to a high of 1,001 persons, and the threshold for personal health data ranges between 1,001 to 1,000,001 persons. Yet, many biomedical research activities, including research to improve clinical

³ 45 CFR Part 160 & Part 164, Subparts A & E.

⁴ European Union (EU) GDPR [website](#) (2024)(Recital 26, GDPR does not apply to anonymous data).

care/outcomes and research on new drugs, devices, or procedural interventions, require personal health data and genomic data (including biospecimens) from much larger cohorts to demonstrate scientific validity. For example, FDA-regulated Phase III investigations of new drugs typically enroll 300 to 3,000 individuals.⁵

Sponsors and governmental regulatory authorities in countries where a trial is conducted must have access to study data to provide appropriate oversight for the study.⁶ Accordingly, researchers obtain a study participant's permission to collect and share the information and specimens described in consent and authorization documents that participants must sign.⁷

The ANPRM's low bulk thresholds for human genomic and personal health information will not accommodate the conduct of international studies that require larger study populations and include study sites in CoCs. The need to obtain a license to permit data sharing for such studies may deter research sponsors from including U.S. sites in multi-national trials that involve CoCs or covered persons, which in turn, will curtail U.S. persons' opportunities to participate in these trials and gain access to studies of novel drugs, devices, and interventions.

We urge the DOJ to work with FDA, NIH, and other federal agencies involved in the conduct of clinical research to identify appropriate bulk threshold levels for genomic and personal health data that would permit the conduct of international clinical trials that include study sites in CoCs. Higher thresholds could be limited to research settings and/or to circumstances in which study participants have expressly consented to share their data and biospecimens with researchers and regulators with researchers, institutions, and regulatory oversight agencies located in specific countries.

Section F, Covered Persons

28. How would the U.S. party to a data transaction ascertain whether a counterparty to the transaction is a covered person as defined above?

As research institutions' experiences with "malign foreign talent recruitment programs" have revealed, individuals' and entities' ties to and associations with foreign countries of concern can be difficult to discern and there are limited tools available in the public domain to assist in due diligence. Corporate and individual records that are publicly available in the U.S. may not be similarly available in other countries and foreign websites can be difficult to access. Further, resources may not be available in English, and despite the wide availability of free, online

⁵ See, FDA "Step 3: Clinical Research" [website](#) (last updated Jan. 4, 2018). ⁶ See, e.g., 21 CFR §§50.25 (informed consent must advise subject about the "extent, if any, to which confidentiality of records identifying the subject will be maintained" and must note "the possibility that the Food and Drug Administration may inspect these records") & 50.27 (required documentation of the elements of informed consent).

⁶ See, e.g., 21 CFR §§50.25 (informed consent must advise subject about the "extent, if any, to which confidentiality of records identifying the subject will be maintained" and must note "the possibility that the Food and Drug Administration may inspect these records") & 50.27 (required documentation of the elements of informed consent).

⁷ See, e.g., 45 CFR §46.116; 21 CFR Part 50, Subpart B; 45 CFR §164.508.

translation tools, in practice these tools can be cumbersome to use and often provide rudimentary translation, as compared to more sophisticated, expensive machine translation software or certified translators. COGR urges DOJ to consider what tools it can make available to U.S. parties to assist in their due diligence efforts to identify persons falling under the definition of covered persons.

32. How should the list be published? How should it be organized? In what format should the Department of Justice publish it?

33. How would industry monitor this list? Would it be more costly for industry if the list were updated continually or only at certain points in time? If updates were made on an individual basis or in batches? Please be specific.

34. How quickly after a covered person is added to the list (or an existing listing is modified) could industry take account of the new information in its compliance programs?

The answers to the foregoing questions are related, and thus, are combined here. The list of covered persons should be made available as a web-based electronic database that permits free access and incorporates free-text search features. This process could be modeled on the U.S. Department of the Treasury Office of Foreign Assets Control's (OFAC) publication of its Specially Designated Nationals (SDNs) List on its website.⁸ The database should also be made available for commercial restricted party screening services (e.g., Visual Compliance⁹) to incorporate into their screening tools that cover multiple government lists of restricted and denied parties. Many institutions rely on these services for compliance with restricted party screening responsibilities.

DOJ's schedule for updating the list and "re-screening" obligations will drive industry monitoring practices. Accordingly, COGR urges DOJ to make such updates available in batches on a regular, periodic, and well-publicized basis (e.g., weekly), to afford institutions adequate opportunity to review the list against contemplated transactions. Further, any proposed rule must make any clear "re-screening" obligations for transactions that did not involve a covered person at the time that the transaction was initiated.

Section G. Prohibitions

39. How feasible is it to contract with prospective customers to prevent pass-through sales, re-sale, or onward transfers of bulk U.S. sensitive personal data or government-related data to countries of concern or covered persons? Do technical means exist to prevent such onward sales or transfers? If yes, what are the technical means?

Aside from incorporating contractual provisions that prohibit onward data transfers or providing access to data solely via a mechanism that is continuously controlled by the U.S. person (e.g., virtual data warehouse), research institutions have limited means to control onward transfers of

⁸ OFAC, Specially Designated Nationals and Blocked Persons List (SDN) Human Readable Lists [website](#) (last updated Mar. 27, 2024).

⁹ Descartes Visual Compliance [website](#).

regulated data. Further, use of the aforementioned tools is subject to substantial limitations. First, contractual provisions may be difficult if not impossible to enforce with respect to transferred data, particularly against entities that are not subject to U.S. jurisdiction. Second, controlled-access data enclaves require both storage and computing environments (e.g., specialized software and data analysis tools) that vary greatly depending on the field of the study. Further, these enclaves may be cost prohibitive for many, if not most, research institutions. Such costs may be particularly burdensome for emerging research institutions, and further limit their ability to participate in important research activities. Finally, while data enclaves can provide certain protective controls, they are not immune to intentional violations such as unauthorized downloads by those who have been granted access for legitimate reasons.

Section H, Exempt Transactions

45. Are there other types of data transactions that should be exempt? Please explain why?

As previously noted, we applaud the ANPRM's establishment of the "official business" exemption for data transactions to the extent that they are for:

“[T]he conduct of the official business of the United States Government by its employees, grantees, or contractors;” or
“[T]ransactions conducted pursuant to a grant, contract, or other agreements.”¹⁰

And we appreciate the ANPRM's explicit acknowledgement that:

[T]his exemption would exempt grantees and contactors of Federal departments and agencies, including the Department of Health and Human Services, the Department of Veterans Affairs, the National Science Foundation, and the Department of Defense, so that those agencies can pursue grant-based and contract-based conditions to address risks that *countries of concern* can *access* sensitive personal data in *transactions* related to their agencies' own grants and contracts, as laid out in section 3(b) of the Order—without subjecting those grantees and contractors to dual regulation.¹¹

This exemption will facilitate the conduct of federally funded research (most of which is fundamental research), but as noted in Example 49, the exemption does not extend to research activities that are not federally funded. Further, it is unclear from the ANPRM whether the exemption will extend to research projects that have both federal and non-federal sources of funding, a common scenario. This omission will have a significant, negative impact on multi-site, international clinical trials, and international public health research that includes sites in CoCs.

Sponsors of new drugs and devices often conduct trials at sites both inside and outside the United

¹⁰ ANPRM at p. 15794.

¹¹ *Id.*

States to gain approval for the drugs/devices in multiple countries.¹² As previously noted, study sponsors require access to study data to provide oversight for the study, and they obtain subjects' consent to collect and share data and specimens. Further, the international good clinical practice requirements that govern the conduct of research involving new drug products that the study sponsor plans to market in multiple countries call for the exchange of data from clinical investigations to drug regulatory authorities in all countries in which marketing approval is being sought.¹³ Such data access permits national drug regulatory authorities, such as the U.S. FDA, to see how the new drug works in various populations, identify adverse effects, and ultimately determine if the drug should be approved, and if so, how it should be labeled. The exchange of information is also necessary to allow institutional review boards, ethics committees, and data safety monitoring committees to effectively oversee the health, safety, and welfare of participants in the clinical trials.

In some cases, a sponsor may support a drug marketing application using only data gathered from clinical trials conducted in a different country, while in other instances drug regulatory authorities may require a sponsor to conduct trials in-country to support marketing approval.¹⁴ For example, in 2023, the FDA approved a Chinese developed cancer drug based on clinical trials conducted in China where the underlying condition was much more common than in other countries, facilitating recruitment of sufficient study subjects.¹⁵ Yet in 2022, the FDA determined that trials conducted in China were not sufficient to support U.S. marketing applications for two cancer treatments, and it required one drug's sponsor to conduct trials in the U.S.¹⁶ Not offering a readily available and easy-to-use pathway for sharing personal health and genomic data (including biospecimens) to facilitate multi-national privately funded research will cripple international research efforts, which are essential both to U.S. drug and device development and to ensuring that U.S. citizens have access to novel drugs, devices, and other interventions that are first developed in CoCs.

Similarly, public health research into global emerging diseases often necessitates the cross-national exchange of personal health data and biospecimens among researchers in all affected countries, which frequently include CoCs. As the COVID-19 pandemic revealed, this research must be rapidly conducted to categorize emerging health threats and develop appropriate

¹² Zheng, et. al., *supra* n. 2 (listing new drugs approved in both China and the U.S. in 2023).

¹³ See, generally, [International Council for Harmonisation, "Technical Requirements for Pharmaceuticals for Human Use \(ICH\) Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice E6\(R2\)" \(Nov. 9, 2016\)](#) (§4.11.1 and §5.16.2 [safety reporting by investigators and sponsors to regulatory authorities]; §5.15 [clinical trial protocol and informed consent must encompass regulatory authorities' direct access to source document for regulatory inspections]; §5.22 [sponsor must provide clinical trial reports to regulatory authorities]).

¹⁴ See, generally, 21 CFR §314.106; FDA Guidance Document – [FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND FAQs](#) (Mar. 2012); NIH, NIAID, [ClinRegs website on China's regulation of clinical research](#) (last updated Nov. 30, 2023) (referencing [NMPA-NO52-2018](#) regarding conditions for the use of trial data generated entirely outside China to support a drug application in China).

¹⁵ [Ben-Ari, E., "Toripalimab Becomes First Immunotherapy Drug Approved for Nasopharyngeal Cancer," National Cancer Institute website \(Jan. 3, 2024\)](#).

¹⁶ [Reuters, "U.S. FDA declines to approve two more China-tested drugs," \(May 2, 2022\)](#)(FDA required the sponsor of one of cited drugs "to test its drug for the U.S. population in a diverse multi-regional trial").

countermeasures.¹⁷ Additional examples of vital, privately funded, multi-national public health research projects that include CoC sites in which various COGR member institutions have participated include:

- (a) *A multi-country study to better understand the asymptomatic Mycobacterium tuberculosis (Mtb) infection, has been underway for nearly seven (7). The study's main goal is to follow participants longitudinally (with repeat blood sampling) to better understand the progression of the disease and the post-exposure time after which an infection is detected. This study will help in determining the effectiveness and timing of post-exposure preventive measures. The study includes collaborating institutions from several countries including India, China, Mongolia, and the United Kingdom. Restricting the transfer of genetic materials among the researchers participating in the study would substantially reduce the impact of the study through loss of the Chinese collaborator.*
- (b) *A US-based investigator has a long-standing collaboration with a researcher at a university in China as they work in similar and narrow area in the field of neurology. The researcher in China has created a modified device to use in imaging to detect a specific abnormality. To confirm the device is accurate at detecting the abnormality in various populations, the researcher in China would like to have his U.S. collaborator test the device on research participants in the United States with the data going back to China for review and collation with data collected from individuals in China.*

We strongly recommend that DOJ consider developing a research-specific exemption that would permit these types of privately funded studies to continue in CoCs. In this vein, we support DOJ's consideration of an exclusion for "data that is lawfully available to the public" including through "sources that are generally available to the public through unrestricted and open-access repositories,"¹⁸ as many researchers deposit their data in such open-access repositories. These repositories promote vital scientific collaboration, and we strongly recommend that DOJ explicitly include such scientific data repositories in any exclusion that it develops.

Alternatively, DOJ could utilize other available mechanisms under the ANPRM to facilitate the conduct of privately funded research, such as increasing the bulk thresholds for human genomic data and/or personal health data used for research purposes, or establishing a general license category that encompasses these activities.

I. Security Requirements for Restricted Transactions

The ANPRM notes that the DOJ "is considering identifying three classes of restricted covered data transactions (vendor agreement, employment agreements, and investment agreements) that would be otherwise prohibited unless they meet certain requirements (security requirements)" that mitigate threats.¹⁹ The ANPRM then describes possible security requirements and notes that the Department of Homeland Security (DHS) "will propose and solicit public comment on the security

¹⁷ See, Singh, S., et. al., "[Challenges to biobanking in LMICs during COVID-19: time to reconceptualise research ethics guidance for pandemics and public health emergencies?](#)," 48 *J. of Medical Ethics* 466-71 (Jun. 23, 2022) ("Global sharing of samples and data should be a priority, not only during the pandemic but even when the COVID-19 outbreak has waned.").

¹⁸ ANPRM at p. 15786.

¹⁹ *Id.* at p. 15795.

requirements through a separate process.”²⁰

In developing these standards, we strongly recommend that DOJ and DHS consider permitting U.S. entities to certify to cyber-security standards to which they may already subject (e.g., the HIPAA Security Rule²¹) so that institutions are not required to comply with multiple, duplicative regulations, adding unnecessary administrative burdens and costs. Further, as opposed to requiring institutions to incur the cost of hiring an independent auditor to perform annual testing of cybersecurity requirements, we urge DOJ and DHS to consider permitting institutions to utilize alternate approaches similar to the annual security risk analysis process required by the HIPAA Security Rule, which may be conducted using internal or external resources, or a combination of both.²²

Section J, Licenses

46. Would general and specific licenses be useful to regulated parties? Why or why not?

49. What, if any, general licenses would be useful to assist in the industry's transition once the rules take effect? Why? Please be specific.

The answers to the foregoing questions are related, and thus, are combined here. If DOJ cannot issue an exemption that covers non-federally funded research, we urge DOJ to instead consider providing a general license that covers such activities. As noted, multi-national clinical research and public health research may, of necessity, require the transfer of genomic and/or personal health data to provide adequate protections for the health, safety, and welfare of participants in all countries. Participants in this research generally provide written informed consent and authorization to the sharing of their data and/or biospecimens, so they are aware of and agree to how, why, and with whom this information will be shared,²³ and much of this information can be shared in a deidentified or anonymized fashion. Further, general license requirements could be developed to ensure that that consent documents in such studies detail all countries in which the research takes place and where and with whom data may be shared.

Section K, Interpretative Guidance

57. Would an advisory opinion process in general be useful? What effect, if any, should the issuance of an advisory opinion have for the party or parties who requested it? For third parties?

²⁰ *Id.*

²¹ 45 CFR Part 160 & Part 164, Subparts A & C.

²² *See*, 45 CFR §164.308(a)(1); Dept. of Health and Human Services, Office for Civil Rights, [Final Guidance on Risk Analysis](#) (Jul. 26, 2013).

²³ *See, e.g.*, 45 CFR §46.116; 21 CFR Part 50, Subpart B; 45 CFR §164.508.

58. Should industry groups or other associations be permitted to request advisory opinions or interpretive guidance on behalf of one or more of their members (noting that such requests would still need to identify all relevant participants in a data transaction)?

59. Should some or all advisory opinions be published? How might the possibility of publication affect a request (noting that any publication would comply with applicable laws regarding confidential business information and similar topics)?

60. If the Department of Justice decides to publish some or all advisory opinions, how should it do so?

The answers to the foregoing questions are related, and thus, are combined here. The implementation of the requirements outlined in the ANPRM will bring about dramatic changes to the conduct of multi-national research involving CoCs. Accordingly, interpretive guidance and advisory opinions will be essential to assisting parties in understanding and applying the final rules. Individuals, entities, and industry groups and associations that represent those individuals/entities should be permitted to request advisory opinions. Advisory opinions should be published (with appropriate redactions for confidential business information) along with clear statements about the extent to which parties and non-parties to the opinions may rely upon such opinions in governing their actions.

Section L, Compliance and Enforcement

70. What are the practicalities of complying with this obligation? What, if any, changes to the way that U.S. persons undertake due diligence would be required because of this standard? What might be the cost to U.S. persons of undertaking such due diligence? Please be specific.

As noted, due diligence in this area can be difficult to carry out because of restrictions on information in CoCs and hurdles that arise from conducting research on materials that are frequently not written in English and require translation. As experience in the research security realm has demonstrated, first-hand costs to research institutions associated with such due diligence activities can be quite high.²⁴ These costs ultimately serve as a barrier to entry for participation in non-federally funded research activities involving CoCs, particularly for emerging research institutions.

We acknowledge the importance of national security concerns, but these interests must be balanced against to the necessity of engaging scientifically with countries whose data, in combination with U.S. data, may be essential to tackling pandemics and other global environmental or health emergencies, especially issues that disproportionately impact individuals in lower socioeconomic levels with limited access to resources, including healthcare. When developing due diligence requirements, we urge DOJ to consider what tools and resources it can provide to reduce

²⁴ See, COGR, [Research Security and the Cost of Compliance, Phase I Report](#) (Nov. 2022).

stakeholder burden.

Section N, Economic Impact

101. What sectors are involved in access to bulk U.S. human genomic data and human biospecimens? Are there any sectors that involve access to one, but not both, of these categories? What is the estimated size of these markets, as well as the overall volume and value of the covered data transactions involving this type of data?

102. What types of commercial transactions involve human genomic data and human biospecimens? Do any of these transactions involve exchange of the data? Do any of these transactions involve access to—but not exchange of—this sensitive personal data?

108. Are there legitimate commercial reasons for a covered person to access data or information covered as part of the classes of restricted covered data transactions? To what degree will an inability to access this data affect that company's ability to provide goods or services to U.S. companies and individuals?

The answers to the foregoing questions are related, and thus, are combined here. Multi-national scientific research, particularly in health sciences, is a sector of the economy that frequently requires access to human genomic data and human biospecimens. This access may be necessary to establish scientific validity of interventions, ensure research integrity, identify safety concerns, and/or satisfy cross-national regulatory requirements for human subjects protections and governmental product approvals. In some cases, this research may ultimately be part of commercial transactions, such as gaining regulatory approval for drugs and devices in multiple countries, but in other instances, this research may be conducted solely for the public good and funded by non-profit organizations. Thus, there are both legitimate commercial and non-commercial reasons for covered persons to access data or information covered under the classes of restricted covered data transactions. Fashioning rules that would prohibit or make it financially infeasible for U.S. research institutions to participate in this vital multi-national research will stifle U.S. scientific advancement.

Section O, Overarching and Additional Inquiries

112. What time, if any, will U.S. persons that are currently engaged in the prohibited covered data transactions contemplated here need to wind-down those transactions? What time, if any, will U.S. persons that are currently engaged in the restricted covered data transactions contemplated here need to comply with the security requirements or else wind-down those transactions?

Multi-national research projects may take anywhere from several months to multiple years to complete depending on their objectives and protocols. For example, longitudinal health studies involve repeated observations of select variables in subject populations over long periods. Accordingly, any prescribed wind-down periods should take such long-term research projects into

consideration and provide appropriate exemptions for their conduct to prevent loss of research data and analysis.

Conclusion

While it may be possible to completely avoid working with countries of concern in some areas, the recent pandemic amply demonstrated that there are instances where research collaborations with CoCs are necessary and require cross-national access to data, biospecimens, and subject populations prevent and address global health issues and public health emergencies. As noted, the ANPRM's exemption for federally funded research addresses many of our concerns in this area. However, not all international research is federally funded. Further, as federal research funds are more constrained, private research funding may, of necessity, become more prevalent. For these reasons, we urge DOJ to develop bulk thresholds, exemptions, and/or general licenses that can accommodate the conduct of these vital research activities.

We once again thank DOJ for the opportunity to comment on this ANPRM. Should you have any questions regarding these comments, please contact me or Kristin West, COGR's Director of Research Ethics and Compliance at kwest@cogr.edu.

Sincerely,

A handwritten signature in black ink that reads "M. M. Owens". The signature is written in a cursive, flowing style.

Matt Owens
President