ACRO Innovate Advocate Collaborate

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Matthew G. Olsen
Assistant Attorney General for National Security
U.S. Department of Justice
National Security Division, Foreign Investment Review Section
175 N St. NE, 12th Floor
Washington, DC 20002

RE: ACRO comment on:
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]

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and clinical technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of the development of new drugs, biologics, and medical devices—from pre-clinical, proof of concept and first-in-human studies, through post-approval, pharmacovigilance, and health data research. ACRO member companies manage or otherwise support a majority of all biopharmaceutical sponsored clinical investigations worldwide and advance clinical outsourcing to improve the quality, efficiency, and safety of biomedical research.

ACRO appreciates the opportunity to comment on this important initiative to ensure the data of U.S. persons is protected.

Specific Comments

Representing the clinical development industry, ACRO thanks the Department of Justice (DOJ) for the exemption of "regulatory approval data" at 202.510 as we requested. We agree that the definition covers "de-identified sensitive personal data that is required to be submitted to a country of concern regulatory entity to obtain or maintain authorization or approval to research or market a drug, biological product, device, or combination product, including in relation to post-marketing studies and post-marketing product surveillance activities, and supplemental product applications for additional uses." We further agree that the definition does not include sensitive personal data that is not reasonably necessary to assess product safety and efficacy. Further, we recognize that exempted "regulatory approval data" does not include human genomic data or biospecimens in bulk.

ACRO appreciates the further exemption of "clinical investigations and post-marketing surveillance data" at 202.511 to the extent that such transactions are "ordinarily incident to and part of clinical investigations regulated by" the FDA, "or clinical investigations that support applications to the FDA for research or marketing permits," or "indicating real-world performance or safety of products, or the collection or processing of post-marketing surveillance data (including pharmacovigilance and post-marketing safety monitoring), and

necessary to support or maintain authorization by the FDA, providing the data is deidentified" as such data transactions are absolutely essential to supporting not only regulatory approval but the ongoing product safety and evaluation assessments that are key to protecting the safety and health of patients.

ACRO understands the Department's stated position that the use of a covered person as a vendor for the preparation of bulk U.S. sensitive personal data would not be permitted if such use of a covered person is not required in order to obtain regulatory approval. However, the NPRM recognizes the fact that regulatory and legal expertise relevant to product approval in a country of concern is likely to be found in that country. We disagree with the assumption regarding Example 3 at 202.510 that such a vendor would have access "to a broader set of data than is required by the regulatory body itself." Thus, we suggest that the language of Example 3 clarify that a vendor or employment agreement with a covered person would be exempt unless such covered person is given access to sensitive personal data that is not required for regulatory submission and is not de-identified.

Section 202.1102 requires U.S. persons invoking the exemption for certain data transactions necessary to obtain or maintain regulatory approval to market a drug, biological product, device, or combination product to keep for a period of at least 10 years, and be prepared to furnish to the Department upon demand, "complete information relative to any act or transaction or covered data transaction… subject to the provisions of this part" and that the Department "may require that such reports include the production of any books, contracts, letters, papers, or other hard copy or electronic documents relating to any such act, transaction, or covered data transaction…" It is important to state that medical product development activities may involve clinical research organizations and technology companies, clinical research sites, institutional review boards, and others in addition to the biopharmaceutical companies that fund clinical trials and submit "regulatory approval data" to health authorities. Similar to the point made above in regard to Example 3, we suggest that the final rule clarify that the record-keeping and reporting requirements at 202.1102 apply to the sponsors of clinical trials, and apply to vendors of clinical trial services and products only to the extent to which they have access to sensitive personal data that is not required for regulatory submission and is not de-identified.

As the NPRM's definition of personal health data is consistent with HIPAA, we note that the de-identified "regulatory approval data" and "clinical investigations and post-marketing surveillance data" exempted at 202.510 and 202.511 may be "key-coded"—as provided for at 45 CFR 164.514—as long as the key is not held by or accessible to a covered person, which will preserve essential product safety and post-marketing surveillance activities.

Conclusion

ACRO strongly supports the purposes of the NPRM to protect national security and the privacy of U.S. persons against countries of concern.

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We thank the Department for the opportunity to comment and look forward to further dialogue about how best to accomplish the protection of U.S. persons without impeding the conduct of clinical research that advances the health of patients around the world.

Please feel free to contact me at dpeddicord@acrohealth.org for further information.

With best regards,

Douglas Peddicord, Ph.D.
Executive Director