

## **Antitrust Guidance for the Observational Medical Outcomes Partnership (“OMOP”) Extended Consortium and its Participants**

The Observational Medical Outcomes Partnership (“OMOP”) (<http://omop.fnih.org>) is a public-private partnership designed to help improve the monitoring of drugs for safety that began in Q4 2008 and is conducting a two-year research project to determine the contribution and utility of using existing healthcare databases to identify and evaluate safety issues of drugs already on the market. OMOP is managed through the Foundation for the National Institutes of Health. Except for patient data, all methods and results (research protocols, data models, database evaluation and quality assurance tools, analytical programs and findings) generated by OMOP will be published or made publicly available.

OMOP’s research plan includes the Extended Consortium, which will allow researchers outside of OMOP’s Research Core to conduct complementary research within their own data environment and contribute their findings to OMOP. Participation in the Extended Consortium is voluntary and participants could include private businesses, non-profits, public or governmental entities within the scientific community, *e.g.*, payors, data aggregators, health plans, academic/research, and health care systems.

OMOP policy requires that all activities of the Extended Consortium be conducted in compliance with the antitrust laws of the United States, including the Sherman Act, 15 U.S.C. § 1 *et seq.* All meetings, communications, decisions, and other activities of the Extended Consortium should be limited to what is reasonably necessary and appropriate to achieve the Extended Consortium’s purpose to enable and encourage participants to conduct research about OMOP’s methods and tools using their own data sets and to share these database research results to maximize public benefit from OMOP’s research.

In addition to the principles stated in the OMOP Antitrust Policy and Guidelines, the following guidance applies specifically to the Extended Consortium and its participants.

1. Participants in the Extended Consortium may discuss and share information with each other and with members and staff of OMOP regarding all of the activities and results of OMOP’s Research Core, including the common data model, standardized terminologies, Health Outcomes of Interest Definition, and analysis methods (collectively “OMOP Activities and Results”).
2. Participants in the Extended Consortium may discuss and share with each other and with members and staff of OMOP the following categories of information regarding application of the OMOP Activities and Results to their own data sets:
  - questions, answers, and other technical information about how to apply OMOP Activities and Results to a participant’s own data sets;
  - results of research projects specified in conjunction with OMOP. To the extent that an Extended Consortium participant’s research project covers matters or kinds of results outside the scope of OMOP’s research activities, such non-OMOP matters or results may not be shared within OMOP or the Extended Consortium;

- lessons learned about the OMOP Activities and Results from utilizing or studying them, and any modifications, extensions, corrections, improvements, replacements, and alternatives for OMOP Activities and Results.
3. Participants in the Extended Consortium should not discuss current or future prices, terms or conditions, pricing policies, costs, profits, or market shares of private-sector companies or goods or services offered by them. To the extent that a joint purchase by participants in the Extended Consortium of goods or services is deemed reasonably necessary for activities of the Extended Consortium, OMOP staff should be informed and legal counsel sought in advance regarding the appropriateness and means to negotiate and complete such a joint purchase.
  4. Participants in the Extended Consortium should not discuss intentions or plans about commercial activities, including product advertising and promotion, research and development outside the Extended Consortium, production or pricing policies, and whether to deal in any commercial sense with specific customers or classes of customers (including governmental programs) or with specific vendors or classes of vendors. For example, participants should not discuss whether to license or otherwise deal with specific providers of data or data consulting services.
  5. Participants in the Extended Consortium should not discuss, speculate or predict how commercial activities of private-sector companies might change in response to OMOP or the Extended Consortium, or in response to regulatory, business or legislative developments. For example, participants should not discuss whether or how they might apply OMOP Activities and Results to their own products that are either on the market or coming on to the market and should not reveal non-public information about their use of datasets in their own data environment.
  6. Participants in the Extended Consortium should not share with each other any non-public, confidential information about commercial activities of private-sector companies or discuss any topic of commercial significance to competing private-sector companies that may involve risks of antitrust compliance.
  7. If there is a need to obtain any non-public, confidential or competitively sensitive information from participants in connection with the Extended Consortium, OMOP staff should consult in advance with legal counsel regarding the appropriateness of collecting such data.

## **1. Antitrust Statement for Beginning of OMOP Extended Consortium Quarterly Calls, Meetings or Web Forums**

It is the policy of the OMOP Extended Consortium to conduct its activities well within the limits of the antitrust laws of the United States. In order to avoid even the appearance of an antitrust problem, the following topics should not be discussed at OMOP Extended Consortium meetings:

- Current or future prices, terms or conditions, pricing policies, costs, profits, or market shares of private sector companies;
- Intentions or plans about commercial activities, including product advertising and promotion, research and development, or whether to deal with specific customers or classes of customers or with specific vendors or classes of vendors; and
- Speculation or predictions about how commercial activities of private-sector companies might change in response to OMOP or to regulatory, business or legislative developments.

## ANTITRUST POLICY ACKNOWLEDGEMENT FORM

**I hereby acknowledge and agree:**

1. That I have received and read a copy of the Antitrust Guidance for the Observational Medical Outcomes Partnership (OMOP) Extended Consortium and Participants and agree to abide by this policy.
2. That I will comply with the guidance outlined in this policy.
3. That this original acknowledgement will be maintained on file by OMOP.

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Name of Extended Consortium Participant (printed)

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Extended Consortium Participant signature

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Date

***Once you have reviewed and signed the form, please email to Emily Welebob, OMOP Senior Program Manager, Research at [ewelebob@fnih.org](mailto:ewelebob@fnih.org).***