IMEDS Research Laboratory and Source Data Management and Access Policy

Through its Innovation in Medical Evidence Development and Surveillance ("IMEDS") program, the Reagan Udall Foundation for the Food and Drug Administration ("RUF") seeks to use observational health data (*e.g.*, health care claims and electronic medical records) to detect and evaluate drug safety and benefits outcomes. As part of the IMEDS program, RUF may acquire or gain access to certain kinds of healthcare claims data, electronic health records data, prescription data, or other observational healthcare data (the "Source Data"), including data that have been "de-identified" pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Standards for the Privacy of Individually Identifiable Health information (the "Privacy Rule") using the statistical method for de-identification or the regulatory safe harbor. Source Data may be contributed in-kind by the owners of such data or purchased from them.

This Source Data is housed in the IMEDS Research Laboratory, which is intended to provide a secure computing platform to support IMEDS methods development and analysis activities by persons involved in the IMEDS project. Such persons include RUF staff (including RUF employees, consultants, detailees, contractors and unpaid volunteers or interns), members of the IMEDS Steering Committee and Scientific Advisory Committee, and outside collaborators or other persons engaged in conducting or providing appropriate oversight of the analyses and experiments required to execute the mission of the IMEDS program (collectively, "Participants").

This Research Laboratory and Source Data Management and Access Policy sets forth the conditions under which, and purposes for which, Participants may access the IMEDS Research Laboratory and the requirements for use of Source Data.

I. IMEDS Research Laboratory Access.

The IMEDS Research Laboratory is available for use by outside investigators interested in participating in IMED's mission to advance the science and tools necessary to support post-market evidence generation on regulated products, including safety surveillance and evaluations, and to facilitate utilization of a robust secondary electronic healthcare data platform for generating better evidence on regulated products in the post-market settings including but not limited to safety, comparative effectiveness and healthcare quality.

In keeping with RUF principles concerning open and transparent research, investigators seeking to use the IMEDS Research Laboratory are required to:

- Place any intellectual property developed within the IMEDS Research Laboratory into the public domain, consistent with the IMEDS Intellectual Property Policy.
- Communicate and educate the research community regarding the project status and results as requested by IMEDS program management
- Within six months, publish or otherwise make publicly available the results of the foregoing analyses and the underlying data supporting those results, consistent with the IMEDS Principles and Policies on Publications and External Communications.

RUF will not charge for access to the licensed datasets and vocabularies but does require that all users of the IMEDS Research Laboratory agree to the terms and conditions of the product licenses. **RUF will support an individual researcher for up to $1,000 per year for costs associated with the utilization of the computing resources. Once the annual dollar amount has been reached, the costs associated with the utilization of the computing resources will be passed through to the investigators with the exception of research that is sponsored by RUF/IMEDS.** Enhancements to the laboratory environment or special needs requiring IMEDS staff support will require prior approval and costs associated with the work will be the responsibility of the requesting institution.

RUF staff, contractors, research investigators, and collaborators are required to accept the following terms and conditions in order to utilize the IMEDS Research Laboratory. Failure to abide by any of these terms and conditions may result in revocation of approved access:

1. Access and utilization to the IMEDS Research Laboratory is restricted to authorized users only.

2. IMEDS Research Laboratory users will not duplicate or move any licensed data outside the IMEDS Research Laboratory.

3. Investigator(s) will use requested datasets solely in connection with the research project described in the approved Data Access Request for each dataset.

4. Investigator(s) will adhere to computer security practices that ensure that only authorized individuals can gain access to the IMEDS Research Laboratory.

II. Uses of and Access to Source Data

The RUF is committed to protecting the confidentiality and privacy of patient data used by Participants in connection with IMEDS. This goal is achieved by various means, including:

- Ensuring Participants' compliance with HIPAA and other applicable federal and state laws and regulations regarding medical data privacy
- Using de-identified data to the fullest extent possible
- Requiring that all Participants adhere to the IMEDS Confidentiality Policy or other equivalent confidentiality agreements

Access to Source Data will be limited to specific Participants in IMEDS and will not be shared outside the IMEDS context or used for non-IMEDS purposes without authorization by both the provider of the data and the IMEDS Steering Committee, unless permitted by the terms of a specific data use agreement negotiated with the provider of the data or otherwise required by law.

Participants who contribute Source Data in-kind (i.e., on a remuneration-free basis) will retain full ownership of existing data they contribute. Neither RUF nor any Participants will gain any ownership rights to Source Data that is contributed in-kind. When a Participant contributes

Source Data in-kind, all lab approved users will have access to such Data and adhere to agreed upon use of Data.

In cases where Source Data is procured on commercial terms from third-party Suppliers, the RUF will negotiate all terms governing such data in the relevant supplier contract, including specific provisions governing who may access such data and when and how it may be accessed.

The IMEDS Steering Committee will have authority to grant or withhold access to Source Data.

With respect to any request for access to Source Data in connection with scientific research that that is not funded by RUF, but that uses data specifically provided by RUF under IMEDS under a data use agreement (i.e., data that is not already in the public domain) ("IMEDS Unfunded Request"), the Participant making the IMEDS Unfunded Request shall submit to the IMEDS Chief Implementation Officer a brief proposal to gain authorized access. The proposal must include the following components in some detail (do not exceed 2 pages, and be very specific in your request):

- *Research Objectives and Aims:* Is the planned research aligned with the mission and goals of IMEDS? Describe the project's objectives and aims.
- *Scope/Proposed Approach:* Does the scope / approach meet one or more of the permitted uses? Discuss your proposed approach by providing a brief summary about what you plan to do to address your listed objective and aims.
- *Impact:* What are the proposed contributions and learnings to the public upon the completion of the research?
- *Experience:* Does the researcher have the appropriate knowledge and experience necessary for handling these types of data? Document names and titles of individuals requesting access.
- *Timeline:* How many months is access needed for? Please state anticipated start and end dates.

This IMEDS Unfunded Request will be reviewed by the IMEDS Scientific Advisory Committee (SAC) and if the SAC so recommends, the proposal will go to the IMEDS Steering Committee for approval. With respect to any request for access to Source Data in connection with scientific research funded by RUF as part of IMEDS ("IMEDS Funded Request"), The Participant making the IMEDS Funded Request will submit through a formal, structured competitive process as announced by RUF. It may be necessary to include certain Source Data in a limited form for illustrative purposes in reports or analyses, including scientific or technical publications. Such Source Data will be released subject to the terms of both this Source Data Management and Access Policy and the IMEDS Principles and Policies on Publications and External Communications.

Any Source Data that becomes part of an invention arising out of the work will also be subject to both this Research Laboratory and Source Data Management and Access Policy and the IMEDS Intellectual Property Policy.