IMEDS Intellectual Property Policy (Attachment D)

Definitions

"INTELLECTUAL PROPERTY" (IP) refers to patents, patent applications, know-how, trade secrets, copyrights, DATA, and computer programs.

"DATA" is a subset of IP and refers to information relating to characteristics and observations of a scientific or technical nature including information and results arising from scientific experiments, regardless of form or the media on which they may be recorded. The term includes information from electronic health records (EHR) and insurance claims, or derived from EHR or insurance claims, proprietary information, technical information and compilations of information. For the purposes of this definition, the term does not include information incidental to the administration of IMEDS or other RUF projects, such as financial, administrative, cost and pricing, or management information.

"IMEDS" refers to the Innovation in Medical Evidence Development and Surveillance program administered by the Reagan Udall Foundation for the Food and Drug Administration ("RUF").

"IMEDS INVENTION" refers to any subject matter and discovery patentable or otherwise protectable under Title 35 of the United States Code that is conceived or first reduced to practice by a PARTICIPANT while acting within the scope of an IMEDS project.

"PARTICIPANT" refers to representatives of FDA, RUF, and other individuals or entities representing academia, advocacy, industry or other organizations that make substantial financial or other contributions, including non-financial contributions through research funded by grants from RUF, to the IMEDS program. For purposes of clarity, members of the RUF Board of Directors, the IMEDS Steering Committee, and the IMEDS Scientific Advisory Committee are considered PARTICIPANTS.

"CONTRACTEE" refers to vendors, suppliers and other parties that have a purely commercial relationship with RUF. A CONTRACTEE is not considered a PARTICIPANT for purposes of this Policy.

In General

All PARTICIPANTS agree to implement the principles of this Intellectual Property Policy. PARTICIPANTS agree to explore all mechanisms available, consistent with their individual missions and the interests of the public health, to implement these principles most effectively. It is understood that existing Federal statutes, regulations and established policies will govern the conduct of any Federal PARTICIPANT.

Disclosure

In general, each PARTICIPANT shall disclose to the RUF Board of Directors or its designee (either of whom may then share it with the IMEDS Steering Committee and/or the IMEDS Scientific Advisory Committee), in writing, pursuant to a confidential disclosure agreement, the existence of any patents or patent applications owned by the PARTICIPANT, controlled by the PARTICIPANT, or licensed by or to the PARTICIPANT that: (i) refer to or rely upon any IP or DATA to be shared in any IMEDS project; or (ii) whose use or practice is reasonably likely to be required to accomplish the objectives of the IMEDS project. The disclosures will include the identity of such patents or patent applications relevant to the IMEDS project and generally summarize their relevant substance, as soon as they become material to the discussion. Confidential information will be kept confidential consistent with the IMEDS Confidentiality Policy.

Any new PARTICIPANT prior to joining the IMEDS project shall agree to conform to the aforementioned principles.

Treatment of pre-existing DATA and IP

Certain types of pre-existing DATA and IP may be contributed by or acquired by IMEDS from a PARTICIPANT in order to achieve the IMEDS project's objectives, including but not limited to:

- Methods or processes for extracting, structuring or normalizing large databases into a common framework and technical infrastructure for housing DATA and facilitating analyses
- Databases or other information technology assets
- Analytical methods for screening and evaluating observational data, as well as processes for integrating and interpreting screening and evaluation results

The following terms will govern the use of pre-existing DATA and IP:

- PARTICIPANTS in IMEDS will retain full ownership of pre-existing DATA and IP they contribute to IMEDS.

- Non-Federal PARTICIPANTS will grant RUF a limited, non-exclusive, royalty-free and remuneration-free license to use and, as necessary, to sublicense to other PARTICIPANTS on similar bases, any non-Federal PARTICIPANT's relevant pre-existing DATA and INTELLECTUAL PROPERTY for worldwide research purposes only in connection with IMEDS.

- Each Federal PARTICIPANT will grant RUF access on a non-exclusive, royalty-free, and remuneration-free basis, and, as necessary, to extend similar access to other PARTICIPANTS to its pre-existing Data, materials, and know-how for WORLDWIDE research purposes in connection with IMEDS. In addition, Federal PARTICIPANTS will consider in good faith requests from other PARTICIPANTS for licenses to inventions under 37 C.F.R. Part 404, including remuneration free research use licenses limited to the scope of IMEDS.

- Neither the RUF nor any PARTICIPANTS will gain any ownership rights to pre-existing DATA or IP of any other party solely as a result of those parties' participation.
    - Pre-existing DATA and IP contributed to the RUF may be governed by confidentiality and other specific agreement terms as necessary

- The RUF will negotiate use agreements for pre-existing DATA and IP for use in IMEDS, if necessary, preferably on a remuneration-free basis.

- In cases where goods and services are procured on commercial terms for IMEDS from third-party suppliers, the RUF will negotiate all terms governing existing IP, and document these terms in the supplier contract.

Treatment of IP Created as a Result

It is foreseeable that IMEDS INVENTIONS may be generated in the course of an IMEDS project, including, but not limited to:

- Methods or processes for extracting, structuring or normalizing large databases into a common framework or technical infrastructure for housing DATA and facilitating analyses
- Analytical methods for screening and evaluating observational data, as well as processes for integrating and interpreting screening and evaluation results

- To the maximum extent possible, any IMEDS INVENTION will be placed in the public domain and made freely available for use. For example, broad availability of analytical methods, tools, and best practices for screening and evaluating observational data that might arise from an IMEDS project are likely to be considered useful to assure the public health and would be expected to follow this principle.

- If making an IMEDS INVENTION freely available will not advance the public health, the RUF Board of Directors, in consultation with the IMEDS Steering Committee, may agree to enable a means to ensure IP protection. Such instances may include but are not limited to, the need to protect information technology know-how or other IP that could be important to incentivize longer-term or larger scale information technology investments necessary to enable a nationwide observational outcome system.

- In the above circumstances, plans and terms will be negotiated between the inventing PARTICIPANTS and the RUF, and will be subject to the approval of the RUF Board of Directors to ensure that the public benefit is achieved. It is anticipated that such terms would include, at a minimum, a remuneration-free license to the RUF with the right to sublicense and/or to transfer the license to another non-profit entity that will further the use of observational data to strengthen the monitoring of medical product safety post-approval, if applicable, at the conclusion.

- In cases where IP is created by CONTRACTEES, the RUF will negotiate all terms governing IP created during the course of the contract. These terms will, at a minimum, include granting the RUF a remuneration-free license to use of the IP with the right to sublicense under similar terms and/or to transfer the license to another non-profit entity that will further use of observational data to strengthen the monitoring of medical product safety post-approval, if applicable.

- PARTICIPANTS will have the right to analyze DATA generated in the course of any IMEDS project in a manner consistent with the scope of the work using their own methods with the express condition that they will disclose methods and results arising out of their analysis to the RUF within a reasonable time to be agreed upon by the RUF Board of Directors.

PARTICIPANTS and CONTRACTEES will not be forbidden by virtue of their participation to challenge the validity or enforceability of patents or other intellectual property of other PARTICIPANTS or CONTRACTEES, including patents or intellectual property arising from RUF-sponsored activities.

- At the conclusion of the work, the IMEDS Steering Committee will make a recommendation to the RUF Board of Directors regarding the disposition and transfer of any rights in IP or DATA that RUF acquires as a result of the work.