COOK RESEARCH INCORPORATED
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Policy on Access to Clinical Study Data

Effective Date: 28 June 2018

Overview

Cook Research Incorporated (CRI) is fully committed to supporting the principles of responsible data sharing, including providing qualified scientific researchers access to deidentified, patient-level data from CRI clinical studies to conduct legitimate scientific research.

Eligibility and Application Process

Qualified researchers who have appropriate competencies and engage in rigorous, independent scientific research may request access to deidentified, patient-level data by submitting a complete research proposal to CRI for review. As part of the proposal, the members of the research team must be identified and must include a biostatistician. Conflict of interest will be assessed for each request; data will not be released to individuals with significant conflict of interest or individuals requesting data access for competitive, commercial, or legal interests.

The researchers should submit complete data access proposals to CRI.DataRequest@cookmedical.com. The following basic information will be required:

- Background and rationale;
- Objectives of the research;
- Scientific hypothesis;
- Statistical analysis plan;
- Publication plan;
- Identification of the research team, including roles and responsibilities and a conflict of interest statement for each member; and
- Curricula Vitae of all research team members.

Scope of Data

CRI will provide access to deidentified, patient-level data from CRI clinical studies for which results are published in peer-reviewed scholarly journals. In general, data will be made available for request immediately after publication and ending 5 years after publication.

There are additional circumstances that may prevent CRI from sharing the requested data, such as:

- CRI may not have the legal authority to share the requested data due to restrictions contained within related contracts;
- CRI may not be able to ensure adequate and appropriate protection of the privacy and confidentiality of research participants. For example, studies of rare diseases that permit re-identification of research participants;

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- CRI may not be able to share patient-level data for products or indications pending regulatory approval;
- Applicable rules and regulations may not allow sharing of the requested data; or
- Providing access to the data may be practically or logistically impossible or unreasonably burdensome to CRI.

Review Process
Researchers will receive an acknowledgement of receipt of their proposals. Completed proposals will be evaluated by a CRI review committee made up of relevant subject matter experts. Applications may also be reviewed by individuals external to CRI, as appropriate and necessary.

The CRI review committee will make the final decision on the data request after consideration of all relevant factors of the application. CRI will notify the requester of its final determination in writing.

Data Sharing Agreement
Prior to accessing the clinical study data, researchers must execute a data sharing agreement with CRI. The data sharing agreement will restrict data use to the stated research purposes. No onward transfer of the data will be allowed. Researchers will also agree to transparency and required disclosures in the publication of their work.

Data Deidentification
Adequate protection of the privacy of research participants is a core value of CRI. Therefore, CRI will enact all necessary measures to ensure that research participant privacy is safeguarded, including deidentification of data prior to granting access.