

Regenstrief Institute RDS Core Policies:

Policy for confidentiality: Data are kept completely confidential per HIPAA Guidelines, INPC Terms and Conditions, and other contractual obligations as appropriate. Data is kept on secure servers managed by IU HTS (Health Technology Services). Data are only provided to a study team once appropriate agreements and approvals are in place. Data is never shared outside of the IRB approved study team.

Policy for partial or waived payments: By mutual agreement and if there is a reduced scope of work Regenstrief may consider partial payments. Waived payments are not applicable. Regenstrief will expect to collect payment per the terms of the fully executed contract. Prompt payment is expected. Regenstrief will contact the customer or their department to collect charges owed. If there is an unresolved issue regarding payment for services, the policy for conflict resolution will apply.

Policy for prioritization of work: Data extraction can take a few hours to several weeks depending on the complexity of the data request and the study protocol. Data requests for feasibility are turned around as quickly as possible. All requests for data should be submitted through the Regenstrief website <https://www.regenstrief.org/data-request/>. Requests are processed in the order of receipt, however under extenuating circumstances a request may be moved up in the queue for faster processing. The data analyst will communicate with the investigator regularly to ensure a clear understanding of data needs and timelines. Investigators are encouraged to include the data analyst on their study team and discuss data extraction and methods as early as possible in the project.

Policy for publications: Regenstrief Institute will be acknowledged for its participation in studies resulting in any publication. Other than acknowledgement of participation in the study Regenstrief should not be specifically mentioned in the publication without the written permission of Regenstrief. Regenstrief and the Covered Entities on whose behalf Regenstrief provided data will not be compared in any identifiable way to other participating health care providers or institutions. Regenstrief agrees that de-identified and/or aggregated data may be used by recipients of the data in publications regarding the study. The recipient of the data will not identify the Covered Entities on whose behalf Regenstrief provides the data in any publications without the approval of the Covered Entity.

Policy for authorship: Inclusion of Regenstrief staff members as authors in publications is expected only when we provide study design and/or data analysis and interpretation of the data. If substantial intellectual contributions are required in data analysis, interpretation and/or manuscript writing are requested, co-authorship should be granted to the RDS Core personnel involved.

Policy for conflict resolution: Conflicts or complaints will be brought to the attention of the Director of the Regenstrief Data Core. If a mutually agreeable solution cannot be reached the issue will be brought before the Advisory Committee for advice and guidance to reach a solution. The Regenstrief Data Core is committed to open and transparent communications to ensure a mutually beneficial resolution to all complaints.