

RDCRN PRINCIPLES FOR THIRD PARTY COLLABORATION

The Rare Diseases Clinical Research Network is committed to fostering third-party partnerships that include collaboration with the biopharmaceutical industry. All such partnerships should advance the overall Network objectives of studying rare disease, including understanding the clinical epidemiology and pathophysiology, accelerating the development of therapies and management tools, and improving the lives of individuals. The goal of this document is to outline key principles that help the RDCRN achieve this goal. For purposes of this document “third-parties” are individuals or entities that are not already recognized as part of the Consortium.

- RDCRN-third-party relationships are enhanced by effective communication about the many activities, capabilities, and resources of the Network. The nature of that communication could be, but is not limited to, helping industry partners appreciate the Network’s scope and breadth of the RDCRN with respect to the rare diseases studied, extensive ties to patient advocacy organizations, the capacity to, and experience with, the conduct of natural history studies, the design, conduct and analysis of clinical trials, and the identification and evaluation of biomarkers.
- Any third-party involvement in the study, including accessing any study data or study results, using the name of the study, or using the name/logo of the RDCRN, NIH, or any NIH institute, is permitted only after concurrence by the Program Official who may consult with others at NIH including the Technology Advancement Office. Involvement of the NIH will help ensure compliance with i) NIH and RDCRN policies and procedures, including protocol development and monitoring processes; ii) possible need for a clinical trial agreement with the NIH; iii) NIH-wide and institute specific policies regarding clinical trials reporting, third-party agreements, data sharing, conflicts of interest, and DSMB/OSMB oversight.
- Any third-party collaboration must be governed by a research collaboration agreement (e.g. CTA, RCA, MOU, etc.) with terms that ensure the collaboration is conducted in accordance with the Cooperative Agreement, and applicable NIH policies and procedures.
- Third-Party Partnership agreements should explicitly include language that describes issues surrounding intellectual property, protection of the investigators’ right to publish (including authorship), access to study samples and data, and respect for the privacy of study participants.
- Proposed partnerships should also comply with any additional Consortium-specific policies and procedures to the extent that they do not conflict with the principles outlined above.