

**National Clinical and Translational Science (NCATS)
Evolving Next-Generation Accrual to Clinical Trials (ENACT)
Cohort Discovery and Research on De-identified Aggregated Data
Regulatory Guidance Overview**

Overview	Cohort Discovery and Research on De-identified Aggregated Data (RDAD) - Conduct data query to identify aggregate patient counts per site across the ENACT network
Topic	Regulatory Minimum Standards
i2b2 Clinical Data Repository	<p>IRB approved protocol specifying what data will be maintained, and the conditions under which data will be maintained and shared; ensuring adequate provisions to protect the privacy of individuals and maintain the confidentiality of data [45 CFR 46.111(a)(7)].</p> <p>Two options to seek IRB approval for the i2b2 Cohort Exploration Data and RDAD Repository:</p> <ol style="list-style-type: none"> 1. New IRB Application - Level of IRB Review recommended*: <ul style="list-style-type: none"> • Expedited, Category 5 <ul style="list-style-type: none"> ○ Waiver of Informed Consent ○ Waiver of HIPAA Research Authorization 2. Modify existing i2b2 Protocol - Allow access and sharing across NCAT ACT federated network <p>* Level of IRB review is ultimately based on institutional and IRB policies</p>
Network Agreement	<i>Governance Work Group</i> – use site agreement for data access/sharing
Cohort Discovery and RDAD across NCATS ENACT work	<p style="text-align: center;"><i>Does this activity constitute human subjects research?</i></p> <p>As only de-identified patient counts or de-identified aggregate data will be shared across the network, this activity does not constitute research or involve human subjects.</p> <p>If confirmation from local IRB is required, submit documentation to IRB and retain for your records.</p>
User Terms of Data Access Assurance	<i>Governance Work Group</i> –User Terms of Query Access agreement for network users to acknowledge access and data use responsibilities prior to conducting data query. Will develop guidelines for dissemination of research findings.
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