N3C Data Access Tiers and Conditions for COVID-19 Related Research

Data	Registered	Controlled	Controlled	Controlled-Plus
Data Type:	Synthetic Data (pending pilot)	Aggregate Data (i.e. counts)	HIPAA Safe Harbor	HIPAA Limited
Description:	Computational data derivative that statistically resembles the original data	Counts and summary statistics representing 10 or more individuals	Data stripped of 18 direct identifiers per HIPAA rules	Data that may contain 3 direct identifiers per HIPAA rules (date, full zip code, and any age)
Capabilities	Registered	Controlled	Controlled	Controlled-Plus
Downloadable Data:	Planned: pending validation & organizational agreement	Downloadable query results	No	No
Custom Software:	Yes	Yes – on downloaded query results	Yes with DAC approval	Yes – with independent IRB and DAC approval
Access Prerequisites	Registered	Controlled	Controlled	Controlled-Plus
Affiliation Requirement:	Planned: no affiliation required (pending pilot validation)	Academic or commercial research organizations	Academic or commercial research organizations	Academic or commercial research organizations
Data Use Agreement Signed by Home Organization:	Required at present (planned to be not required pending pilot)	Required	Required	Required
Human Subjects Training:	Required at present	Required	Required	Required
NIH Security Training:	Required at present	Required	Required	Required
Request Submission and Approval Steps	Registered	Controlled	Controlled	Controlled-Plus
Data Use Request:	Required at present	Required	Required	Required
Rationale for Accessing Identified Data:	N/A	N/A	N/A	Required
General description of research project (objectives, testable hypothesis, planned analysis):	Yes	Yes	Yes	Yes
Abstract of research project (posted publicly):	Yes	Yes	Yes	Yes
Approval Process:	DAC	DAC	DAC	DAC + IRB