

The CCHS NOW Registry statement on compliance with the GDPR

The CCHS NOW Registry is a subsidiary of the CCHS Network, Inc. The CCHS NOW Registry is an independently IRB evaluated and approved research project. The CCHS NOW Registry data collection process follows *in perpetuity* proper HIPAA and GDPR protocols related to the collection and management of data supplied by CCHS families.

To ensure compliance with HIPAA and GDPR protocols, appropriate technical and organizational measures have been established to protect the integrity of the registry. These actions include, but are not limited to:

1. *Limited access to data.* Only CCHS NOW Registry Principal Investigator (PI), Co-Investigator (CI), Archivist (A), and/or System Administrator (SA) have access to patient data files. These persons are HIPAA trained and certified to administer/oversee the database and its use. As of October 22, 2021 the PI of this study is Vandana Dole, Ph.D., the Archivist is Linda Dokas, Ph.D., and the System Administrator is Melinda Riccitelli, Ph.D. There is no current CI.
2. *The use of password and firewall protected computers.* Additionally, no login information or passwords are saved on the computers.
3. *Anonymization of data.* To unequivocally ensure patient privacy, *no data* is *shared* publicly or privately without anonymization of responses. Patient data downloaded onto password protected computers will be de-identified prior to download. On occasion, for administrative purposes only (e.g. contact a participant to complete a survey started) a participant's email may be downloaded; but at no time is data/survey responses coupled to an individual participant.
4. *A rigorous and methodical screening of data requests.* The data collected by the CCHS NOW Registry is intended to be willingly and cooperatively shared with members of the CCHS research community. Nonetheless, any requests by a researcher or CCHS specialists for de-identified data will undergo a thorough screening process, on a case-by-case basis, by the CCHS NOW Registry Board. The CCHS NOW Registry Board consists of the PI, CI, SA, and A, as well as medical specialists within the field of CCHS and the Chair of the CCHS Network Research Advisory Board (RAB). Furthermore, IRB approval will be obtained prior to sharing de-identified data with a third party. De-identified data will be shared with a third party only after an agreement is established with the CCHS NOW Registry for use and sharing of the data.
5. Data will only be collected for patients who have agreed to the informed consent, and the patient has the right to revoke this consent at any time.
6. The only data collected by the CCHS NOW Registry are the answers to questions which the patient has chosen to respond to. No other patient data will be collected. The data will be retained indefinitely, or until the patient chooses to revoke consent.
7. The CCHS NOW Registry team will work continuously and closely with the National Organization of Rare Disorders (NORD) to minimize, identify, and remediate database vulnerabilities that may arise using a variety of tools that are available.
8. The goal of the CCHS NOW Registry is to expand the CCHS community's knowledge and understanding of the syndrome in a productive and positive manner.

As an organization, we hold data protection and research integrity as a serious and essential responsibility. We are committed to maintaining data security and research integrity at the high level.