

Protocol Builder® Training

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Objectives

- Overview of Protocol Builder® application
- How to access Protocol Builder®
- Overview of availability of Umbrella Protocols at Nicklaus Children's Hospital for chart review studies.
- Review regulatory guidelines for use of Umbrella Protocols for chart review studies

ProtocolBuilder™

Protocol Builder is a cloud-based protocol writing technology that makes it faster and easier to develop investigator-initiated clinical research protocols that meet IRB and regulatory standards. It is a robust, yet simple-to-use application and can be accessed conveniently on laptops, desktops, and iPads.

Key Benefits of Protocol Builder:

- **Reduces missing sections and errors to speed acceptance of protocols**
- **Improve adherence to IRB and regulatory standards**
- Enable collaboration among contributors
- Advance the ability to publish research
- Save significant time and effort developing protocols
- Save instructors and mentors time and effort for protocol writing instruction for fellows and residents
- **19 different protocol templates**

ProtocolBuilder™ - Resident & New Investigator Program

The application also includes a Resident & New Investigator Program, which includes:

- A Chart Review Protocol Template. Designed specifically for chart review studies - with only the relevant sections and necessary guidance. No unneeded and confusing instructions.
- Deep Protocol Guidance and Sample Text. Gives writers a head start on the section with section guidance and sample text that helps create structure for the section, with one click.
- Observational Research Design Training. Learn about the scientific method and different observational design options with real case studies, delivered live by BRANY's training expert.
- Tutorial Videos, Articles and Collaboration Features. New tutorial videos, relevant articles to resident research projects and collaboration features to help the mentoring process between faculty and students.

Protocol Builder Access

How to get to Protocol Builder

- NCHS direct link -
<https://app.protocolbuilderpro.com/register/nicklaus-health>
- Research Institute intranet page
- ProtocolBuilder™ webpage (not for first time use/registration)

Existing umbrella protocols allowing secondary analysis of clinical data

- Cardiology – Jun Sasaki, MD
- Craniofacial – Anthony Wolfe, MD
- Endocrinology – Pedro Pagan, MD
- Neurosurgery – Toba Niazi, MD
- Spine Surgery – Stephen George, MD
- Urology – Alireza Alam, MD
- Rehab (ACL) – Lauren Butler, DPT

Regulatory conditions for use of umbrella protocols

All studies covered under this protocol will involve secondary analysis of existing data from protocol specified clinical databases.

The sub-project protocol template will also include the regulatory requirements that all studies will follow i.e. that the data collection will involve secondary analysis of clinical data, that any data collected should be maintained in a password-protected, secure database, etc. This information will not be modified for any sub-project.

Regulatory conditions for use of umbrella protocols

All data will be collected through chart review and/or through querying the databases directly.

Direct patient identifiers such as name or medical record number will only be gathered for the purposes of sample population identification and will not be exported for sub-analysis. Identifiers that may be part of a Limited Data Set (as defined by the HIPAA regulations) may be exported for analysis but data will be kept in a password-protected file and the dataset will be de-identified after analysis is complete.

Data collected for the research sub-project will only be available to the study team and or for project oversight by the PI of this protocol or RI staff and will not be made available to anyone else.