Protocol Builder:  
A Better Tool For Writing Protocols for Investigator-Initiated Studies

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Introduction

• A secure, web-based application to help Institutions create better quality investigator-initiated protocols faster and easier

• Designed to meet Federal/Industry Regulatory Standards
  • 18 various Protocol Types – Observation and Interventional; NIH IND/IDE
  • Expert Guidance icon – Detailed explanation of the requirements for each field
  • Smart Forms with Branching Logic – Predictive and reduces the need for double-entry of text
  • Resource Center – Provides commonly used Research forms and allows addition of supporting documentation
  • Reference Builder - Import references from a variety of reference software solutions (ris and nbib files)

• Allows for development and review of protocol document by multiple individuals (Investigators, Coordinators, Administration, etc.)
A systematic analysis of 8 CNHS IRB-reviewed protocols written by our most experienced investigators revealed:

1. Disorganization and inconsistency among those written by different researchers
2. Essential sections missing (e.g. Protocol version/date; Adverse Events definition and reporting; IRB Review process; Removal of subjects/Study discontinuation; Study monitoring; Appendix/References, etc.)
   a. Especially prevalent in Observational/Behavioral studies/ those not reviewed directly by NIH
Protocol Builder – Analysis Feedback

• Product and Feasibility Analysis Presentation Feedback
  • Presented to senior representatives of the CTSI-CN, CRI, IRB, SRC, and QA
  • Overwhelmingly positive reaction regarding need and functionality

  • IRB/SRC/QA
    • Protocol consistency would allow for more efficient study review
    • Quicker turnaround
    • Reduce deviations found in future FDA/IRB/Sponsor audits
    • Fewer IRB contingencies

  • Investigators
    • Guided experience reduces errors significantly
    • Better communication among study team due to constant accessibility
    • Can ensure accuracy of template in relation to institutional and federal standards
Protocol Builder – Access
New Protocol Writing Technology

Protocol Builder™ is now available at Children’s National. This secure, cloud-based technology can help you write research protocols faster and more easily. It provides organization, guidance, and collaboration tools for your observational or interventional research protocols. It can be used on your laptop or through an iPad app.

Register below to get started today!
Protocol Builder – Getting Started

[Image of Protocol Builder interface]

- Start a new protocol
- Test Test Test
  01/12/2017
- Adoptive Transfer of Cord Blood T cells to Prevent and Treat CMV, EBV and Adenovirus Infections after Transplantation
  01/12/2017
- Energy Expenditure and Metabolic Control Among Youth with T1 Diabetes
  04/27/2016

Important News

NEW NIH IND/IDE Template
Announcing the new NIH IND/IDE Template, which provides the structure strongly recommended by the NIH to write NIH funded protocols.

To use this template, simply select “NIH IND/IDE Template” from the Protocol Type drop-down menu when you...
Protocol Builder – Getting Started

Protocol Set Up

- File Name *
- Principal Investigator *
- Protocol Type *
  If you're unsure, click here for help

Select Protocol Type
- Repository
- Observational Retrospective
- Observational Prospective
- Observational Prospective w/Repository
- Interventional FDA Approved Drug/Biologic
- Interventional FDA Approved Drug/Biologic w/Repository
- Interventional Investigational New Drug/Biologic
- Interventional Investigational New Drug/Biologic w/Repository
- Interventional Non-Significant Risk Device
- Interventional Non-Significant Risk Device w/Repository
- Interventional Significant Risk Device
- Interventional Significant Risk Device w/Repository
- Interventional Combination
- Interventional Combination w/Repository
- Interventional Behavioral
- Interventional Behavioral w/Repository
- NIH IND/IDE Protocol Template
- Social Behavioral

Save
Protocol Builder – Features

Dashboard – Provides Snapshot of Protocol
Protocol Builder – Features

Content Menu and Step-by-Step Progress
Protocol Builder – Features

Embedded Editing Tools

- Add abbreviations
- Add glossary terms
- Add footnotes
- Insert Tables

Build references
6.2.2.1 Adverse Events Definition

 Specify how adverse events will be defined and assessed for causality (relationship to intervention) and graded for severity (provide an adverse event grading scale).

 The relationship, severity, and expectedness (including level and frequency) of an adverse event should be assessed based on previous experience with the intervention and reasonable judgment.

 This section should also describe:

 - Time frame for collecting adverse events (i.e., from consent or time of start of study until end of intervention or follow-up).
 - Frequency and process for eliciting adverse event information from research subjects (include how often, by whom and what records will be reviewed to collect adverse events).
 - Specific management plans for expected or unexpected adverse events. Expectedness of adverse events should also be described in informed consent and be consistent with the protocol.
 - AE reporting procedures (including how often, by whom and to who adverse events will be reported).

 Ensure reporting timelines meet IRB and FDA requirements. Refer to Adverse Event Reporting in the Resource Center section for details.
Final Checklist to Ensure Everything is Complete

- 1. Review Cover Page information for accuracy
- 2. Make sure necessary appendices are attached
- 3. Check to see references are entered correctly
- 4. Ensure tables display properly and are sourced if necessary
- 5. Look over abbreviations and descriptions
- 6. Check glossary terms and definitions

CREATE VERSION
Protocol Builder – Features

Contact List

User Roles

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Protocol Builder – Features

Organized, Professional Output - .pdf or .word

CLINICAL STUDY PROTOCOL

A Randomized Multi-Center, Double-Blind, Placebo-Controlled Study of a New Modified-Release Tablet Formulation of Prednisone in Patients with Rheumatoid Arthritis

Study Number: NCT01207

Primary Objective
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Secondary Objectives
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Secondary Objectives - Repository
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Primary Outcome Variables
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Secondary Outcome Variables
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Study Duration
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Study Design
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All general/technical questions regarding Protocol Builder may be directed to Mr. Jurran Wilson (juwilson@childrensnational.org; 202.476.2196)

Wishing you great success with your research endeavors,
The Children’s National Protocol Builder Team