ProtocolBuilder®

PROTOCOL BUILDER

PROTOCOL TEMPLATES OVERVIEW

For more help on selecting the right template for your study, visit the **Protocol Template Assistant** on the Protocol Set Up Page.

QA/QI TEMPLATE

Quality Assurance and Quality Improvement (QA/QI) studies are defined as systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery. QA/QI projects often include activities such as surveys, review and analysis of identifiable data, or process or performance improvements compared to an established standard.

CHART REVIEW TEMPLATE

Retrospective Chart Reviews evaluate patient data that is existing at the time the protocol is submitted to the IRB for initial approval. This type of chart review uses information that has usually been collected for reasons other than research.

Prospective Chart Reviews evaluates patient data that DOES NOT YET EXIST at the time the protocol is submitted to the IRB for initial review.

Combination studies may involve a combination of both retrospective and prospective chart reviews.

OBSERVATIONAL vs. INTERVENTIONAL RESEARCH

When conducting research, there are two basic features an investigator must address: manipulation of a variable of interest or as we say, an exposure, and randomization of study subjects to groups receiving those exposures. Understanding what combination of these two factors is occurring can help us to recognize different types of study designs.

In an interventional design, the investigator does both manipulation of study variables and randomization of subjects to groups. An example of this is the randomized,

controlled clinical trial where an investigator manipulates a variable (ex. 10 mg vs 20 mg of a drug) and randomly assigns subjects to each group.

In the observational design, there is neither manipulation of exposure nor randomization of subjects. These are sometimes called "natural experiments" as the investigator simply observes the natural course of events as they are occurring in nature.

OBSERVATIONAL PROTOCOL TEMPLATES

Observational protocol types:

- Observation of an FDA-approved drug
- Observation of an FDA-approved device
- Observation of individual or group characteristics or behavior, or human evaluation factor (includes processes, procedures, etc).

INTERVENTIONAL PROTOCOL TEMPLATES

Interventional protocol types:

- FDA-Approved Drug
- Investigational New Drug (IND)
- Non-Significant Risk Device
- Significant Risk Device (IDE)
- Combination

SOCIAL BEHAVIORAL PROTOCOL TEMPLATES

Social Behavioral protocol types:

- **Social Behavioral:** Social, behavioral, and education research (SBER) encompasses a range of methodologies and tackles questions that seek to improve our understanding of human behavior, attitudes, beliefs, and interactions as well as social and economic systems, organizations, and institutions. The primary focus of SBER is on the actions of diverse groups including individuals and families, and regional populations and nations. Often SBE research utilizes methods such as interviews, surveys, focus groups, observation, and/or behavioral manipulations. Census and employment data as well as records from education, social service, or healthcare programs may also be incorporated.
- **Behavioral Intervention (including benign behavioral intervention):** Behavioral interventions are interventions designed to affect the actions that individuals take with regard to their health. The typical medical intervention is a clinical trial of a particular drug, surgery, or device. In the trial, doctors provide different services to different

people, and then evaluate the outcomes. Variation in patient behavior is generally shunned; a strong emphasis is placed on making sure that patients do exactly what is expected from them. With behavioral interventions, in contrast, patient behavior is the key and the goal is to change it.

A benign behavioral intervention must be brief in duration (although data collection may take longer). Also, the intervention must be harmless, painless, and not physically invasive. Further, the intervention must not be likely to have a significant adverse lasting impact on subjects. The investigator must have no reason to believe that the intervention will be offensive or embarrassing to subjects, and should take into consideration the subjects' population, the context of the research, the topic, and other characteristics of the study.

REPOSITORY TEMPLATES

Research repositories (also called registries, banks, or libraries) are used to store data and/or biospecimens for future research use, either by the research team who collected them or to share with other researchers.

Repository protocol types:

- Repository without Broad Consent
- Repository with Broad Consent

"Broad consent" is defined as consent for an unspecified range of future research subject to a few content and/or process restrictions. Broad consent is less specific than consent for each use, but more narrow than open-ended permission without any limitations (i.e. "blanket" consent). *Check with your organization to be sure the procedures are in place to meet the regulatory requirements related to the use of broad consent.*

Are Investigators Required to Use Broad Consent?

Investigators are never required to obtain informed consent through a broad consent process; it is an available optional procedure. Instead of obtaining broad consent, an investigator may choose the following: 1) Conducting the research on non-identifiable information and non-identifiable biospecimens, and request that the IRB waive the requirement for additional prospective informed consent; or 2) Obtaining consent for a specific study. Even if the investigator wanted to use the biospecimens with identifiers attached, the option still exists of asking an IRB to waive the requirement to obtain additional prospective informed consent instead of using broad consent.

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TEMPLATES LIST

Repository
Repository without the use of Broad Consent
Repository with the use of Broad Consent
Observational
QA/QI
Chart Review
Observational study of individual or group characteristics or behavior, or human factor evaluation
Observational study of a FDA Regulated Product
Interventional
FDA-Approved Drug
Investigational New Drug (IND)
Non-Significant Risk Device
Significant Risk Device (IDE)
Combination
Social Behavioral Educational (SBER)
Behavioral Intervention (incl. benign behavioral intervention)
Social Behavioral (with Revised Common Rule updates)
NIH
NIH and FDA Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials
NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans