# **Nova Southeastern University**

# **Institutional Review Board**

# **Research Protocol Template**

## **What is this template?**

The Institutional Review Board (IRB) Office has developed the following Research Protocol Template for use by the Nova Southeastern University (NSU) research community. The Office recommends that researchers create a detailed protocol template in preparation for submitting their study via the *New Protocol Submission xForm* in IRBManager.

## **When should this template be used?**

It is strongly recommended that a detailed protocol attachment should accompany each *New Protocol Submission xForm* for initial review of studies that are clinical trials involving medical, surgical, or dental interventions; or for any type of investigator-initiated, multi-site clinical trial or clinical trial with NIH funding.

If your College or Department has developed a standard research protocol template to describe human research activities, you may continue to use that template in lieu of this template. Colleges and Departments are encouraged to develop their own templates and to compare their templates to the IRB template to ensure that they are asking for similar content.

If you have a protocol from an external sponsor or cooperative group, attach that protocol to the *New Protocol Submission xForm* and **do not** use this template. Investigators may also choose to use this template for studies that are **not** clinical trials.

If **do not** have a College, Departmental, external sponsor, or cooperative group research protocol template, the IRB Office recommends you use this template.

## **How to use this template:**

Use this template to create a research protocol as follows:

* Black font is required for all studies.
* ***Italicized blue font*** is optional depending on the type of study. Delete as applicable.

## **Before you attach the Research Protocol to your IRB submission, you MUST:**

1. Delete this instructions page.
2. Change all **BLUE** text to **BLACK**.
3. Remove all Comments, Notes, and/or Track Changes.

**IRB Research Protocol Template**

1. Title Page (Version Date)
	1. Title
	2. Date / Version #
	3. College Association/Unit
	4. PI and other key personnel – contact info and roles
	5. *Funding source - if any*
		1. *Contracted Services*
		2. *Subawards*
	6. Site
		1. On Campus Location
		2. Off-Campus Location
		3. Online
2. *Protocol Summary*

*Brief description. (Similar to Abstract on grant.gov submission)*

1. Background / Aims
	1. Purpose Statement
	2. Objectives +/- Hypotheses
	3. *Impact*
2. Study Design (including Basic Timeline)
	1. Methodology
	2. Schedule of Events
	3. List of Data Collection instruments
3. Eligibility / Participant Population
	1. If Retrospective:
		1. How participants are identified
		2. Selection Criteria
	2. If Prospective:
		1. Inclusion/Exclusion criteria (i.e., eligibility)
		2. Screening (i.e., finding patients)
		3. Recruitment (i.e., presenting study)
		4. *Randomization*
4. Consent Process/Waiver of Consent, HIPAA Authorization
	1. Describe whether informed consent will be used and if so, how obtained?
	2. If Waiver of Consent, describe why waiver is applicable.
	3. *HIPAA Applicability and whether supervising entity is Nova vs Other.*
5. Data Analysis
6. Risk/Benefit Assessment
	1. Potential Risk
	2. Potential Benefits
	3. *Adverse Event Management (for prospective trials)*
7. Privacy and Confidentiality (How will study protect participant privacy)
8. Data Storage and Security
	1. Where and how data will be stored and secured?
	2. *For all extramural researchers receiving Federal grants and contracts, provide data management plan describing long-term preservation of, and access to, scientific data in digital formats, or explaining why long-term preservation and access cannot be justified.*
	3. *How will data integrity and accuracy be ensured? (i.e., quality checks on data entry)*
9. *Data Collection Instruments*