

SOP-GN-007	HOW TO PREPARE A SOP	Date Approved:
Approved by:	Date Revised: Revised by:	Page 1 of 2

I. INTRODUCTION/BACKGROUND

The CTN staff is undergoing a major effort in implementing good quality clinical trials and studies in CTPs across the US. Since we need to communicate how to do this effort, personnel are developing several Standard Operating Procedures (SOPs) for distribution CTN-wide.

II. OBJECTIVE/PURPOSE

This procedure provides a guideline on how to write a SOP, including its format.

III. RESPONSIBILITIES

Individuals participating in Committees, Subcommittees, Workgroups and Protocol Teams are required to develop SOPs, or at least parts of them.

This procedure applies to any individual who is responsible of creating a SOP.

IV. PROCEDURE

- 1) Select the blank document (see attachment 1).
- 2) Use Microsoft Word, Times New Roman font, type 12 size.
- 3) Establish margins of 1" from top, bottom, left & right margins.
- 4) Fill the header sections:
 - a) SOP #: Please consult with NIDA prior to assigning a number in order to prevent duplicate numbers.
 - b) Title: Assign a title and use Uppercase, Bold letters
 - c) Date Approved: Insert date
 - d) Approved by: Insert name of the individual. Usually is the Chair of the approving Committee
 - e) Revision: SOPs need to be revised at least every 18 months. Insert data and the name of the revision official
 - f) Pages: This section fills automatically.
- 5) Write the information in the main sections:
 - a) Introduction: Enter a brief introduction, background or rationale regarding the SOP.
 - b) Objective: This is the purpose of the SOP.
 - c) Responsibilities: Who is supposed to do this procedure, when is supposed to be done, etc.
 - d) Procedures: Write detail steps on how to do the process, methodology, etc. Some of the methods need more detail than others, use your judgment when writing the steps.
- 6) Add a Reference Section is desired, or needed, but is optional.
- 7) Obtain written approval of the SOP prior to publish CTN wide.
- 8) Post the document in Live Link according to current Live link guidelines.
- 9) Contact Ms. Rosa at NIDA for more information.

CTN#XXXX	TITLE	Date Approved:
Approved by:	Date Revised: Revised by:	Page 2 of 2

I. INTRODUCTION/BACKGROUND

II. OBJECTIVE/PURPOSE

III. RESPONSIBILITIES

IV. PROCEDURE