**IIS Final Report Recommended Format**

The purpose of this document is to assist investigators in writing a final clinical study report. The Final Report is intended to provide Stryker Neurovascular with a comprehensive summary of the study conduct with pertinent analyses and statistical tables or figures, and study conclusions. Depending on the type of study, not all sections will apply.

1. **TITLE PAGE**

* Sponsor Name and Address
* Principal Investigator(s) Name
* Statistician(s) Name
* Imaging Core Laboratory
* Clinical Protocol Number and Approval Date(s)
* Clinical Trial Registry Number
* Date of Report
* Author(s) of Report

1. **TABLE OF CONTENTS**
2. **EXECUTIVE SUMMARY OR SYNOPSIS**

* Study type
* Date of first and last patient enrolled
* Evaluations performed
* Primary endpoint result
* Secondary endpoint result
* Adverse event summary

1. **LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS**
2. **ETHICS**

* EC or IRB Approval
* Ethical conduct
* Informed Consent
  + When and how obtained

1. **INVESTIGATORS AND SITES**

* List with affiliations

1. **STUDY OBJECTIVES**
2. **INVESTIGATIONAL PLAN**

* Study design
* Subject population
* Inclusion/Exclusion criteria
* Treatments administered
* Method of randomization
* Blinding
* Duration of treatment
* Adverse Event reporting
* Endpoints
* Statistical analysis plan
* Sample size determination
* Monitoring plan

1. **PATIENT DISPOSITION**
2. **PROTOCOL DEVIATIONS**
3. **DATA ANALYSIS**

* Demographics and other baseline characteristics
* Treatment Compliance
* Results in table format
  + Statistical tests performed
  + Handling of missing data
  + Subgroup analyses

1. **SAFETY EVALUATION**

* Adverse Events
* Serious Adverse Events with relationship to procedure and device
* Deaths
* Unanticipated Adverse Events

1. **DISCUSSION AND OVERALL CONCLUSIONS**
2. **REFERENCES**
3. **APPENDICES**
4. **PUBLICATION PLAN**