

# Writing a Study Protocol for Therapeutic Recreation Studies in Canada

(Based on ICH-GCP Guidance  
Document)

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# “Standard” Headings

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- Title Page
- Table of contents
- List of abbreviations
- Introduction (background information)
- Objectives
- Study Procedures (overview – trial design)
- Medicine & Dosage
- Study Procedures (detailed, by period and/or by phase, treatment of subjects)

# “Standard” Headings cont’d.

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- Patient Population (incl./excl., withdrawal criteria)
- Efficacy and Safety Parameters
- Statistical Analysis
- Ethical and Regulatory Considerations
  - Approval, Informed Consent Procedure, Confidentiality & Record Keeping, Adverse Reactions, Monitoring, Publication of Results
- References
- Appendices

# Example of Protocol Structure (Table of Contents)

1.	INTRODUCTION.....	6.	WARNINGS/PRECAUTIONS.....
2.	TRIAL OBJECTIVES.....	7.	Ethical Aspects and Good Clinical Practice Compliance.....
3.	INVESTIGATOR(S) AND OTHER TRIAL PARTICIPANTS.....	7.1	Good Clinical Practice.....
4.	TEST DRUG AND CONTROL AGENTS .....	7.2	Informed Consent and Subject Information.....
4.1	Investigational Product(s) .....	7.3	Monitoring by the Sponsor .....
4.2	Supply, Packaging, Labeling and Storage.....	7.4	Documentation .....
5.	INVESTIGATIONAL PLAN.....	7.5	Premature Termination of Trial/Closure of Center .....
5.1	Overall Design and Plan of Trial.....	8.	Adverse Events.....
5.2	Selection of Subjects.....	8.1	Adverse Event Monitoring.....
5.2.1	Primary Diagnosis .....	8.2	Adverse Event Definitions .....
5.2.2	Number of subjects .....	8.3	Adverse Event Documentation .....
5.2.3	Inclusion Criteria.....	8.4	Reporting of Serious Adverse Events .....
5.2.4	Exclusion Criteria.....	9.	STATISTICS .....
5.3	Method of Assigning Subjects to Trial Groups and Blinding Procedure .....	9.1	Sample Size Estimation .....
5.4	Planned Dosage and Duration of Treatment.....	9.2	Statistical and Analytical Plan .....
5.4.1	Dosage and Administration .....	9.3	Interim Analysis/Analyses .....
5.4.2	Duration of Treatment .....	10.	USE OF DATA AND PUBLICATION.....
5.5	Assessment Periods .....	11.	REFERENCES .....
5.6	Observations and Measurements: Assessment for Treatment Effects .....	12.	APPENDICES.....
5.7	Subject's Compliance.....	12.1	Trial Flow Chart.....
5.8	Concomitant Therapy .....	12.2	National Variations (for Multinational Trials only) .....
5.9	Removal of Subjects from Trial.....	12.3	Statistical Methods (Details).....
5.10	Criteria for Evaluation of Trial Objectives and Safety .....	12.4	Bioanalytic Methods.....
5.10.1	Description of Subject Groups for Analysis .....	12.5	Instructions for Handling Biological Samples Including ABRA Guidelines (if applicable) .....
5.10.2	Trial Objectives.....	12.6	CAP Severity Classification
5.10.3	Safety.....		
5.10.4	Pharmacokinetics and Drug Concentration Data (if applicable) .....		

# Protocol CONTENT

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# Objectives

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- Clear statement detailing **WHAT** is being investigated - follows from identified corporate need
- Define what questions are to be answered from the study: primary vs. secondary outcomes (GCP 6.3 & 6.4)
- Define which of the research questions are most important/critical for product registration and/or marketing

# Trial Design - Feasible ?

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- When the trial design doesn't work:
  - state of technology does not allow for data collection
  - equipment needed is too expensive to buy or operate
  - too many subjects required
  - too much manpower required
- May need to re-work objectives to allow for more feasible trial design

# Patient Population

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Inclusion Criteria: minimum criteria required for the subjects/patients to be included in trial

Exclusion Criteria: the presence of any one criterion renders the subject/patient ineligible to be included in the trial

Withdrawal Criteria: when, how, replacement of subjects, timing of data collection, follow-up (GCP 6.5.3)



# Introduction

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- Background on disease/medicines currently used
- What are the limitations of current therapy
- Pre-clinical & clinical data on new medicine
- Summary of known & potential risks
- Background of hypothesis being tested
- Rationale for the trial (GCP 6.2)

# Introduction

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Be sure to highlight advantages (real or proposed) of the new therapy over current therapy

# Introduction

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## Sources of information

- previous protocols
- literature review
  - journal articles
  - books
  - treatment guidelines
- physicians
- Therapeutic recreation advisory boards

# Efficacy and Safety Parameters

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Dependent upon trial objectives/design

Efficacy parameters (GCP 6.7)

- primary and secondary outcomes
- method of evaluation

Safety parameters (GCP 6.8)

- method and timing for assessment and recording of AEs
- procedures for eliciting reports and type of follow-up

# Study Procedures - Methodology

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- Time and events schedule
- List of specific measurements and evaluations
  - Screening phase
  - Baseline phase
  - Treatment phase
  - Post-treatment phase

# Study Procedures-Discontinuation

- When & how to withdraw subjects from the trial
- Type & timing of data collected for withdrawn subjects
- Whether or not to replace subjects
- Follow-up procedure for withdrawn subjects
- Reason for withdrawal (GCP 6.5.3)

# Statistical Analysis

- Size of treatment effect that is deemed clinically significant
- Sample size calculation & justification
- Plan of analysis
- Significance level
- Interim analysis, if applicable
- Procedure for accounting for missing data, withdrawals, etc. (GCP 6.9)

# Ethical, Regulatory and Administrative Issues

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- Consent: Procedure for administration of informed consent
- REB review: Institutional reviews for approval
- Statement of GCP compliance (GCP 6.2.5)
- Confidentiality statement
- Record retention: who is responsible and how long



# Ethical, Regulatory and Administrative Issues, cont'd

- Monitoring: timing and purpose of monitoring
- Publication policy (GCP 6.15)
- Direct access to source documents (GCP 6.10) .....”the sponsor should ensure that it is specified in the protocol that the investigator/ institution will permit direct access to source documents”

# Ethical, Regulatory and Administrative Issues, cont'd

- SAE reporting: responsibilities of sponsor and investigator
- Procedures used with early termination of subjects/study
- General considerations for CRF completion and handling
- Procedures for developing study budgets and schedule of payments

# Title Page (as per GCP 6.1)

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- Title
- Protocol identifying number
- Protocol version number
- Date
- Amendment number and date, if applicable
- Sponsor's name and address and telephone number

# Title Page, cont.

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- List and signatures of main/resource people involved (titles, addresses, contact numbers)
  - Protocol authors (Therapeutic recreation Specialist and Statistician)
  - Sponsor's Monitor
  - Sponsor's Study Manager
  - One consulting/co-ordinating Investigator (or qualified Therapeutic Recreation Specialist)

# Title

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Should include at least:

- Interventions
- Applications

Optional:

- study design
- study objectives
- duration of therapy

# Next page...

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- Table of contents
- List of abbreviations

# References

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- list of publications referenced in the protocol
- general guidelines for referencing are available on the Internet
- be sure to read and use original source article

# Appendices

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Study Flow Chart

Questionnaires:

- Specifically developed by company/investigators to be used in study
- Other standardized questionnaires used in study

Guidelines for:

- use of devices used in the study



# Appendices-con't

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Used to be, but no longer:

- Tri-council Policy Statement - Canada
- Copy of ICH GCP
- Copy of informed consent form
- Copy of the CRF

# Study Overview/Synopsis/Outline

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- Type of study design
- Study Objectives
- Method of randomization
- Study duration (number of days, weeks)
- Number and type of visits/periods

# Reference

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ICH-GCP Guidelines: [www.ICH.org](http://www.ICH.org)