DRAFT TEMPLATE FOR WRITING HOMEOPATHIC CLINICAL TRIAL PROTOCOLS– VERSION-I

Title

[The Title is short yet powerful description of the study to be undertaken. It may include phase, design, site, drug, and target disease(s)]

Example: A phase II, randomized, double-blind, placebo-controlled, multi-center study of the effects of XXXX on infarct size in subjects with diabetes mellitus presenting with acute myocardial infarction.

Study Summary

Title	
Short Title	
Methodology/Design	
Study Duration	
Study Centre(s)	
Objectives	
Number of patients	
Source of patient population	
Diagnosis and Inclusion Criteria	
Exclusion Criteria	
End points	
Type of homoeopathic approach (Acute/Chronic/Individualized/Miasmatic)	
Dose & Route	
Repetition & Frequency	
Duration of treatment/therapy	
Whether Placebo controlled, if yes, details of placebo	
Statistical methodology to be used	
Study Team (Names only)	
Protocol preparation team (Names only)	
Protocol amendments	
Revisions	

Study Team

S. No.	Name	Degree/ Affiliation	Correspondence Address	Contact Number	Email Id	Role in study	Has similar work undertaken by the team member in past?

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Table of Contents

List of Abbreviations

Introduction

The introduction should be written in a simple yet informative way. It must be addressed in a clear manner so that it is comprehensible to readers who don't have specialist knowledge in that area. It must clearly state and, if helpful, illustrate the background work done. It must include a summary of a search of the literature to indicate why this proposal is necessary and what it aims to contribute to the field. The section should end with a brief statement of what is being reported in the article. Broadly the subsections of introductions may be:

Background information

Preclinical studies done

Prior research work done/Clinical research/Case Studies/Case Series/Observational/Cohort etc.

Rationale/need of undertaking study

Proposed/Expected role (Hypothesis) of Homoeopathy in condition(s) to be studied

Study Objectives

Primary objective(s)

Secondary objective(s)

Study Design

Type of design adopted

Phase of the study (in details)

Endpoints

Primary endpoint(s)

Secondary/Safety end points

Subject Selection

Inclusion Criteria

Exclusion Criteria

Proposed sample size

If same size is calculated on the basis of previous pilot/clinical research, a clear explanation must be given here.

Subject Screening, Recruitment

Source of Patient Population

Screening Process

Recruitment/Enrolment of Subjects

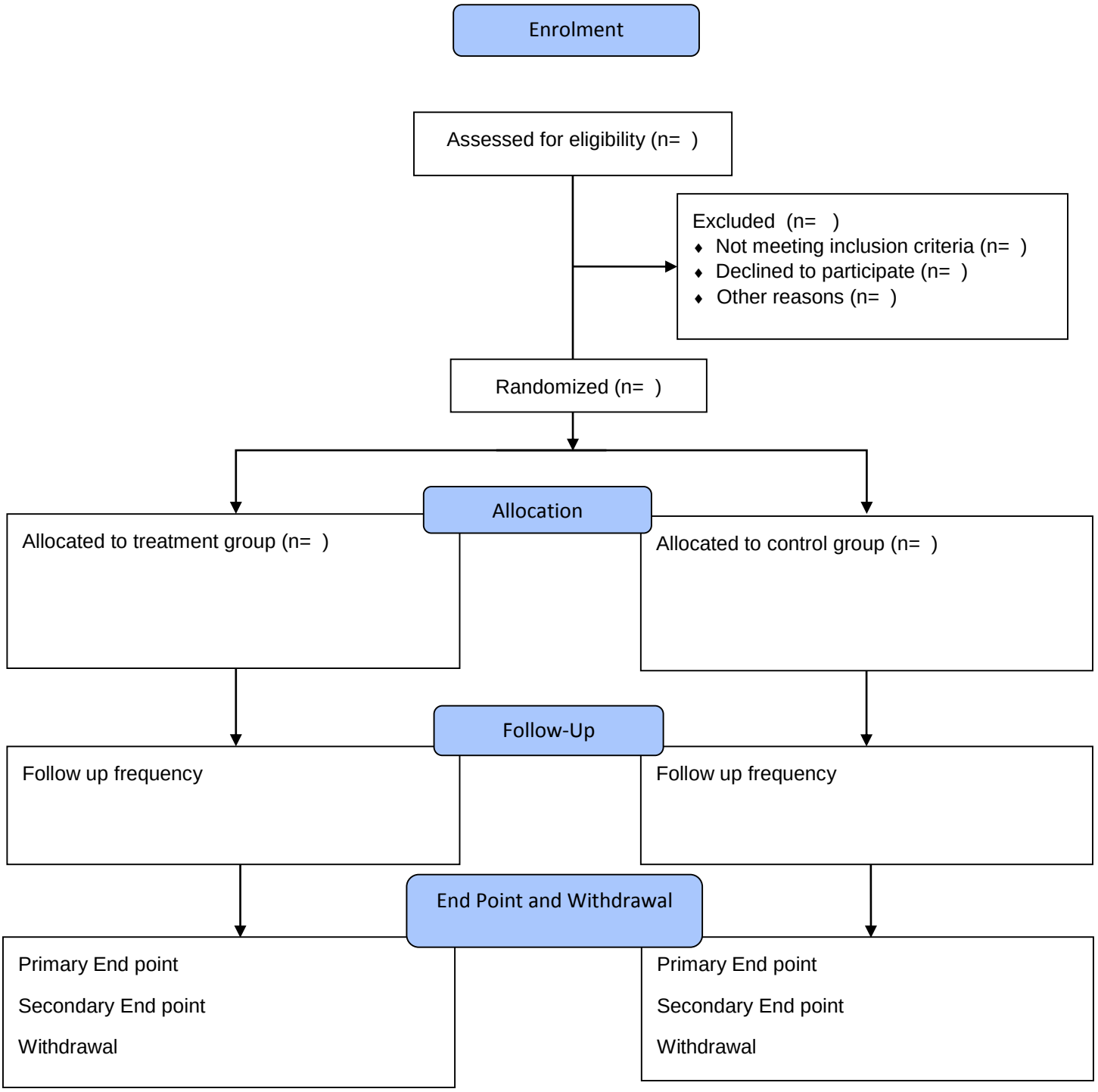
Study Site

Randomization

Method for Assigning Subjects to Treatment Groups

Description of Intervention and Control group(s) and their allocation

Flow diagram of enrolment, screening and allocation (As per CONSORT)



Outcome measures

Primary Outcome Measure

Secondary Outcome Measure

Sensitivity/Specificity/Reliability of Investigations to be done

Repetition of Investigation – Investigative Follow up

Follow up outcome measures table

Follow Up

The follow up may depicted in flow chart which is easier to comprehend.

Treatment

Study Drug(s)

Treatment Regimen

Procurement and Administration of Study Drug

Selection of Medicine

Selection of Potency

Dose

Prescription

Change of Prescription

Subject Compliance Monitoring

Steps to Maximize Adherence and Retention

Withdrawal

When and How to Withdraw Subjects

Early Withdrawal of Subjects

Data Collection and Follow-up for Withdrawn Subjects

Statistical Plan

Sample Size Determination

Statistical Methods

Subject Population(s) for Analysis

Safety and Adverse events

Definitions

Recording of Adverse Events

Reporting of Serious Adverse Events and Unanticipated Problems

Unblinding Procedures

Stopping Rules

Monitoring

Data Handling and Record Keeping

Confidentiality

Source Documents

Records Retention

Study Monitoring, Auditing, and Inspecting

Auditing and Inspecting

Ethical Considerations

Data and Safety Monitoring Board (DSMB)

Study Finances

Logistics and Manpower

Budget requirements (head wise and item wise) with detailed break-up year wise

Total Grant-in-Aid required for the study

Publication Plan

Study time line/Milestones

Protocol amendment

References

Preferably in Vancouver style

IPR values

Annexure

Case Taking Proforma

Logistics required

Patient Information Sheet

Consent Form

Family History Form

Memorandum of Understanding

Etc.