Contents of the Research Protocol

General Information

- Protocol title, identifying number, version number, and date.
- Name and address of the sponsor and applicant (if other than the sponsor).
- Names and titles of the investigators responsible for conducting the study, and the address and telephone number of the trial sites.
- Name, title, address, and telephone number of the qualified physician who is responsible for all study–related medical decisions.
- Names and addresses of all institutions involved in the study (including clinical laboratories and other medical or technical departments).
- Addresses and telephone numbers of all clinical laboratories and/or institutions involved in the trial.

Background Information

- A description of the issue the study is addressing as well as its public health significance.
- Findings from clinical or nonclinical studies that may be significant to the proposed study.
- Summary of the known potential risks and benefits to human participants.
- A statement that the trial will be conducted in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
- Description of the study population.
- References to relevant literature and data
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Study Objectives and Purpose

A detailed description of the major (primary) and minor (secondary and exploratory) objectives and the purpose of the trial.

Study Design

The scientific integrity of the study and the credibility of the data obtained from the study largely depend on the study design. This section of the protocol should describe:

- Primary and secondary endpoints to be measured and how they will be measured.
- Study type (e.g., double-blind), with a schematic diagram of the study design, procedures, and stages.
- Measures that will be taken to avoid or minimize bias (e.g. randomization, blinding).
- Dosage and dosage regimen, dosage form, packaging, and labeling of investigational products.
- Expected duration of participant participation, sequence and duration of all study periods, including follow–up.
- "Stopping rules" or "discontinuation criteria" for individual participants, parts of the study, and the entire study.
- Accountability procedures for the investigational product, including the placebo and comparator.
- Maintenance of study treatment randomization codes and procedures for breaking codes.
- Identification of any data to be recorded directly on the CRFs and considered to be source data.

Selection and Withdrawal of Patients (optional)

- Criteria for inclusion and exclusion of participants.
- Procedures for withdrawal of participants (participant or investigator-initiated):
    - When and how to withdraw participants from the study/investigational product treatment.
    - Type and timing of data to be collected for participants who withdraw from the study.
    - Whether and how participants are to be replaced.
    - Follow–up for participants withdrawn from trial treatment.

Treatment of Participants (optional)

- Pharmacological treatment:
    - Names of all products to be administered.
    - Doses.
    - Dosing schedules.
    - Method(s) of administration (i.e., oral, intramuscular).
    - Other medications or treatments permitted (including rescue medication) and not permitted before and/or during the study.
- Other interventions (i.e., chiropractic, physical therapy, social therapy, behavioural therapy, counseling):
    - Name of intervention (i.e., Motivational Interviewing, Cognitive Behavioural Therapy).
    - Frequency of sessions.
    - Duration of each session.
    - Method of each intervention (i.e. individual, group).
    - Treatment adherence.
- All interventions:
    - Period(s) of intervention, including follow–up periods for participants in each group.
    - Procedures for monitoring participant compliance.
    - Identification of who will administer an intervention.

Statistics

This section describes the strategy for analysing the data collected during the study, including:

- Statistical methods to be employed, including the timing of any planned interim analyses.
- Total number of participants to be enrolled. (In multi–centre studies, the minimum and maximum number of participants to be enrolled at each study site should be specified.)
- Reason for the choice of sample size, including reflections on (or calculations of) the power of the study and clinical justification.
- Level of significance to be used.
- Criteria for termination of the study.
- Procedure for accounting for missing, unused, and false data.
- Procedures for reporting deviations from the statistical plan (any deviations from the statistical plan should be described and justified in the protocol and/or in the final report, as appropriate).
- Selection of participants to be included in analyses (e.g. all randomized participants, all dosed or treated participants, all eligible participants, all evaluable participants, per a stated definition of “evaluable”).

Ethics and Data Management

This section should describe ethical considerations relating to the study and measures taken to protect human participants and maintain confidentiality of study data.

A detailed data management plan describing the way study data will be gathered, documented, submitted, verified, and archived should be included.

The data management plan describes the procedures that will ensure data integrity throughout the study and at all study sites, including:

- A description of the data system design and development.
- Data collection methods and activities.
- Methods of data entry and editing.
- Procedures for data monitoring (including query resolution), reporting, and transfer.
- Data recipients and procedures for data dissemination.
- Handling of personal data (anonymization/ pseudonymization)

Financing and Insurance (if applicable)

This section describes how the study will be financed and insured.

Supplements

This section supplies any additional information that may be required, depending on the nature of the research. For example, the informed consent template, the therapy manual, a patient information handbook, etc., may be included as attachments.

References

https://gcp.nidatraining.org