

Non-FDA Regulated Clinical Trial Protocol Checklist

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The **bolded items below** represent information the institutional review board (IRB) expects in a protocol for this type of research. The non-bolded items should be included in the research protocol as applicable and are considered best practice.

STUDY INFORMATION

High-level detail about the study and Principal Investigator (PI)

Study title (must match title in eResearch)

Date of initial protocol version

Dates of subsequent protocol versions

Protocol version number

PI name, contact information, U-M department affiliation

PI responsibilities

Specialized training, skills, or qualifications required for study team members

Sponsor information

Statement of compliance

PROTOCOL SUMMARY

Brief overview of the clinical trial

Study description/synopsis (table or abstract), **including the hypothesis(es) or research question**

Study Aims

Primary study objective (include secondary objective, as applicable)

Endpoints (measurable outcome) **for the objectives**

Population, sample size

Study location/centers (types, multi-site indication)

Study duration

Phase/stage (as applicable)

SCHEDULE OF ACTIVITIES

Display of procedures that will be accomplished for each interaction with study participants. Include visits, contacts/touchpoints and timeframes.

Schedule of activities (table, abstract, list, study schema, flowchart, CONSORT or STROBE diagram format acceptable)

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BACKGROUND & RATIONALE

Overview of the relevant background information and rationale for the study. It should include a clearly stated research question or study purpose.

Study background (key information/data that contributed to the hypothesis or research question)

Research question, detailing as applicable:

Study rationale

Justification for interactions/interventions

Study aims, hypothesis(es), objectives

Outcomes/endpoints details

STUDY POPULATION

Description of the study population.

Anticipated enrollment numbers (n) and attrition rate

Age range of study population

Inclusion and exclusion criteria and how they will be applied

Any expected changes in legal or cognitive capacity of participants (e.g. children coming of legal age, adults with dementia)

STUDY DESIGN

Description of the research methods and procedures.

Overview of study design and type (e.g., parallel groups, cross-over, factorial, single group, SMART, step-wedge, etc.)

Framework of study (superiority, equivalence, noninferiority, exploratory, etc.)

Interaction/intervention details

Duration of interactions/interventions, including follow-up period(s)

Permitted and prohibited alternative procedures

Method and criteria for randomization and allocation of participants, including control groups

Blinding methods and procedures

Number of expected sites and list of participating sites (as applicable)

Plan for communicating among sites (data, protocol modifications, etc.)

RISKS & BENEFITS

Description of any physical, psychological, social, legal, economic, or informational risks to participants or others, and potential benefits to participants or others.

Known risks to participants and likelihood of their occurrence

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Known potential benefits to participants, community or society

Assessment of risk/benefit ratio

Risk mitigation plan

RECRUITMENT

Description of how, when, and who will recruit, methods for recruitment, and where recruitment will occur.

Planned recruitment strategies

Pre-screening activities and/or procedures to identify potential participants

Use of any established subject pools

INFORMED CONSENT/ASSENT

Description of the process of obtaining consent and/or assent.

Informed consent/assent process (who, what, where, when, and how)

Recording/documentation of consent/assent

Justification for waiver of documenting consent/assent

CONFIDENTIALITY AND PRIVACY

Describe practices and strategies for preserving and supporting participant privacy and confidentiality of study data.

Plans to ensure privacy during research activities

Plans to maintain confidentiality after collection of data

DATA ANALYSIS PLAN

Describe the general approach to data analysis, including the coding, interpretation and reporting of the study data.

Data analysis methods (statistical tests, assessments, etc.)

Sample size and accrual target

Justification of sample size/power analysis

Plans for interim analysis

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DATA MANAGEMENT AND SHARING

Describe the plan for the management of the study data (i.e., organization, documentation, storage, and preservation). Define the circumstances and criteria for sharing study data and/or biospecimens with other researchers.

Data identification, and plans for de-identification

Who will have access to study data/biospecimens

How will data/biospecimens be shared

Shared data/biospecimen identifiability

Data organization methods (coding, identifiers, metadata)

Data storage methods and timeframes, including access and archiving considerations

Data collection and management responsibilities

Data access, distribution, or reuse considerations

Names of data/biospecimen repositories used for sharing

Description of data/biospecimens to be shared

DATA SAFETY AND MONITORING PLAN

As applicable, describe how the study's conduct and progress will be independently monitored for quality assurance and control.

Monitoring plan, including the monitoring body (who), type, frequency, extent, reporting responsibility, auditing responsibility

Clinical monitoring/assessments

Data Safety and Monitoring Board information

STUDY COMPLETION/ OFF STUDY CRITERIA

Describe the criteria for participant completion of the study, participant withdrawal or discontinuation, and early termination or suspension of the study

Criteria for an individual participant's completion of the study

Plan for participant's data and/or specimens upon withdrawal

Plan for early termination or suspension of the study

Subject replacement plan

ADVERSE EVENTS & UNANTICIPATED PROBLEMS

Identify how the study team will report adverse events, etc. to the IRB and/or others, as applicable.

AE reporting timetable

Grading and/or adjudication regarding type of event

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PROTOCOL DEVIATIONS

Describe protocol deviation reporting plan and planned deviations.

Deviation reporting plan

Planned deviations

REFERENCES

Citations and References

List of abbreviations

Appendices