HUMAN RESEARCH PROTECTIONS PROGRAM
UNIVERSITY OF MICHIGAN

U-M General Human Research Protocol Checklist

Table of Contents

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

Summary of overall study plan.

- ☐ **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**
- ☐ **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/schema** (table, abstract, list, study schema, flowchart, CONSORT or STROBE diagram format acceptable)

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 study population.

- ☐ **Anticipated enrollment numbers (n) and attrition**
- ☐ **Age range of study population**
- ☐ **Inclusion/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., descriptive, correlational, causal-comparative, quasi-experimental, experimental, survey)
- ☐ Randomization & allocation of participants
- ☐ **Interaction/intervention details**
- ☐ Duration of interactions/interventions
- ☐ 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 other risks to participants and potential benefits to participants or others.

- ☐ **Known potential risks to participants and likelihood of their occurrence**
- ☐ **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**
- ☐ **Identification and approach of potential participants**
- ☐ Pre-screening activities
- ☐ 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

Describe the general approach to data analysis.

- ☐ **Approach to analysis/analysis plan**
- ☐ **Sample size and accrual**
- ☐ Justification of sample size/power analysis
- ☐ Plans for interim analysis

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 the completion of the study and next steps.

- ☐ **Criteria for an individual participant's completion of the study**
- ☐ **Plan for participant's data and/or specimens upon withdrawal**
- ☐ Subject replacement plan
- ☐ Plan for early termination or suspension of the study

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

PROTOCOL DEVIATIONS

Describe protocol deviation reporting plan and planned deviations.

- ☐ **Deviation Reporting Plan**
- ☐ Planned deviations

REFERENCES

- ☐ Citations and References

- ☐ List of abbreviations
- ☐ Appendices