

## Cedarville University IRB Submission Proposal

Project Title

Principal Investigator

- a. Name
- b. Phone
- c. Email

Co- or Sub-investigators

- d. Name(s)
- e. Phone(s)
- f. Email(s)

Faculty Advisor (if student-led research)

- g. Name
- h. Phone
- i. Email

Funding Agency Name

(Please list the name of the funding agency supporting the project. If not applicable, you may skip this section.)

Proposal Version:              Date

(Enter the submission date for the current version of the proposal. Please add the new date each time the protocol is revised and resubmitted.)

### Project Synopsis

Study Duration	
Study location(s)	
Research Question(s) or Hypotheses	
Number of Participants	
Main Inclusion/Exclusion Criteria	

## 1. Background and Rationale

Instructions for this section:

- This section specifies the reason(s) for conducting the research. Primary investigators should include the purpose of the research, the research question(s), and how the research will contribute to existing knowledge;
- Include previous research (e.g., pre-clinical and clinical studies) leading up to and supporting the purpose of the research;
- Rationale for conducting the research (including the potential benefits to individuals, society, literature, etc.);
- This section should include references and descriptions of the most relevant studies published on the subject; and
- Primary Investigators should submit references as an appendix at the end of the proposal.

## 2. Research Question(s) and/or Hypotheses

Instructions for this section:

- Specify the key research question(s) being answered and/or the key hypotheses being examined;
- Research questions and/or hypotheses should use simple, specific language. Do not use discipline-specific professional jargon; and
- List and number each question and/or hypotheses individually.

## 3. Participant Selection and Recruitment

Instructions for this section:

- Address inclusion and exclusion criteria;
- Identify the participant population targeted for the research. Include total anticipated enrollment numbers and any group/cohort breakdown numbers;
- If not recruiting actual participants (e.g. database query for eligible tissue samples, secondary analysis of existing data), state how and who will identify eligible samples/data;
- If excluding a particular population (such as males or females, non-English speakers, certain age groups) provide a justification for the exclusion;
- If including any vulnerable populations (children, pregnant women, prisoners, diminished capacity, non-readers, etc.), state why their inclusion is important, any specific benefits, and any additional protections;
- Methods of recruitment and enrollment;
- Describe any randomization processes, if applicable;
- Sampling (if applicable): explain how sampling will occur; and
- Describe the process for handling withdrawals of participants.

#### 4. Consent process and procedures;

Instructions for this section:

- Describe the location and circumstances of the consent process (e.g., private setting, group setting, online, through email or postal service, over the phone, etc.). **If the location is outside of Cedarville University, IRB approval will be contingent on receiving documentation indicating approval from an official representing the agency, business, school, or location;**
- Describe who will conduct the consent discussion with participants (e.g., principal investigator, research assistant/coordinator, co- or sub-investigator, etc.);
- How will it be ensured that participants have sufficient opportunity to consider whether to participate;
- Describe how possible undue influence or coercion will be minimized; and
- Upload consent/assent form(s) as an appendix at the end of the proposal.

#### 5. Research Design and Methods

Instructions for this section:

- Explain the study design and choice of methodology (may include a study schema to provide an illustration);
- Describe any measures taken to eliminate bias;
- State the study duration/timeline;
- If there is incomplete disclosure, deception, placebo, or a sham procedure, provide the rationale, the process, and any de-briefing measures;
- Any test articles being studied, such as:
  - Drugs (dose, method, schedule of administration, dose modifications, and toxicities)
  - Devices
  - Supplements (dose, method, schedule of administration, dose modifications, and toxicities)
  - Food or color additives
- Identify and describe all tools and survey measures. For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this research.

#### 6. Study Activities (if applicable)

Instructions for this section:

- Describe the study activities, including:
  - The procedures and/or interventions

- The parameters to be measured (e.g., lab tests, x-rays, or other testing)
- Administration of questionnaires, surveys, etc.
- The data that will be collected
- Indicate what study activities happen when, including, when applicable, a study schedule that notes number and length of study visits for subjects, such as any of the following
  - Screening for eligibility
  - Enrollment/baseline
  - Treatment/intervention period
  - Follow-up
  - Final study visit
  - Early termination visit
  - Unscheduled visits
- If research includes more than one study session or visit, you may include a schedule of assessments chart to illustrate which procedures occur at a visit.

#### Example Schedule of Assessments

	Visit 1	Visit 2	Visit 3	Follow-up phone call
Medical History	X			
Questionnaire #1	X	X	X	X
Blood draw		X		
Questionnaire #2		X	X	

## 7. Risks and Benefits

Instructions for this section:

- Describe all reasonable foreseeable risks or discomforts in the protocol (or other protocol materials, e.g. Investigator's brochure) and the Consent Form. Classify risks and discomforts as common, uncommon, or unlikely/rare).
  - Include all non-medical risks – psychological, legal, social, financial/economic, etc.
  - Include all medical risks, such as:
    - Complications of surgical and non-surgical procedures.
    - Drug side effects and toxicities.
    - Device complications/malfunctions.
    - Radiation risks.
  - If risks/discomforts listed in a separate document (e.g., investigator's brochure or device manual), this section can be omitted.
  - If it is reasonably possible that a previously unknown condition (an incidental finding) could be discovered about the subject (e.g., disease, mental health, thoughts of harm to self or others, genetic predisposition, etc.), describe how

this will be handled.

- Indicate if any medical or psychological resources are available to participants.
- Benefits \*Compensation/gifts/reimbursements are not benefits.\*
  - Potential benefits to the individual participants.
  - Potential benefits to society.

## 8. Data Security & Privacy/Confidentiality

Instructions for this section:

- Describe the data and/or biological samples collection methodology (including who will perform what tasks and who will have access to the data).
- Describe data protection/security plans during all phases of the research. Specify formats (e.g., hardcopy, electronic file, etc.) and the location [PI office, computer (stand-alone or networked), secure server, mobile device (e.g., flash-drive, external hard drive, tablet, etc.), cloud (specify service/vendor), etc.], and additional protections (password protection, encryption, anonymizing techniques, restricted access, confidentiality agreements, etc.).
- Provide the length of time the data and/or samples will be kept.
- Describe whether data and/or samples will be kept confidential (i.e., data/samples can be potentially linked to participants, such as through a code key) or anonymous (i.e., impossible to link data/samples to participants).
- If there are non-Cedarville collaborators, specify what will be shared with them and explain how it will be transferred and how confidentiality will be maintained (e.g., no identifiers will be sent, only aggregated data sent, etc.).
- If data and/or samples will potentially be shared with other researchers in the future for research purposes not detailed in this study, explain how it will be transferred and how confidentiality will be maintained (e.g., no identifiers will be sent, only aggregated data sent, etc.).
- If data/samples will be destroyed, describe when and how destruction will occur.
- Describe recordkeeping and record retention plans. Specify the format (e.g., hardcopy, electronic file, password protection, encryption, etc.) and the location [PI office, computer (stand-alone or networked), secure server, mobile device (e.g., flash-drive, external hard drive, tablet, etc.), cloud (specify service/vendor), etc.].  
\*Remember that research records must be kept for at least 3 years from the completion of the study.\*

## 9. Data and Safety Monitoring

Instructions for this section:

- For studies that are minimal risk, describe how potential problems will be monitored and handled (e.g., breaches of confidentiality, emotional upset), including procedures for reporting deviations from the approved study plan and procedures

- for recording and reporting unanticipated problems and/or adverse events.
- For clinical studies or research involving more than minimal risk to subjects, describe:
    - Who will monitor adverse events (AEs) and unanticipated problems (UPs) involving risks to subjects or others and when events will be assessed
    - How AEs or UPs will be recorded and communicated amongst research team members and who is responsible for making the reports
    - Identify how often AEs and UPs will be monitored and what events will be reported to the sponsor and/or the IRB
    - Describe stopping rules for the study
    - Describe what occurs if a subject withdraws prematurely

## 10. Publication and/or Presentation Plans

Instructions for this section:

- Describe plans for sharing the findings from the research. List potential publications, workshops, books, videos, webinars, sermons, presentations, and/or social media posts planned to share results of the research.

## 11. Appendices

May include:

- Data collection forms, case report forms (CRFs).
- Study tools (e.g., questionnaires, surveys, instructions, interview protocols, etc.).
- Detailed specimen processing and/or banking procedures.
- Instructions for procedures or devices.
- Literature searches.
- Approval for research at locations outside of the university.