# IRB Application and Research Proposal Outline
## Yo San University
### Institutional Review Board

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<th>For Institutional Review Board Use Only</th>
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<tr>
<td><strong>Date Received:</strong></td>
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<tr>
<td><strong>IRB Log No.:</strong></td>
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<tr>
<td><strong>Reviewer(s):</strong></td>
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<td><strong>Review Type:</strong></td>
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See Chapter 7, Section H, of the *IRB Handbook for Research with Human Subjects* for assistance.

## Signatures (Required)

*I hereby verify that the information provided on this form and in its attachments are true and accurate. I further agree to abide by the decision of the Institutional Review Board.*

_________________________________________  Date _______________________

Researcher’s Signature

For electronic submission, a check mark in this box will serve as a written signature:

*I hereby verify that I have reviewed this application and approve its submission to the IRB. (Faculty advisor’s / dissertation chair’s approval is required for all learners; supervisor’s approval is required for employees.)*

_________________________________________  Date _______________________

Faculty/Advisor/Program Chair or Dean/Supervisor Signature

Approval submitted separately  Approval attached
(by fax, e-mail, pdf, or regular mail)  (separate signed form)

- Use the following page numbering style: Page 1 of 5, Page 3 of 15, etc. Principal investigator’s name and study title should be included on every page—in the header or footer.
- E-mail the application and research proposal and study documents to the IRB Coordinator in MSWord attachment(s) at IRB@yosan.edu (*Electronic submission is preferred.*)
- **No part of the research study, including recruitment, may begin until officially IRB approved. Conditional approval is not final approval.**
**Print and fill out Page one of the IRB application by hand or fill in on line and print; You cannot save the data/form.**

**IRB Application**

1a. Principal investigator’s (PI) name:

**Mailing address (include city, state, country, postal code):**

**Phone numbers:**

*Cell phone number:*

*Home phone number:*

*Work phone number:*

**E-mail address:**

1b. List of key personnel and study staff:

**Note:** All personnel listed below are required to complete NIH PHRP training course. HIPAA training is also required if personnel will be accessing protected health information.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Affiliation***</th>
<th>Obtain Consent? (Y, N or NA)</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
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<tr>
<td>*Co-researcher, if any</td>
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<tr>
<td>Study coordinator, if other than PI</td>
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<tr>
<td>**Other, if applicable</td>
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For the IRB’s purposes, “co-researchers” are individuals who are actively involved in the study design, implementation, data analysis, reporting, etc. Co-researchers’ names are included on the final report.

**if other, specify specific role.**

***Affiliation: Specify **Yo San** or other academic or professional affiliation.
Other individuals may help distribute or pick up questionnaires or surveys or help enter data into a computer. Although they are not co-researchers, they must follow the guidelines for maintaining confidentiality and protecting subject identity.

2. **Type of review requested (Double click to check a box):**
   - [ ] Full  
   - [ ] Expedited

3. **Researcher’s connection to Yo San University:**
   - [ ] Student  
   - [ ] Staff  
   - [ ] Faculty

4. **Student’s degree program:**
   - [ ] MATCM  
   - [ ] DAOM

5. **Student’s area of concentration or employee’s department name:**

6. **Name of faculty advisor / program chair or supervisor:**
   Record “To be determined” if not yet assigned.

7. **Purpose of study (Circle all that apply):**
   - [ ] Capstone  
   - [ ] Dissertation (DAOM)  
   - [ ] Thesis  
   - [ ] Internship  
   - [ ] Seminar  
   Other (specify)

8. **Possible future uses of the study results (Circle all that apply):**
   - [ ] degree program document only  
   - [ ] future professional journal articles  
   - [ ] trade publication(s)  
   - [ ] public presentation(s)  
   - [ ] other (specify)

9. **Media use (Circle all that apply):**
   - [ ] audio recordings  
   - [ ] video recordings  
   - [ ] photographs  
   - [ ] none  
   - [ ] other (specify)

10. **Name of other participating institution(s), if any:** (e.g., researcher’s employer, school, university, clinic, hospital, government or private agency; other).

Submit copies of approval letters from other institutions and IRBs as soon as they become available. YSU’s IRB may grant approval prior to obtaining approval from other participating institution(s).

11. **Prospective funding source(s) including self funding—not financial aid, and the dollar amount:** Include contact name(s), address(es), and telephone number(s); title of study submitted to funding source(s); name of principal researcher if different from name in No. 1. Also include type of funding applied for—grant, subcontract, contract, fellowship, other; and date of planned submission to funding source(s).

12. **Collaborative research:**
   - [ ] Yes  
   - [ ] No

13. **If yes to No. 12:** Include name of lead institution, contact names, addresses, and telephone numbers; names of collaborating researchers, contact names, addresses, and telephone numbers.
14. **Conflict of interest**
Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have a financial interest in the sponsor (profit, non-for-profit) of the research?  
☐ Yes  or  ☐ No

If yes, attach a completed copy of the Financial Disclosure Form

**Required Format and Content for IRB Research Proposals**

**Answer each question under the boldface headings, with each section containing the information described in this outline. Do not ignore or delete items that do not apply; include a statement to that effect. Proposals should be no longer than 15 pages, double-spaced, not including attachments.**

**Research Proposal Outline**

1. **Title of the Research Study/project:**

2. **Purpose and Potential Value of the Study.**
   
   A. State research question(s).

   B. State hypotheses, if applicable.

   C. State reason(s) for conducting this study.  
   *Consider starting with: “The purpose of this study is to...”*

3. **Context of the Study.**
   
   This section allows researchers (you) to place their own research in context within the larger body of knowledge on a given topic. It demonstrates the researcher’s familiarity with the issues involved in their proposed study, including A and B, and thus manifest their qualifications to conduct the study and to confirm potential benefits of the study. *(A worthwhile new contribution cannot be made if one does not know what has been done before.) This may identify research procedures and instruments that have been successfully utilized in the past.***

   **Provide a brief summary of the literature that pertains to your proposed study including at least 5 – 10 references, with a reference list using APA format. While this section can be brief (a few paragraphs will generally suffice), it should included the following:**
   
   A. **Justify the importance of the study;**
   
   • Why is your study important or needed?
B. **Place the study in historical perspective;**
- Provide a brief initial review of the literature you have located on your topic.
- Describe what specific part you plan to study; what gap in the literature will your research fill?
- Does it hope to confirm a finding that has already been reported, but is not generally accepted? Does it help to clarify conflicting results in the literature? Does it provide new findings?
- What will your study add to the body of knowledge?

**References must be cited in APA format in this section.**

4. **Location of the Study.**
Identify study locations where you will meet with participants, including the Internet (e.g., school, library, homes, and so on).

For Literature Review: Consider stating “This study will be conducted on PI’s personal computer and through internet library links”.

5. **Dates of the Study.**
Proposed start date must be after the date of IRB approval of the application, and estimated duration of the study should include all your interactions with all subjects—the entire data-collection process, which may include follow-up questions or clarifications.

Consider: “Research will begin on November 20XX and will end by January on 20XX (13 months later).”

6. **Academic discipline that guides the research study / project protocol:** (e.g., acupuncture, western medicine, Qi Gong, cultural studies).

7. **Subjects (Participants).**
If no human subjects will be enrolled, state “There will be no human subjects enrolled in this study.”

A. Indicate the maximum number of study participants you hope to enroll:

B. How many participants do you expect you will need to recruit, consent and/or screen to meet the target number above?

C. Indicate the **specific inclusion criteria** for enrollment of each of the groups of research participants in this study. Include demographics (e.g., children, students, adult women, specific profession, age, race, gender, and so on).
If there are any inclusion criteria based on gender, pregnancy/childbearing potential, race, ethnicity or language spoken, explain the nature of and scientific rationale for the inclusions.
D. Indicate the specific exclusion criteria for each of the groups of research participants in this study. (Describe characteristics or other factors that will make an individual ineligible (e.g., outside the designated age range; not in selected profession; not a first-generation college graduate). If there are any exclusion criteria based on gender, pregnancy/childbearing potential, race, ethnicity or language spoken, explain the nature of and scientific rationale for the exclusions.

E. Identify and describe participants in a protected population, if any. (See IRB Handbook, Chapter 3.)

8. Sensitive data collection: (Circle one: substance abuse, sexual behavior/orientation/abuse; criminal activities; none; other (specify);)

(See Protected Populations in IRB manual.)

9. Participant Payment and/or Costs.

If no human subjects are enrolled, state “There will be no human subjects enrolled in this study and therefore this is not applicable.”

If you will enroll human subjects, state whether any type of payment will be offered to subjects for participating. If you will not pay participants, state that participants will not be paid.

A. Describe any other offered payments or incentives (e.g., a snack or tee shirt).

B. Describe the conditions under which the payment or incentive will be made (e.g., only after completing the study; for all participants even if do not complete the study). Note: If participants are students and will receive extra credit as incentive to participate, you must provide an alternative of equal or greater value to any students who do not participate.

C. Describe any likely participant expenses, such as for travel, food, or parking, while participating in the study. If you will reimburse participants, state the form of evidence of expenses (e.g., parking receipts, mileage estimates, food receipts) needed for reimbursements.


If no human subjects are enrolled, state “There will be no human subjects enrolled in this study and therefore this is not applicable.”

A. Describe the recruitment process (in person, by telephone, letter, or e-mail), media used (ads, flyers, letters, brochures, posters, e-mail messages, or Web site notices, etc.), including for non-English speaking potential participants.

B. How do you want potential participants to contact you for questions and/or to volunteer (in person, telephone, e-mail)?
C. Describe what participants will be asked to do over the course of the study.

D. State the total time commitment for participants. (This estimate should include any follow-up interviews, debriefings, etc.; not your time to prepare and/or analyze data.)

11. Participant Confidentiality.
If no human subjects are enrolled, state “There will be no human subjects enrolled in this study and therefore this is not applicable. Only public record of already de-identified participants will be used.”

A. Will you, the researcher (and any co-researchers), know participants’ names or otherwise be able to identify them? If yes, they are not anonymous subjects.

B. How will you preserve participant confidentiality and identity during the study and after the study is concluded (e.g., number codes, pseudonyms, collect and place surveys and informed consent forms into separate envelopes, other)?

C. How will study records be secured during the study? Where will they be maintained? Who will have access to them?

D. State whether anyone other than yourself and any co-researchers, such as a transcriber, data-entry person, witness for informed consent, tester, etc., will have access to study data. Describe this person’s qualifications and how you will ensure that he/she maintains subject confidentiality and identity protection.

E. When will study records and data be destroyed (three years minimum required after study is completed) and by whom? All links between participants’ names and their code numbers or pseudonyms should be destroyed when the study is completed.

12. Data Collection, Analysis, and Reporting.

- Describe methodology (ies) you will use to collect and analyze data.

- For Research Synthesis, state “Research Synthesis data will be compiled through online literature searches of peer-reviewed journals via the the following databases: *ie: PubMed, eCAM, HighWire, Google Scholar, BioMed Central*

- List all search terms

- No research older than what year (20xx) will be used

- Subject type- human, animal or both

- Article languages ie English, Chinese

- Types of publications ie: Published books, classroom notes and lectures

- Include any additional inclusion/exclusion criteria that are applicable
B. Describe any surveys, questionnaires, or other data-collection instruments used in your study and how the instruments were developed and tested, and provide validity / reliability information, if applicable. Provide a copy of permission to use instrument if needed.

C. Include hard copy of survey or questionnaire or links to Internet surveys, questionnaires, online focus group interview, questions, Web sites, etc., after instrument is available for review online. Describe how the survey or questionnaire or other data collection instrument will be used in your study.

D. Describe any audio or video recordings or photographs, if any, to be made during the study and how they will be used in degree program documents and future publications, professional presentations, exhibitions, other.

E. Expert interviews: State whether or not you will conduct them. Provide questions to be asked, format, and attach Interview Consent Form.

F. Describe how you will report the data and to whom (e.g., dissertation / thesis / culminating project presentation and report, future journal articles, future professional presentations, other).


If not applicable, state “No informed consent will be needed for this research synthesis because no subjects will be enrolled.”

A. Describe how and when you will present the informed consent form to participants and obtain assent (children) / consent (e.g., public presentation, regular mail, or email, at interview, when distribute survey).

B. State how you will answer questions about the study (e.g., telephone, e-mails, face-to-face discussions, when present consent form before interview, or when distribute surveys).

C. Describe your informed consent process for children under the age of 18, for participants with mental or physical disabilities, or for participants who speak a language other than English.

D. How will you ensure that children give their assent freely with no influence from parents/guardians or coercion from a teacher/instructor or other authority figure?

E. Will you prepare a separate consent form for the use of audio or videotapes, photography, or other media and for public release of real names and photos? If yes, describe it and submit with the appropriate form.

F. Describe how will you ensure that the participant—child or disabled person—also consents to participate (to the extent that he or she is able to give consent) if a participant’s parent, guardian, or legal representative must sign a consent form?
G. Provide appropriate forms and explain how authorizations / permissions will be obtained from participants if the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Rule applies to your study; (e.g., typically in hospital or other health facility settings when collecting personal health information (PHI)).

H. For expert interviews, attached proper informed consent form and well as questions to be asked.

14. Expected benefits

A. Describe potential benefits (write may benefit, not will benefit) for participants (if none, state none).

B. Describe potential benefits (write may benefit, not will benefit) for the larger community (e.g., knowledge gained from study, possible implementation of new curriculum; contribution to the literature on the topic).

*Examples of larger community: Western and Traditional Chinese Medicine, patients.*

15. Potential risks.

**If no human subjects are enrolled, state:**

*No human subjects will be enrolled in this research project. Therefore, there are no risks.*

A. Describe all potential risks to participants (physical, social, cultural, emotional (includes embarrassment), psychological, legal, etc.).

B. Describe precautions to minimize risks (e.g., number codes, pseudonyms).

C. Describe procedures used to provide data protection in the event of an unanticipated event (e.g., computer crash, loss of confidentiality).

D. Explain how you will handle situations in which a participant becomes emotionally upset or angry when responding to sensitive interview or survey questions (e.g., stop the interview, offer to refer participant to an affordable, no-cost, or full-service counseling service at the participant’s expense).


Evaluate potential risk(s) in relation to expected benefits to participants and others. Benefits must outweigh risk.

If no human subjects are enrolled, state:

*No human subjects will be enrolled in this research project. Therefore, the benefits outweigh the risks.*

17. Attachments.
• Attach all the following documents that apply to your study:
• Financial Disclosure Form
• Recruitment materials—letters, notices, posters, e-mails, presentation scripts
• Informed consent forms / letters / scripts / handouts, including translations and Interview informed consent form (for expert interviews)
• Questionnaires / surveys / other data-collection instruments
• Interview questions or guide
• Resumés for researcher and co-researchers, if any; (not needed for assistants).
• HIPAA information and authorization / permission forms
• Confidentiality agreements, if used, for any individuals who will assist in the collection, synthesis, and/or analysis of data; e.g., transcribers, statisticians, data entry persons
• Professional association ethical guidelines (NCCAOM) for Human Subject Trials
• Data extraction Form