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

For Institutional Review Board Use Only	
Date Received:	Degree Program or Department:
IRB Log No.:	Certification / Approval Date (if applicable):
Reviewer(s):	Date Forwarded for Review:
Review Type: ☐ Review for Exemption ☐ Expedited Review ☐ Full Review	

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 (by fax, e-mail, pdf, or regular mail)

☐ Approval attached (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.**

IRB Application

1. **Principal investigator's (PI) name, mailing address (*include city, state, country, postal code*), and contact information (*include home, work, and cell telephone numbers as well as e-mail address*):**

2. **Type of review requested:**

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:**

7. **Title of research study / project:**

8. **Purpose of study:**
   dissertation thesis culminating study methods course
   capstone learning experience seminar internship other

9. **Possible future uses of the study results (*indicate all that apply*):**
   degree program document only future professional journal articles
   trade publication(s) public presentation(s) other

10. **Media use:** audio recordings video recordings photographs
    none other

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

12. **Subject / participant information:** (e.g., age range, target population); include members of protected populations such as children ages 2–12; pregnant women; neonates / newborns / infants less than age 2; adolescents ages 13–18; other (specify).

13. **Number of participants:**

14. **Sensitive data collection:** (e.g., substance abuse, sexual behavior / orientation / abuse; criminal activities; other; none).

15. **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).

16. **Co-researcher(s):** Include names and institutional affiliations; attach resumes.

17. **Prospective funding source(s)—not financial aid:** Include contact names, address, and telephone number; title of study submitted to funding source(s); name of principal researcher if different from name in No. 1 (e.g., from funding source); type of funding applied for—grant, subcontract, contract, fellowship, other; date of planned submission to funding source(s).

18. **Collaborative research:** Yes No

19. **If yes to No. 18:** Include name of lead institution, contact names, addresses, and telephone numbers; names of collaborating researchers, contact names, addresses, and telephone numbers.

Required Format and Content for IRB Research Proposals

Use the following bold face items as headings, with each section containing the information described in this outline. Do not ignore items that do not apply; include a statement to that effect. Proposals should be no longer than 15 pages, double-spaced, not including attachments.

[*No need to include the text of lettered questions (A, B, C, D) or Notes in responses; just supply requested information*.]

Research Proposal Outline

1. Name / Title of the Study.

2. Name of the PI (and co-researchers, if any).
Note: 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. Co-researchers are not participants / subjects whom the PI has chosen to call "co-researchers." 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.

3. 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.
D. Describe anticipated value of the study to the larger community (i.e., what you expect to learn, and how it will be of value to others).

4. Context of the Study.
Provide a brief summary of the literature review that pertains to your proposed study (just a few paragraphs will suffice) and a brief bibliography or reference list that includes entries pertinent to your proposed study. While this section can be brief, it should demonstrate your familiarity with the issues involved in your proposed study and thus manifest your qualifications to conduct the study and to confirm potential benefits of the study.

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

6. Dates of the Study.
Month/day/year that you wish to begin collecting data and month/day/year that you expect the study to conclude data collection and all interactions with participants.

Note: 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.

7. Subjects (Participants).
List characteristics of potential participants, including demographics (e.g., children, students, adult women, specific profession, age, race, gender, and so on).
A. Identify and describe participants in a protected population, if any. (See IRB *Handbook,* Chapter 3.)
B. Describe eligibility criteria for participation in the study (e.g., women between the ages of 18 and 25; first-generation college graduates).

C. Describe characteristics or other factors that will make an individual ineligible—the exclusion criteria (e.g., outside the designated age range; not in selected profession; not a first-generation college graduate).

8. Participant Payment and/or Costs.

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.

9. Methods and Procedures for Recruitment and Participation.

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.)

10. Participant Confidentiality.

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.

11. Data Collection, Analysis, and Reporting.

A. Describe methodology(ies) you will use to collect and analyze data.
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. Provide a copy of permission to use instrument if needed.
C. Include links to Internet surveys, questionnaires, online focus group interview questions, Web sites, etc., after instrument is available for review online.
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. 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).

12. Informed Consent.

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 e-mail, 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)).

13. Expected benefits.

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

14. Potential 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).

15. Risk-to-Benefit Ratio.

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

16. Attachments.

Attach all the following documents that apply to your study:

- Recruitment materials—letters, notices, posters, e-mails, presentation scripts
- Informed consent forms / letters / scripts / handouts, including translations
- 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