Adler Graduate School Institutional Review Board Application
Cover Page and Checklist

Date Signed

Date Submitted

IRB Staff Only

______   Date(s) Reviewed
______   Date Additional Information received (if applicable)
______   Date Approved

Contents (Check all that apply). Please list here (and include with your application) all forms, questionnaires, a sample consent document, demographic sheets, any advertising intended to be seen or heard by prospective and recruited study participants, and other materials to be used with participants.
Adler Graduate School Institutional Review Board Application

✓ COMPLETE the form by inserting your responses.
✓ All responses need to be typed.
✓ Click on a gray area next to a question and start typing. The gray area will be expanding as you type.
✓ For Yes-No questions or other gray boxes, click on a gray area/box and type an X mark, where needed. Do not delete gray boxes next to the questions/options that you have not chosen.
✓ You cannot delete any text in this application.
✓ Be sure to answer all questions completely. Applications with any missing information/unanswered questions will be returned. If a question is not applicable, answer “N/A” rather than leaving the question unanswered.
✓ Please edit the header by typing your name and the title of your project.
✓ Once completed and before being submitted, the application needs to be saved as a PDF file. When hard copy materials are required, these documents must be added to the application as additional files.
✓ Please make sure that the signature page (p. 24) and the IRB decision page (p. 25) remain two separate pages.
✓ Each file must be saved with your first name, last name, the words AGS and IRB, and the version number (based on a number of revisions) as a document name. For example, Jane Doe will have her first file saved as JaneDoeAGSIRB1.
✓ EMAIL the completed form as an attachment to: IRB@alfredadler.edu, IRB-Chair.

Please check below the type of application you are submitting on this date:

| Full IRB Review | Request for Exempt/Expeditied Review |

Principal Investigator:

Full address

Phone(s) #:

Email:

Co-Investigator (if applicable):

Phone #:

Email:
Project Title

Are any other organizations involved? □ Yes  □ No

If answered Yes, agency/organization title and the name (names) of responsible parties; and brief description of involvement

If answered Yes, and the proposed research involves human subjects, was the permission to use human participants requested and granted through the organization’s IRB? □ Yes  □ No

If answered Yes to the question above, please submit appropriate documentation. Please list all documents attached and mark each document to correspond with this list (a, b, etc.).

If you checked Request for Exempt/Expedited Review above, please complete the following section. If you checked Full IRB Review, please type NA here and go to section A for a full IRB application. Requesting exempt status does not guarantee the exempt status. You may not start any activities involving human participants until your request is approved and you have this approval in writing. You may be asked to submit additional information.

In order for a study to be exempt, at least ONE of the five categories listed below must apply. Please check the category under which you apply and explain below.

Exempt Category 1:

a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

AND

b) no identifiable information on participants is collected

Exempt Category 2:

a) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.

AND
b) no identifiable information on participants is collected

Note: This exemption does not apply to the following types of research; 1) research involving children that includes surveys, interviews, and observations of public behavior when the investigator is a participant in the activities being observed; and 2) research in which information is recorded in such a manner that participants can be identified and disclosure of the information could reasonably place the participants at risk.

Exempt Category 3:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if:

a) human participants are elected or appointed public officials or candidates for public office;

OR

b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exempt Category 4:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: All of the data or materials must exist prior to proposing the research.

Exempt Category 5:

Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or otherwise examine:

a) public benefit or service programs;
   b) procedures for obtaining benefits or services under those programs;
   c) possible changes in or alternatives to those programs or procedures; or
   d) possible changes in methods or levels of payment for benefits or services under those programs.

Note: In order to be eligible for this exemption, all of the following must apply:
   The research is conducted pursuant to specific federal statutory authority.
   The research has no statutory requirements for IRB review.
   The research involves no significant physical invasions or intrusions upon the privacy
interests of subject.
The research has authorization or concurrence by the funding agency.

In this space, please justify your request for exempt.

A. Brief Description of Proposed Project

A1. State the purpose/objective/aims of your Project, in one or two sentences in language that can be understood by an individual who is not a specialist in the field.

A2. Research Question to be answered

A3. Hypotheses to be tested (if applicable)

A4. Describe previous research related to this topic

A5. Describe the gap or controversy in the existing research, as identified in the literature that this study will address

B. Research Design

Please select the research design you propose to use

B1. Qualitative
   Historical
   Ethnographic
   Phenomenological
   Grounded Theory
   Other
B2. Quantitative

Descriptive
Developmental
Case/field study
Correlational
Causal-comparative
Experimental/quasi-experimental
Other

B3. Mixed

Qualitative/quantitative
Other

B4. Explain why this research design is appropriate for your study

B5. Check ALL the different procedures planned for this study:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records review – retrospective</td>
<td>Any study-related activities carried out online</td>
</tr>
<tr>
<td>Records review – prospective</td>
<td></td>
</tr>
<tr>
<td>Questionnaires/Surveys</td>
<td>International Research</td>
</tr>
<tr>
<td>Interviews</td>
<td></td>
</tr>
<tr>
<td>Audiotaping/Videotaping</td>
<td>Data involving Children</td>
</tr>
<tr>
<td>Social or Behavioral Intervention</td>
<td></td>
</tr>
<tr>
<td>Behavioral Observation</td>
<td>Data on adults diagnosed with neurocognitive disorders, MI, or SA?</td>
</tr>
<tr>
<td>Education Research</td>
<td></td>
</tr>
<tr>
<td>Study involving persons whose primary language is other than English</td>
<td>Other (describe)</td>
</tr>
</tbody>
</table>

C. Research Staff
Co-Investigator (if applicable), including contact information

If there is more than one researcher involved, explain the division of tasks among research staff. What will be the roles and responsibilities?

**Conflict of Interests:** Do any members of the research team or any of their immediate family members have any direct or indirect financial interest in the sponsor of this research and/or in the results of this research?

- Yes
- No

If answered Yes, please explain

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**D. Data Collection Methods**

D1. Identify and mark one or more of the following data collection methods and briefly explain each activity.

- Testing human participants
- Interviewing human participants
- Asking human participants to complete surveys/questionnaires
- Reviewing files containing information about human participants
- Other procedures (explain below)

D2. Interview questions and any and all instruments must be attached to this application.

- ✓ Please list all documents attached and mark each document to correspond with this list (D2a, D2b, etc.).
- ✓ Please attach data collection information separately for each major phase, research strategy, tool, involved population, etc. that you plan to use. It will help the review committee if you present the materials in the same order that you present them in this application and if you label each clearly in terms of the research activity, so the committee knows which questions, scales, etc. go with which research activity.
✓ If the research involves interviews that could evolve as the research progresses, include a list of discussion topics and any “starter” questions for each topic that can reasonably be expected to be covered.

D3. If you propose to use any instrument under a copyright protection, please describe any provision that you have made to use the instrument in research. If no standardized instrument or any other measure that can be reasonably seen as having proprietary protection used in the study, you must state it clearly.

Please attach all the copyright licenses giving you permission to use instruments under copyright protection. Please mark each document to correspond with this list (D3a), (D3b), etc.)

D4. Please explain how you will access existing participant data.

Please submit documentation signed by persons authorizing your access to participants’ files or other sources of data. Please mark each document to correspond with this list (D4a), (D4b), etc.)

E. Data Analysis and Security.

E1. Specify the location(s) of the study

E2. Describe the methods of data collection and data analysis, as well as record-keeping process.

Attach copies of surveys, interview schedules, code sheets, instruments and other documents that you plan on using. An original instrument must be included with this application, if you propose to use it.

NOTE: If any standardized instrument or any instrument under copyright protection will be used, submit copyright permission(s) to use the instrument(s). Please mark each document to correspond with this list (E2a), (E2b), etc.)
E3. Explain how and for how long the records will be disposed once the study is concluded. Specify the type of data (demographic questionnaires, interviews, audio and video recordings, art items, etc.) and for how long each type of data will be stored.

E4. Include the physical address of the place where records will be kept.

E5. Explain who will have access to each type of data during the research and while they are stored following the research activity. Identify person(s) responsible, security procedures, and procedures in place to respond to requests for records.

E6. Describe how and when each type of the data will be destroyed

E7. Describe specific safeguards to be employed to protect confidentiality of data. Please describe every checked item:

- Coding
- Removal of identifiers as soon as possible
  
  Please describe the timeline

- Limitation of access to data
- Locked file cabinets
- Protection of computer-based data systems
- Other (Please describe)

E8. Will the data that identifies individual subjects be published or in any way be disclosed to third parties other than project personnel?

  Yes

  No

If answered Yes, please explain here and be sure to incorporate in the consent form.
E9. Will the data collected in the course of the study be considered as sensitive data, e.g. mental health, HIV status, SS#, etc.?

Yes

No

If answered Yes, provide the rationale for why this data is needed and explain how the projected benefits of having the data will outweigh the reasonably expected risks to participants.

If answered Yes, could any of this data, if disclosed, have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?

Yes

No

E10. Describe any other resources needed for the protection of subjects in the conduct of this research (e.g., participant communication needs language translation services.)

E11. If appropriate, describe how the Privacy Rule under the HIPAA will be observed.

F. Population and Sample Characteristics

F1. Describe the characteristics of the population

F2. Describe the characteristics of the records

F3. State the approximate number of records or participants in the sample and a rationale for your estimate
F4. State the characteristics of the participants, including age, gender, student status, conditions of vulnerability if any, dwelling status, and anything else of importance. If you state that your participants are not vulnerable, explain why you believe they are not vulnerable.

F5. If your research includes vulnerable participants, state the rationale for their inclusion. Provide a statement on how the benefits of using vulnerable participants will outweigh the risks.

F6. If your research includes participants who don’t speak English or whose mastery of English language may be reasonably seen as impacting their ability to voluntarily consent to research participation and/or freely withdraw from participation, explain how the communication (recruitment, consent, data collection, and debriefing) will be handled. Include all the flyers, consent forms, data collection forms, or any other documentation in BOTH languages with this application. Please mark each document to correspond with this list (F6a, F6b), etc.)

If you don’t speak the language of participants, explain how persons (research associates) with direct access to your non-English speaking participants and/or their personal data will be recruited, educated, and supervised. Include the following information about each associate: name, address, phone number, educational background, and current professional affiliations. Confirm that the study associates will not have familial or employment/business ties to any research participants.

G. Sampling Procedures, Location, and Participants Identification

G1. State the source of the participant population and explain a rationale for your choice.

G2. Describe how you will identify and recruit participants.

G3. Which of the following recruitment methods will be used?

<table>
<thead>
<tr>
<th>Recruitment Activity</th>
<th>Yes</th>
<th>No</th>
<th>Explanation</th>
</tr>
</thead>
</table>

Attach fliers, recruitment letters, invitations, posters, pamphlets, bulletin board notices, and script for promotional presentations and/or solicitation phone calls/e-mails. Please mark each document to correspond with this list (G3a), (G3b), etc.)

G4. Explain how you will select participants from available volunteers. Describe all selection procedures, including any screening procedures.

Attach any screening instruments, and narratives of scripts that you will use. Please mark each document to correspond with this list (G4a), (G4b), etc.)

G5. Will any groups or categories of subjects be excluded from this research?
Yes
No

If answered Yes, please specify and provide the rationale for excluding these subjects and the process of exclusion.

G6. Include any information about use of incentives if relevant. Will you use any compensation?
Yes
No

If answered Yes, describe the nature of the compensation. Provide amounts and schedule of payments.

How did you determine this level of compensation?

Are the terms of the participation agreement and the amount of payment specified in the informed consent form?
Yes
No

G7. How will you assure that participants are not in any way coerced to participate?

G8. Location of participants (check all that apply)
K-12
Outpatient
Inpatient
University/College
Shelter/nursery
G9. Special participants Characteristics (check all that apply)

- Inpatient
- Adults in acute psychiatric distress/with MICD, or SPMI
- Prisoner/halfway house resident
- Minors
- Minors who are wards of the state
- Adults without legal capacity to consent
- Normal volunteer (adults)
- Other (specify)

G10. Please provide a rational for use of special groups or subjects whose ability to give voluntary informed consent without special arrangements/accommodations may be in question (e.g., persons with cognitive impairments, persons residing in care facilities or other institutions, persons whose primary language is other than English, other groups)

G11. If the proposed study is conducted through organizations or agencies where you plan to recruit the participants or use existing data, submit the approval documentation signed by an authorized agent. Please mark each document to correspond with this list (G11a), (G11b), etc.)

G12. Describe any identifiers to be collected from the participants and the procedures to protect their confidentiality.

G13. Study setting: Describe the setting(s) in which research will be carried out (e.g., school, clinic, home, lab, etc.). Explain whether the type of setting might present any additional risks to human participants.
H. Informed Consent

H1. Describe the process of obtaining consent from adults, an assent from children and others who cannot consent, consent from parents/guardians of minors and others who cannot consent, along with detailed description of any distinctive aspects of the process.

H2. Which of the following apply to this research?

- Informed consent will be obtained from all participants and documented with a signed, written consent form.
- Informed consent will be obtained from participants, but no signed consent form will be used. If so, complete a form to request a waiver of documentation of consent.
- Fully informed consent will not be obtained from all participants because it is impossible logistically to obtain consent (for example, participant observation research, classroom observation, etc.). If so, request a waiver of consent without deception.
- Fully informed consent will not be obtained from all participants, because some deception, withholding information, etc., will be involved. If so, request a waiver of consent with deception.

Attach all and any forms that are either given or presented to participants in any form in order to obtain consent. These forms include (but are not limited by): consent form for participants in general, script for verbal project description if participants are illiterate, assent form for children and other participants who may not legally consent; consent for parents/legal guardians, video/photo release form. Please mark each document to correspond with this list (H2a), (H2b), etc.)

H3. If you plan to obtain consent without use of a consent form, justify your plan and explain how you will be sure that you have obtained an informed, educated, and voluntary consent.

H4. If you plan not to use a full informed consent or not to use consent at all, justify your plan and explain how you will ensure safety of participants in your study.

H5. Describe the methods for protecting the identity of the individual participants. Explain what steps you will take in case of intentional or unintentional breach of confidentiality.
H6. Do you plan to recruit and use children in your study?

Yes
No

H6.1 If answered Yes, what is the age range of the children participating in this research?

H6.2. If answered Yes, are any of the children wards of the State, an agency, institution, or entity, including foster care?

Yes
No

H6.3. If answered Yes, provide the details, including which entity has legal custody of the children.

H6.4 Are any of the children have psychiatric diagnoses (or diagnosable conditions)?

Yes
No

H6.5 If yes, justify their inclusion in this research, and specific risk protections built into the study design and procedures.

H6.6 What permission will be obtained from parents/guardians?

Permission will be obtained from a single parent/guardian
Permission will be obtained from both parents/multiple guardians
A waiver of consent is requested
Other

Please include copies of permission forms and any script that you plan to use to gain a verbal permission or to explain your written consent. Please mark each document clearly to correspond with this list ((H6.6 a), H6.6 b), etc.)
If you plan to obtain permission from a single parent/guardian or if you request a waiver of consent, please justify your decision. Please refer to IRB explanations of procedures, if necessary.

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H7. If the research is conducted in a group setting (e.g., a classroom), what provisions have been made for children who do not have parental/guardian permission to participate?

Will the children that you will study generally be capable of providing assent?

- All are capable
- None are capable
- Some are capable

H8. Please justify your determination, referencing the age, maturity, and psychological state of the children.

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H9. Describe how assent will be obtained, including what information will be provided to participants. Describe how assent will be documented and maintained. Attach copies of assent forms, if any.

List here and attach copies of any scripts or materials used in explaining the research in order to gain assent. Please mark each document to correspond with this list (H2a), (H2b), etc.)

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I. **Use of the Internet**

I1. Do you plan to use the Internet in any of the study activities?

- Yes
- No

If answered No, please skip this section and go to section J.

If answered Yes, but the Internet will be used only to make recruitment announcements, and no data collection/analysis/storage will take place online (anonymous or not), as well as no communication will take place online between an investigator and prospective/consented participants, please confirm by initialing here and go to section J.
If answered Yes, and the above statement does not apply, please proceed to answer the following:

I2. How do you plan to use the Internet?

   To recruit participants
   To observe internet activity
   To collect and/or analyze data about participants
   Other, specify:

I3. Will online activity (e.g., chat rooms) be observed?

   Yes (complete part I3.1)
   No (skip to part I4)

I3.1 Describe the setting and nature of the online activity:

I3.2 Will the participants be aware that their activity is being observed?

   Yes (make sure to include this in Informed Consent)
   No (provide justification below)

I4. Describe the safeguards that will be employed to protect confidentiality of data collected over the Internet. Include technical information such as encryption, firewalls, etc.

I5. Expertise. Describe the technical expertise of the investigator and the MP Chair or a Reader with regard to conducting research using the Internet:

I5.1 Have you consulted any technical experts with respect to the design of this study and/or protecting the confidentiality of data collected over the internet?
Yes
No

If answered Yes, please provide details, including all the names and the expertise areas.

If answered Yes, please make sure to prepare an associate agreement that will include provisions concerning confidentiality and data protection. Please include the agreement template as a part of this application and mark it clearly as an item I5.1

Has the agreement been included and attached to this application?

Yes
No

J. Research Activities

J1. Describe the activities in which participants will participate step-by-step, including the time commitment and any equipment that will be used. Also include a schedule of activities that you will be using.

J2. Will you be using a control group? If so, describe all the activities for your control group.

J3. Specify any factors that would make you discontinue your research due to physical or emotional stress on the part of participants (not on your part), and how you would bring the research to a stop. This answer should address both specific participants and the project as a whole.

J4. Describe your contingency plan in case you become incapacitated in any way.

J5. If you plan to use deception, provide your rationale for using it

K. Risk of Harm to Participants. Harm/Benefit Ratio
K1. Describe any potential risks of physical harm to participants. If you do not anticipate any risks, write “no known risks.” Explain how you arrived at your conclusion of “no known risks.”

K2. Describe your methods for minimizing the risk of physical harm and explain all the steps you will take in a case of possible harm to a participant.

K3. Describe how you would report an incident of harm if such an incident occurred.

K4. Describe how you will inform participants of the physical risks and what you will do to mitigate these risks or their effects. Describe availability of medical services that may be required as a consequence of research participation and payment arrangements related to these services. If none are available, what provisions are made when necessary?

K5. Describe any psychological risks that may be faced by participants in this research. If you do not anticipate any risks, write “no known risks.” Explain how you arrived at your conclusion of “no known risks.”

Describe how you will inform participants of the psychological risks and what you will do to mitigate these risks or their effects. Describe availability of any psychological services, including counseling that may be required as a consequence of research participation. If none are available, what provisions are made when necessary?

K6. Describe any social risks that may be faced by participants in this research. If you do not anticipate any risks, write “no known risks.” Explain how you arrived at your conclusion of “no known risks.”

Describe how you will inform participants of the social risks and what you will do to mitigate these risks or their effects. Describe availability of social services, including support services that may be required as a consequence of research participation. If none are available, what provisions are made when necessary?
K7. Describe any financial risks that may be faced by participants in this research. If you do not anticipate any risks, write “no known risks.” Explain how you arrived at your conclusion of “no known risks.”

Describe how you will inform participants of the financial risks and what you will do to mitigate these risks or their effects.

K8. Include your debriefing script, fliers, notes with resources, and on-site help/supervision available. Please mark each document to correspond with this list (J8a, J8b), etc.

K9. Anticipated Benefits: state any anticipated direct benefits to participants in the proposed research.

K10. State any anticipated benefits to the field of mental health and/or society-at-large or others. Note that you may not count benefits to yourself in this answer.

K11. Explain how you calculated the ratio between anticipated risks and benefits to research participants.

K12. Risk Classification.

What is the overall risk to participants in this research?

    Minimal

    Greater than Minimal

(please note that if the research involves greater than minimal risk, then it is not eligible for exemption)

K13. If you checked “Minimal” above, please explain why this category is appropriate
K14. If the classification is greater than minimal risk, describe all possible harms (including non-physical harms) in detail, assess their seriousness and estimate the possibility of the harms occurring.

K15. Describe other alternative and accepted procedures that were considered and which might involve less risk, if any. Explain why they will not be used.

K16. For all research involving more than minimal risk, describe the data and safety monitoring plan (DSMP).

The DSMP should address the following statements.

a. A description of the plan to monitor research progress and subject reactions, including who will do the monitoring and how monitoring will be accomplished

b. A plan for dealing with adverse events and unanticipated problems involving risk to subjects or others

c. A description of the plan to assure compliance with reporting of adverse events and/or unanticipated problems involving risks to participants or others

d. A description of the plan to assure data accuracy and protocol compliance

Please attach this document as an appendix.

**Signatures required for approval of application**

(Please initial each item and then sign below)

By signing this application, I certify that information provided in this application is correct.

I will conduct the study identified above in the manner described above.

If I decide to make any changes concerning any items in this application, or any changes occur beyond my control (whether resulted in injury to a participant or not), or if any problems occur which involve risk or the possibility of risk to participants or others, I will immediately report such occurrences or contemplated changes to the Adler Graduate School Institutional Review Board and will seek written approval prior to continuation of the study.

I understand that the proposed study may not be initiated until written approval is granted. I understand that this study, once approved, is subject to continuing review and approval by the IRB.
I have read, understood, and agree to follow the Adler Graduate School IRB Guidelines

Primary Investigator Printed Name  DATE

Primary Investigator(s) Signature(s)

Adler Graduate School Institutional Review Board Decision

Approved

Not Approved

Comments:

__________________________________________________________             Date
IRB Chair

__________________________________________________________             Date
President
Type your Name Here

Type the Title of Your Project Here