REGENT UNIVERSITY
HUMAN SUBJECTS REVIEW BOARD APPLICATION

Please submit one electronic copy of this form at www.regent.edu irb. Supporting documents can be submitted in hardcopy as necessary.

1. PROJECT REVIEW
   □ New Project (The HSRB will assign an ID#) ____________________________
   □ Revised Project (Enter ID#) ____________________________
   □ Renewal (Enter ID#) ____________________________

2. PRINCIPAL INVESTIGATOR ____________________________________________
   Address __________________________________________ Phone _____________
   E-Mail __________________________________________ Date _______________

   List of all project personnel (including faculty, staff, outside individuals or agencies)
   ____________________________________________
   ____________________________________________

   If you are a student, please provide the following additional information:
   This research is for □ Dissertation □ Thesis □ Independent Study
   □ Other ____________________________________________

   Faculty Advisor’s Name: ____________________________________________

3. TRAINING
   □ I have completed human subjects research training. Training Date: __________

4. PROJECT TITLE ___________________________________________________

5. IS THIS RESEARCH BEING SUBMITTED AS PART OF A FUNDED RESEARCH PROPOSAL? □ Yes □ No
   If yes, please identify the funding source:
   ____________________________________________

6. ANTICIPATED LENGTH OF HUMAN SUBJECTS CONTACT:
   Beginning Date _______________ Ending Date _______________

7. DESCRIPTION OF PARTICIPANTS:
   Number ___________ Age Range ___________________

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Briefly describe subject population: __________________________________________
________________________________________________________________________

8. **INDICATE THE REVIEW CATEGORY FOR WHICH YOU ARE APPLYING.**

- I am applying for an **exempt review**, based on *one or more* of the following categories (check all that apply):

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

  - Research involving the use of survey procedures, educational tests (cognitive, diagnostic, aptitude, achievement), interview procedures or observation of public behavior, if information from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

    - Note: This category cannot be used for research involving children.

- I am applying for an **expedited review**, based on meeting *all* of the following conditions (check all that apply):

  - Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

    - Note: Expedited review cannot be claimed for research involving prisoners.
Research poses no more than minimal risk to subjects (defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.")

Research limited to one or more of the following data collection procedures:

- Collection of data through noninvasive procedures routinely employed in clinical practice
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
- Collection of data from voice, video, digital, or image recordings made for research purposes
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Note: Some research in this category may be classified as exempt; this listing refers only to research that is not exempt.

Continuing review of research previously approved by the convened HSRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

I am applying for full board review.

9. PROJECT DESCRIPTION
Briefly describe (or attach) the methodology and objectives of your research (including hypotheses and/or research questions), the data collection procedures, and any features of the research design that involve procedures or special conditions for participants, including the frequency, duration, and location of their participation. The description should be no longer than 3 pages single space. Attach addendums for materials and detailed descriptions of the research if more space is needed. Please note that complete chapters of thesis/dissertation proposals will not be accepted.
<table>
<thead>
<tr>
<th><strong>HSRB Project Description Checklist</strong></th>
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</thead>
<tbody>
<tr>
<td>a) Is your data completely anonymous, where there are no possible identifications of the participants.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>b) Will you be using existing data or records? If yes, describe in project description (#9 above)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>c) Will you be using surveys, questionnaires, interviews or focus groups with subjects? If yes, describe in #9 and include copies of all in application.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>d) Will you be using videotape, audiotape, film? If yes, describe in #9</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>e) Do you plan to use any of the following populations? Regent students, Regent employees, Non-English speaking, cognitively impaired, patients/clients, prisoners, pregnant women? If yes, describe which ones in #9</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>f) Do you plan to use minors (under 18)? If yes, describe in #9 and give age ranges</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>g) Are sites outside of Regent engaged in the research? If yes, describe in #9 and give consent letter or their IRB information</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>h) Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/elder/physical abuse, immigrations status, etc? If yes, describe in #9.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>i) Are you using machines, software, internet devices? If so describe in #9</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>j) Are you collecting any biological specimens? If yes, describe in #9</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>k) Will any of the following identifying information be collected: names, telephone numbers, social security number, fax numbers, email addresses, medical records numbers, certificate/license numbers, Web universal resource locators (URLs), Internet protocol (IP) address numbers, fingerprint, voice recording, face photographic image, or any other unique identifying number, code or characteristic other than “dummy” identifiers? If yes, describe in #9</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>l) Will there be data sharing with any entity outside your research team? If so, describe who in #9</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>m) Does any member of the research team or their family members have a personal financial interest in the project (for commercialization of product, process or technology, or stand to gain personal financial income from the project)? If yes, describe in #9.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>n) As applicable, do you plan to provide a debriefing to your participants?</td>
<td>No</td>
<td>Yes</td>
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<td>--------------------------------------------------------------------------</td>
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<tr>
<td>If written, include in application as addendum</td>
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<td>o) Will there be any inducement to participate, either monetary or nonmonetary? If there is inducement please describe how the amount is not coercive in #9.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>p) Will there be any costs that subjects will bear (travel expenses, parking fees, professional fees, etc. If no costs other than their time to participate, please indicate)? If yes describe in #9</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>q) Will subjects be studied on Regent University campus? If yes, please describe where the study will be done in #9</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>r) Will subjects be obtained by internet only? If yes, please describe what internet forums or venues will be used to obtain participants in #9</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>s) Are you using the Regent University consent form template? Whether using the template or requesting an alternate form, you must include a copy in your submission.</td>
<td>No</td>
<td>Yes</td>
</tr>
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</table>

10. PARTICIPANT RECRUITMENT
Describe the sources of potential participants, how they will be selected and recruited, and how and where you will contact them. Describe all relevant characteristics of the participants with regard to age, ethnic background, sex, institutional status (e.g., patients or prisoners), and their general state of mental and physical health.

_______________________________________________________________________
_______________________________________________________________________

11. INFORMED CONSENT
Describe how you will inform participants of the nature of the study. Attach a copy of your cover letter, script, informed consent form and other information provided to potential participants.

_______________________________________________________________________
_______________________________________________________________________

** EXEMPT APPLICATIONS SKIP TO QUESTION 17: ATTACHMENTS **
12. **WRITTEN CONSENT**

☐ I am requesting permission to waive written consent, based on one or more of the following categories (check all that apply):

☐ The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

☐ I will be using a written consent form. Attach a copy of the written consent form with this application.

13. **CONFIDENTIALITY OF DATA**

What procedures will be used to safeguard identifiable records of individuals and protect the confidentiality of participants?

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

**EXPEDITED APPLICATIONS SKIP TO QUESTION 17: ATTACHMENTS **

14. **RISKS AND BENEFITS**

Describe in detail the immediate or long-range risks, if any, to participants that may arise from the procedures used in this study. Indicate any precautions that will be taken to minimize these risks. Also describe the anticipated benefits to participants and to society from the knowledge that may be reasonably expected to result from this study.

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

15. **DEBRIEFING STATEMENT**

The two major goals of debriefing are dehoaxing and desensitizing. Participants should be debriefed about any deception that was used in the study. Participants also should be debriefed about their behavioral response(s) to the study. Please describe your debriefing plans and include any statements that you will be providing to the participants.

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

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16. **DISSEMINATION & STORAGE OF RESULTS**

a) How and where do you plan on disseminating the results of your study?

b) For electronic data stored on a computer, how will it be stored and secured (password, encryption, other comparable safeguard)?

c) For hardcopy data, how will it be stored (locked office or suite, locked cabinet, data coded by team with master list secured separately, other)?

d) What are your plans for disposing of data once the study is ended (give method and time)?

17. **ATTACHMENTS**

Attach copies of all relevant project materials and documents, including (check all that apply):

- A copy of your training certificate (required for principal investigator)
- Surveys, questionnaires, and/or interview instruments
- Informed consent forms or statements
- Letters of approval from cooperative agencies, schools, or education boards
- Debriefing statements or explanation sheet

18. **AFFIRMATION OF COMPLIANCE:**

By submitting this application, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research. I agree to follow the university policy as outlined in the Faculty & Academic Policy Handbook (available online at [http://www.regent.edu/academics/academic_affairs/handbook.cfm](http://www.regent.edu/academics/academic_affairs/handbook.cfm)) to ensure that the rights and welfare of human participants in my project are properly protected. I understand that the study will not commence until I have received approval of these procedures from the Human Subjects Review Board. I further understand that if data collection continues for more than one year from the approval date, a renewal application must be submitted.

I understand that failure to comply with Federal Regulations (45 CFR 46, available online at [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)) can result in confiscation and possible destruction of data, suspension of all current and future research involving human subjects, or other institutional sanctions, until compliance is assured.

Signature of Principal Investigator ________________________ Date __________

Signature of Co-Investigator (if applicable) ________________________ Date __________
To Be Completed By HSRB

Assigned ID # ______________________________

☐ Approve
☐ Recommend Revisions
☐ Reject

______________________________
HSRB Member

______________________________
HSRB Member (if applicable)

______________________________
HSRB Member (if applicable)