SHAW UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB)

NEW PROTOCOL APPLICATION FORM

INVESTIGATOR INFORMATION

Study Title:

Principal Investigator: 

Title: 

Department: 

Campus Address:

Phone #: 

Fax #: 

Email:

Rank

Administrator

Faculty

Staff

Student

Undergrad. student

Masters student

Doctoral student

(Check all that apply):

Study Coordinator:

Phone #: 

Fax #: 

Email:

Faculty Advisor (required if the PI is a student):

Phone #: 

Fax #: 

Email:

Will your research be a collaborative effort with another institution(s)?

☐ YES  ☐ NO

If yes, name of institution(s):

*All study personnel associated with this project are required to complete human subjects training as described in the Shaw University Research Investigator’s Manual. Please identify all study personnel in the chart below. Personnel include principal and co-investigators, faculty advisor, study coordinator, statisticians, research assistants and all others who will interact with research participants or data. Attach an additional sheet if necessary.

<table>
<thead>
<tr>
<th>Name of Personnel Member (also list credentials - PhD, etc.)</th>
<th>Role in Study</th>
<th>Affiliated w/Shaw?</th>
<th>Training Certificate Attached?</th>
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</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>☐ Yes ☐ No</td>
<td>☐ Yes ☐ No</td>
<td>☐ Yes ☐ No</td>
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<tr>
<td>Study Coordinator</td>
<td>☐ Yes ☐ No</td>
<td>☐ Yes ☐ No</td>
<td>☐ Yes ☐ No</td>
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<tr>
<td>Faculty Advisor</td>
<td>☐ Yes ☐ No</td>
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</tbody>
</table>

For IRB Use Only

Final Review/Determination Received:  ☐ Exempt category ☐ Expedited category ☐ Full Board

IRB Chair Signature: ____________________________  Date Approved: ____________________________

Expires: ____________________________

SAVE THE FORM TO YOUR COMPUTER. TYPE OR CHECK YOUR RESPONSES.
FUNDING INFORMATION

Has or will your research proposal been submitted for funding? □ YES □ NO

Sponsor(s) (identify all possible sources of funding):

Sponsor/Grant #: Anticipated start date:

PROTOCOL INFORMATION

Check all of the following that apply to your research protocol:

☐ Minors (under the age of 18) ☐ Focus group
☐ Pregnant women ☐ Class research assignment
☐ Prisoners ☐ Secondary data analysis
☐ Persons with mental, emotional, or physical disabilities ☐ Biological specimens (e.g. saliva, blood)
☐ Elderly ☐ International research
☐ Students in a class taught by the PI ☐ Surveys/questionnaires
☐ Part of dissertation or thesis

Please answer the following questions in narrative format (Use as much space as you require):

1. Describe your purpose, hypotheses, and methodology you will use.

2. Describe your participants (inclusion/exclusion criteria, age range, sex, number of participants).

3. Describe your method of recruitment.

4. Will existing data or datasets be used? If yes, identify the source.

5. What are the anticipated risks and how do you plan to minimize them?

6. Are illegal activities involved?

7. Is deception involved?

8. Are there any anticipated benefits to participants or society? If yes, describe.

9. How will prior consent be obtained?
10. Will the data you collect or receive include any of the identifiers on the following list?

- [ ] No
- [ ] Yes  *If yes, check all that apply:*

- [ ] Participant Names
- [ ] Telephone numbers
- [ ] Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- [ ] Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
- [ ] Fax numbers
- [ ] Electronic mail addresses
- [ ] Social security numbers
- [ ] Medical record numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers (VIN), including license plate numbers
- [ ] Device identifiers and serial numbers (e.g., implanted medical device)
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including finger and voice prints
- [ ] Full face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic or code, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

11. With whom will identifiable (contains any of the 18 identifiers listed in question 10 above) data be shared outside the immediate study personnel? For each, explain confidentiality measures. Include data use agreements, if any.

- [ ] No one
- [ ] Coordinating Center:
- [ ] Statisticians:
- [ ] Consultants:
- [ ] Other researchers:
- [ ] Registries:
- [ ] Sponsors:
- [ ] External labs for additional testing:
- [ ] Journals:
- [ ] Publicly available dataset:
- [ ] Other:

12. Data security for storage and transmission. Check all that apply.

**For electronic data:**
- [ ] Secure network
- [ ] Password access
- [ ] Encryption
- [ ] Other (describe):
  
  *Describe how data will be protected for any portable device:*

**For hardcopy data (including human biological specimens, CDs, tapes, etc.):**
- [ ] Data de-identified by research team (stripped of the 18 identifiers listed in question 10 above)
- [ ] Locked suite or office
- [ ] Locked cabinet
- [ ] Data coded by research team with a master list secured and kept separately
- [ ] Other (describe):
13. How will the data you collect be used?

PRINCIPAL INVESTIGATOR ASSURANCE
My signature testifies that I have read and understand the Shaw University Research Investigator’s Manual. I assure the IRB that all procedures will be conducted as I have stated in this application. Any modifications to the methodology will be submitted to the IRB for approval prior to implementation.

Principal Investigator’s Signature _________________________________ Date ____________

FACULTY ADVISOR ASSURANCE
My signature testifies that I have read and understand the Shaw University Research Investigator’s Manual. I have reviewed and approved the research proposal for the student principal investigator listed in this application and assure that the student is under my direct supervision.

Faculty Advisor’s Signature ______________________________________ Date _____________

The following items should be submitted to the Shaw University IRB to complete your application:

☐ New Protocol Application Form
☐ Consent Form, Assent Form, Parental Consent Form as applicable
☐ Grant proposal as submitted to potential sponsor/funder (if applicable)
☐ Recruitment materials (e.g. posters, flyers, letters, email text, newspaper text, radio scripts…)
☐ Data collection instruments (e.g. surveys/questionnaires)
☐ Focus group questions
☐ Human subjects training certificates for all research personnel

Submit the following number of complete applications in response to the type of review you are requesting:

- **Full Board Review** – original + 8 copies of application and all attachments (1 copy of the grant proposal)
- **Expedited Review** – original + 1 copy of application and all attachments

Submit directly to:

Shaw University IRB
IHSCR, Room 207
118 E. South Street
Raleigh, NC 27601