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INTRODUCTION

Purpose of the Institutional Review Board

The Institutional Review Board ("IRB") of the University of The Bahamas (UB) is responsible for reviewing research proposals for the purpose of protecting the rights of individuals who are the participants of any research project conducted by faculty, staff, and/or students of the University.

The IRB:

(1) safeguards the rights and welfare of participants at potential risk in a research project and related activity; and,
(2) protects the University and its employees and students from possible liability related to conducting research.

The IRB also serves as a repository of information for all research projects conducted at UB University. It is the policy of UB University that no research involving human participants be undertaken until the proposed research has been reviewed and approved according to procedures established by the IRB.

Federal Compliance

The University of The Bahamas’ Institutional Review Board is registered with the U.S. Department of Health and Human Services (HHS) and as such follows the guidelines as laid out by that body. In 1991, revised federal regulations were issued. These regulations, part of the Code of Federal Regulations ("CFR"), comprise the core regulatory structure for research involving human participants. The federal regulations place responsibility on the University, through the IRB, and on the Principal Investigator¹ to ensure that high ethical standards are maintained for all research involving human participants.

Given its desire to seek funding in concert with American institutions, UB complies with the federal regulations and uses these regulations as Guidelines when reviewing non-governmentally funded research proposals. Faculty, staff, or students of UB who are interested in viewing the US federal regulations can refer to CFR Title 45 – Public Welfare and Human Services, Part 46 - Protection of Human Participants² http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf (2009) and the Belmont Report http://ohsr.od.nih.gov/guidelines/belmont.html which can be accessed at the noted websites, or on the following website -- http://sourcebook.od.nih.gov/ethic-conduct/Conduct%20Research%206-11-07.pdf maintained by the National Institutes of Health, Office of Human Participants Research. These IRB Guidelines may also be viewed and downloaded from the UB University web page.

¹ The Principal Investigator is defined as “the person or persons who are held responsible for meeting all UB IRB requirements.” The Principal Investigator is typically the faculty member overseeing the research project.
² 34 C.F.R. 97.00 provides the same regulatory Guidelines under the heading “Education: Protection of Human Participants.”
These IRB Guidelines are intended to provide instruction to Principal Investigators interested in conducting research involving human participants. Research is broadly defined by the US federal regulation as: “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Classroom activities that are solely for instructional purposes generally do not have to come before the IRB. However, it is the responsibility of the instructor to consult with the IRB Chair to determine whether classroom activities and/or course assignments fall under IRB regulations.

In addition to its review functions, the IRB is committed to serving as an educational resource for the UB community. Workshops, presentations to faculty and student groups, as well as individual consultations with the IRB may be arranged by contacting the Chair of the IRB (irb@ub.edu.bs).

**OVERVIEW OF RESPONSIBILITIES**

Any person proposing to conduct research involving human participants must prepare a project proposal application for review by the IRB. The IRB has the responsibility of reviewing and approving all research and related activities involving human participants. The IRB is responsible to the President and to the University for keeping abreast of, developing, and adhering to research policies that are consistent with the Code of Federal Regulations (“CFR”), and by extension UB requirements. Furthermore, the IRB is responsible for providing faculty, staff, and students with the resources to familiarize themselves with regulations governing research involving human participants.

The IRB reviews and has the authority to approve, require modifications of or disapprove any research involving human participants. The IRB is further charged with ensuring that participants give proper informed consent.

The IRB Chair determines whether the proposed research (1) is exempt from review; (2) is eligible for expedited review; or, (3) requires a full review by the entire IRB. The IRB will notify Principal Investigators and the University in writing of its decision to approve or disapprove proposed research and state reasons for its decision. Principal Investigators will be given an opportunity to respond in person or in writing.

The processes of review and approval include the consideration of the methods to be used in collecting research data, selecting participants, obtaining informed consent, and protecting the confidentiality of participants. The IRB also considers the benefits and risks to participants, ethical implications of the proposed research, and compliance with federal regulations.

For research involving children, the IRB is responsible for determining that no risk is presented to children as research participants. Research involving children can proceed “only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.”

An electronic submission of a proposal by the faculty, staff, student researcher, or Principal Investigator affirms that approved procedures will be followed in the conduct of research involving

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3 Regulation 45 C.F.R. 46.102
4 Regulation 45 C.F.R.
human participants, a requirement of the application process.

It is the responsibility of the Principal Investigator to comply with all IRB decisions, conditions and requirements. If the IRB determines that research is not being conducted in accordance with its guidelines, the IRB has the authority to suspend or terminate its approval.

IRB REVIEW PROCEDURES

New Research Projects

Research utilizing human participants cannot begin until the IRB issues its approval.

It is the responsibility of the Principal Investigator to carefully read and follow these Guidelines while preparing all necessary forms. Careful preparation of the IRB proposal will aid in expediting the review and decision-making process. To learn proposal requirements, please refer to the section of these Guidelines entitled “Instructions for Principal Investigators” starting on page 8.

(1) Complete IRB Research Review Form

Faculty, staff, and students who are planning to conduct research must complete an “IRB Research Review Form” (see Appendix A) and submit it and all necessary documentation to the IRB Chair by email (irb@ub.edu.bs). Regulations require UB to maintain all IRB records for three (3) years after the end of a study; in addition, the researchers are required to keep detailed records three years with many professional organizations requiring 5 years. These records, additional research forms, and other IRB materials are kept in the Office of Academic Affairs. A list of the names and phone numbers of IRB members and the IRB Administrator are circulated at the beginning of each academic year and can be found on the University website under “Academic Policies.”

(2) Submit All Necessary Forms and Documents

Applicants must also submit a proposed “Informed Consent Form” (see example at Appendix B). Carefully read and follow the “Instructions for Principal Investigators” starting on page 8, for guidance regarding how to complete all necessary documents. A list of additional necessary materials can be found on the “IRB Research Review Form” (see Appendix A).

(3) Determination by IRB Chair

After receipt of a research proposal, the IRB Chair will verify that all necessary forms and documents have been submitted and will:

(a) exempt the research from IRB review; or
(b) call for an “Expedited Review;” or,
(c) bring the proposal before the entire IRB for review.

If a full review is required, the IRB Chair will deliver (via email) copies of the proposal to all IRB
members. It is the responsibility of the IRB to determine whether a project is approved, requires revision before commencing, or is disapproved and therefore may not be conducted (see “IRB Determination Form,” Appendix C).

See Appendix D, Levels of IRB Review for detailed explanation.

(4) Issuance of a Decision

For research to be approved, the IRB must find that all of the following requirements are satisfied:

(a) Risks to participants are minimized by using procedures that are consistent with sound research and that do not unnecessarily expose participants to risk.
(b) Risks to participants are reasonable in relation to anticipated benefits. The IRB will consider risks and benefits that may result from the immediate research, not long-term applications.
(c) Selection of participants is equitable.
(d) Informed consent will be sought from each prospective participant.
(e) Informed consent will be appropriately documented.
(f) The research plan makes adequate provisions for monitoring data to ensure the safety of participants.
(g) There are adequate provisions to protect the privacy of participants and maintain the confidentiality of data.

To minimize any infringement on freedom of research, the UB IRB is obligated to avoid judgments about the importance of proposed research. The IRB is prohibited from making judgments about the long-term applications and potential policy implications of the research.

Researchers are informed of IRB decisions in an e-letter from the IRB sent within one (1) week after the proposal has been reviewed by the entire IRB at a regularly scheduled meeting, or within two (2) weeks submittal of a proposal if an “Expedited Review” has been used. The requirements for different “Levels of Review” can be found on page 32 of these Guidelines.

Investigators are not permitted to involve human participants in research before proposed research is approved by the IRB. Once approved, on-going studies must be submitted annually to the IRB for re-approval.

(5) Continuing Review

The IRB will continue to review research granted approval. The IRB will conduct a review of each research project at intervals appropriate to the degree of risk, but not less than once per year. The IRB has the authority to observe (or have a third party observe) the informed consent process (see pages 10-12 of these Guidelines) and the research.

(6) Changes to Research Protocol/Adverse Effects on Participants

Any changes in research protocol or any adverse effects on participants must be communicated
immediately to the IRB Chair. Instructions regarding changes to research protocol, adverse effects on participants, renewed approval, and project completion are described immediately below.

(7) Maintenance of Records

The IRB will prepare and maintain for at least three (3) years adequate documentation of the following:

(a) copies of all research proposals reviewed;
(b) minutes of IRB meetings (showing attendance, voting and actions taken);
(c) records of interviews;
(d) copies of all correspondence with the IRB;
(e) list of IRB members.

Previously Approved Projects

Research utilizing human participants cannot continue beyond one (1) year without being re-approved by the IRB.

Re-Approval of Research

Any project that exceeds a period of one (1) year in duration must be reviewed and be re-approved by the IRB prior to the beginning of the second and each successive year of the research project. Renewed approval (see “IRB Research Review Form,” Appendix A) must be sought at least forty-five (45) days prior to the anniversary date of the previous approval for the research project.

In cases where a researcher is seeking approval for a new project that is identical to a project previously approved by the IRB, renewed approval (see “IRB Research Review Form,” Appendix A) should be obtained.

The “Informed Consent Form” (see Appendix B) can be used for a maximum of (1) year from the date of the Form’s approval. In cases where a project is continuing beyond one year, permission for continued use of the “Informed Consent Form” must be requested at least forty-five (45) days in advance of the one-year anniversary date of the form. Such permission is granted in conjunction with the re-approval of the research project.

When applying for re-approval of a research project, or reporting changes to research protocol or adverse effects on the participants, the “IRB Research Review Form” (see Appendix A) must be fully completed again. Investigators are free to submit a copy of materials that were submitted during the initial review process, if no changes are being made, along with originals of any new materials that the investigator wants the IRB to consider.
Multi-Site, Multi-Investigator Research Projects

To ensure that all research projects meet UB standards in safeguarding the rights and welfare of participants, and to protect the University from liability, it is the responsibility of the UB investigator to ensure that proposals satisfy approval protocols.

Proposals approved by IRBs of Universities with whom UB has partnerships, or in instances where another investigator, other than a UB investigator, is the principal, need not undergo a full UB IRB review.

In any multi-site, multi-investigator research project, it is the responsibility of the UB investigator to ensure that any use of project data and/or materials from a UB IRB approved project satisfy UB IRB standards.

Procedures in the Event of Changes to/Discontinuation of the Research Project

If a research protocol changes in any way after a research project has been approved, the investigator must not proceed with the proposed changes without prior written approval of the IRB. The Principal Investigator must notify the IRB if the project is discontinued.

Procedures in the Event of Adverse Effects on Participants

If a researcher becomes aware of, or suspects any adverse effects on human participants, the research project must be immediately discontinued and the IRB must be immediately notified. It is the researcher’s responsibility to notify the IRB in writing of any adverse effects to research participants within one week of the researcher’s first awareness of the adverse effects.

INSTRUCTIONS FOR PRINCIPAL INVESTIGATORS

Participant Recruitment and Selection

IRB decisions are intended to ensure equity in the selection of participants. The IRB will take into account the purpose of the research and the setting in which the research will be conducted. The IRB is particularly sensitive to the special challenges of research involving vulnerable populations, such as children, prisoners, pregnant women, persons who are mentally disabled, or persons who are economically or educationally disadvantaged.

If you are recruiting participants from another institution, you may need to get approval from that institution’s IRB, as well as from UB University’s IRB. If the other institution does not require its own IRB review, you may be asked to provide written documentation of the institution’s approval of the project.

In most instances, it is inappropriate for a researcher to use his/her own students as participants. Nevertheless, the IRB recognizes that use of a researcher’s students may, at times, be necessary. Researchers must substantiate the need to use his/her own students as participants and propose an acceptable plan in accordance with IRB requirements and policies. In such cases the plan must emphasize
the voluntary nature of participation and students’ freedom to not participate without consequences. In cases where a research study poses minimal or greater risk and involves vulnerable participants (children, prisoners, pregnant women, people who are mentally or physically disabled, persons who are economically or educationally disadvantaged), the research proposal must undergo “Full Review.”

**Project Description**

The following must be included in the project description:

1. **General Description**: Briefly describe the overall goals of the proposed research project and the general procedures to be followed.
2. **Significance of the Project**: Provide a brief theoretical and empirical rationale for why you believe this research project is important.
3. **Participant Population**: Describe the characteristics of the participant population. Include the anticipated number, age range, gender, racial and ethnic composition, and health status of the participant population. Identify the criteria for inclusion in the project. If the project involves vulnerable populations, such as pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable, please explain the rationale for their involvement. If the participant population is limited to a specific racial or ethnic group or is gender-specific, explain the rationale for exclusion/inclusion. Briefly describe the site(s) from which you will draw your participant population and/or locate your research project.
4. **Research Methods**: Explain all research methods, including participants, paying particular attention to describing interview procedures if applicable.
5. **Sources of Research Material**: Identify research materials (e.g., records or data) that will be obtained from participants. Indicate whether the material or data will be obtained specifically for research purposes. Also indicate the use of already existing records or data.
6. **Participant Recruitment**: Describe plans for the recruitment of participants and the informed consent procedures to be followed, including the circumstances under which informed consent will be sought and obtained.
7. **Informed Consent**: Describe how participants will be informed about the nature of the research project, protected against coercion to participate, and provided with procedures for refusal or termination of participation. Include provisions for obtaining consent from parents/guardians of minors and assent from participants who are minors, maintaining confidentiality, privacy, and anonymity.
8. **Risks**: Describe any potential risks to confidentiality, legal and/or financial interests, physical, psychological or social well-being, and assess their likelihood and seriousness.
9. **Protection Against Risks**: Describe the procedures for protecting against potential risks identified above and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary intervention in the event of adverse effects on the participants. Also, describe provisions for confidential storage of data. In particular, describe procedures for maintaining participants’ confidentiality.
10. **Benefits**: Discuss the specific anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result from participation in the research project.
Format Notes

- Although it is common to utilize the terminology “human subject” to define an individual who participates as a participant in a research project, it is entirely appropriate to substitute the word “participant”.
- Application materials should be typed and submitted electronically.
- Please be sure to define any technical terms in lay terminology, including descriptions of special equipment and/or procedures.

ELEMENTS OF VOLUNTARY INFORMED CONSENT

A “Research Investigator” must obtain “Informed Consent” from each participant. “No investigator may involve a human being as a participant in research unless the investigator has obtained the legally effective Informed Consent of the participant or the participant’s legally authorized representative.”5 A “research investigator” includes faculty, staff, or students conducting research designed to contribute to “generalizable knowledge.” It does not include students and faculty engaged in course projects designed to address the educational goal of providing research training for students and that pose no risk of physically or psychologically harming participants.

If the research project poses no risk of harm to participants (e.g., observing them on a street corner) and if the research project qualifies for “Expedited Review,” the IRB may waive the requirement for written “Informed Consent” and consider returned research instruments as evidence of “Implied Consent”. “Implied Consent” applies only to participants over eighteen (18) years of age participating in survey research that does not include confidential information that may reveal the identities of participants.

If “Informed Consent” is necessary, an “Informed Consent Form” must be approved by UB’s IRB before the research project begins.

“Informed Consent Form”

Investigators must include a copy of proposed “Informed Consent Form(s)” when submitting research proposals for IRB review. The approved “Informed Consent Form” is valid for a maximum of one (1) year. In cases where a project is continuing beyond one (1) year, permission to continue use of the “Informed Consent Form” must be requested at least forty-five (45) days in advance of the one-year anniversary date of the previous “Informed Consent Form”. Such permission is granted in conjunction with re-approval of the research project.

If a research project includes individuals with language backgrounds other than English, the IRB will require that the “Informed Consent Form” be translated into the language most appropriate for each participant in the research project. The “Informed Consent Form” written in both English and in the second language must be submitted with the other application materials.

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5 Regulation 45 CFR 46.116
“Informed Consent Forms” must explain the research to be undertaken and must satisfy legal requirements for informed consent. In addition, they should also be simple and non-threatening. A sample “Informed Consent Form” is Appendix B.

“Informed Consent Forms” must be written in easy-to-comprehend, non-technical language. Also, “Informed Consent Forms” must not encourage or require a participant to waive any of his/her legal rights. Signed “Informed Consent Forms” must be retained by the researcher for a minimum of three (3) years after the termination of the project.

All “Informed Consent Forms” MUST include the following information:

(1) Research project title.
(2) Date of the proposal.
(3) Researcher name(s) and degrees (e.g., M.S.W., Ph.D., Ed.D., etc.).
(4) A statement that the study involves research, an easily understood explanation of the purposes of the research, the expected duration of the participant’s participation, and a simple description of any procedures to be followed.
(5) A description of any reasonably foreseeable risks or discomforts to the participant and a statement that the participant has been made aware of any and all possible risks or discomforts.
(6) A description of any benefits to the participant or to others that may reasonably be expected from the research.
(7) A statement describing methods for maintaining confidentiality of records that identify research participants.
(8) An offer to answer questions and a statement of whom to contact for answers to questions about the research and the participant’s rights. The researchers’ campus address and telephone number must be provided, and if the researcher is a student, the faculty advisor’s campus address and telephone number must also be provided.
(9) A statement of whom to contact in the event of research-related injury to the participant.
(10) For research involving more than minimal risk, an explanation as to whether any treatment is available if research-related harm occurs, what that treatment will consist of, and where further information regarding treatment may be obtained.
(11) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
(12) A statement concerning cost reimbursement or compensation to the participant, if any.
(13) A Statement that the human participant has read the contents of the “Informed Consent Form,” has had an opportunity to fully discuss any concerns and questions, and fully understands the nature and character of his/her involvement in the research project and any possible risks and consequences.
(14) Signature spaces as appropriate; for example,
Researcher(s) Agency
Official Faculty
Advisor Research
Participant
Parent/Guardian

(15) Sufficient space to indicate IRB approval of the Form.

The following information may also be necessary in an “Informed Consent Form”:

(1) A statement that the treatment or procedure may involve unforeseen risks;
(2) Anticipated circumstances under which the participant’s participation may be terminated;
(3) Additional costs to the participant that may result;
(4) The consequences of a participant’s decision to withdraw from the research project and procedures for withdrawal;
(5) A statement that significant new findings developed during the research may influence the participant’s decision to continue to participate;
(6) The approximate number of participants in the study.

Research Projects Involving Children

For research involving children under eighteen (18) years of age, additional requirements for consent must be satisfied.

(1) The assent of the child must be obtained. The child must affirmatively agree to participate in the research project.
(2) The permission of the child’s parent/legal guardian must be obtained. The parent/guardian is responsible for signing the “Informed Consent Form.”

Research Investigators Responsibilities

(1) Ensuring that consent is documented by use of an “Informed Consent Form” (see sample in Appendix B) approved by the IRB and signed by the participant or the participant’s legal representative, unless this requirement is expressly waived by the IRB.
(2) Ensuring that each person signing the “Informed Consent Form” is given a copy of that Form.
(3) Maintaining consent documents signed by human research participants for at least three (3) years following the termination of the project.

Waiving Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed “Informed Consent Form” for some or all participants if it finds either:
(1) The only record linking the participant to the research project would be the “Informed Consent Form” and the principal risk of the research project is potential harm resulting from disclosure of confidential information contained in the “Informed Consent Form.” (For example, in the case of an anonymous survey, consent may be implied by return of the survey.); or,

(2) The research presents no risk of harm to participants and involves no procedures for which written consent is normally required outside of a research context.

The reasons for requesting that consent be waived must be explicitly stated in a separate memorandum accompanying the application materials submitted to the IRB. When a waiver is obtained, the IRB may still require the research investigator to provide participants with a written statement regarding the research.

REFERENCES


APPENDICES

APPENDIX A: IRB Research Review Form

APPENDIX B: Sample Informed Consent Form

APPENDIX C: IRB Determination Form

APPENDIX D: Levels of IRB Review

APPENDIX E: Glossary
**APPENDIX A: IRB Research Review Form**

**IRB RESEARCH REVIEW FORM**

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<th>Submit to:</th>
<th>Pandora Johnson, PhD</th>
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<tbody>
<tr>
<td>Chair, IRB</td>
<td><a href="mailto:irb@ub.edu.bs">irb@ub.edu.bs</a></td>
</tr>
</tbody>
</table>

**Please Note:**
- Do not begin your research (including contacting potential research participants) until you are notified that your application has been approved by the IRB. Notification will take **between two (2) and four (4) weeks**. Consult the IRB Guidelines on [http\www.ub.edu.bs](http\www.ub.edu.bs). If you have any questions, contact the IRB Chair.
- **The IRB requires submission of the Research Review Form and all relevant documentation (including a copy of your current NIH Certification, accessed at this link - https://phrp.nihtraining.com/users/login.php) electronically via irb@ub.edu.bs**

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**APPLICANT INFORMATION**

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**Principal Investigator 1 Contact Information:**

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<th>Mailing Address:</th>
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<tbody>
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<td>Email:</td>
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University of The Bahamas IRB Guidelines (As of February 2017)
Adapted with permission of Wheelock College, Boston, MA
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## Principal Investigator 2 Contact Information:

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### University of The Bahamas (UB) Co-Investigator(s)

(OTHER FACULTY/STAFF AND/OR STUDENT(S) IF APPLICABLE)

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### Collaborators outside UB: (if any)

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## PROJECT SUMMARY

### Type of Project: (check all that apply)

- [ ] FACULTY RESEARCH
- [ ] CLASS PROJECT
- [ ] INDEPENDENT STUDY
- [ ] INDIVIDUAL STUDENT PROJECT
- [ ] OTHER (EXPLAIN):

### Method of Study: (Check all that apply and attach samples)

- [ ] EDUCATIONAL TEST(S)
- [ ] STANDARD PSYCHOLOGICAL TEST(S)
- [ ] SURVEY OR QUESTIONNAIRE
- [ ] INTERVIEW(S)
- [ ] STUDY OF EXISTING DATA
- [ ] OTHER (DESCRIBE):
**Location(s) of Activity:** (Identify and describe)

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<td>UB Students</td>
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<td>Adult non-students</td>
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<td>Individuals with mental, physical, or emotional handicaps</td>
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<td>Pregnant Women</td>
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<td>Prisoners</td>
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<td>Economically or educationally disadvantaged</td>
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<th>Explanation (description and source)</th>
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</tr>
<tr>
<td>☐ Funding necessary, will apply</td>
<td></td>
</tr>
<tr>
<td>☐ Funding approved</td>
<td></td>
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</tbody>
</table>
PROJECT DESCRIPTION

Research Project: (Describe)
Significance of the Study: (Describe)

Explanation of inclusion or exclusion of specific racial or ethnic groups.

Describe populations(s) from which participants will be drawn (age range, gender, health status, racial or ethnic groups, vulnerable participants).

Research Methods

What will participants be asked to do, what will be done to them, and what information will be gathered?
Describe research materials. (Append copies of interview guides, instructions, tests, or questionnaires.)

If participants will be interviewed or observed, who are the interviewers or observers and how will they be trained?

Describe number of times various procedures will be conducted and the estimated length of the procedure:

Describe the provisions for maintaining materials or data securely and confidentially.
How will participants be recruited? Is an inducement or remuneration offered? (If so, append copy of letter or ad.)

How will you ensure that selection of participants with regard to gender, race, and ethnic background meet standards for inclusion?

Other relevant characteristics of participants, such as institutional affiliation:

- If there is a cooperating institution, submit evidence that its approval of the project has been obtained: (Append letters)
- Is approval of another institution’s IRB required? Why or why not? If required, submit evidence of approval.

How will you explain the research to participants and obtain their Informed Consent to participate? (Append “Informed Consent Form”)

If participants are minors or not competent to provide Informed Consent, how will Informed Consent be obtained?
How will participants be informed that they can refuse to participate in any aspects of the project or may terminate participation whenever they please?

If participants are students or clients, how will you protect them against feeling coerced to participate?

Are participants deliberately deceived in any way? If so, provide rationale for the deception; describe the deception; its likely impact on participants; and how you will later explain it to them.

How will the following be protected? (See Glossary for further information.)

1) **Privacy:** (Protecting information about participants. This refers to an individual and his/her concerns about controlling access to personal information.)

2) **Confidentiality:** (Protecting data about participants.) Access to data is limited. Consider how coding will be separated from information obtained; how data will be stored and when it will be destroyed; whether data will be used in the future and; if so, how permission for future use will be obtained.

3) **Anonymity:** (Protecting access to unique names and identifiers. In most cases highly specific identifiers should never be attached to the data.)
Protection of human participants
Do participants risk any stress or harm by participating in this research? If so, how will participants be protected?

Benefits
How will participation in this study benefit participants?

How will participants be “debriefed” and what alternative referrals can you make, if necessary?

Will participants receive a summary of results or other educational materials? If so, explain.

Are there any other procedures or details of the project that the IRB should consider to assess how your project protects human participants?

Applicant’s Electronic Signature: ____________________________ Date: _________________

Faculty Sponsor’s Electronic Signature: ____________________________ Date: _________________
(Required if Principal Investigator is a student.)

6 Note: Please append an electronic signature.
ATTACHMENTS INCLUDED AS APPROPRIATE

(Please verify that you have included all necessary materials by placing a checkmark in each of the relevant boxes.)

☐ Recruitment letters or fliers
☐ “Informed Consent Form(s)”
☐ Instructions to participants
☐ Interview Guide or other research protocol (questionnaires, tests, observation system, etc.)
☐ Compensation guidelines
☐ Information sheets or “debriefing” method
☐ Letters of approval from cooperating institution(s)
☐ Explanation for exemption from federal regulations
☐ NIH Certification

Return completed application to:

Pandora Johnson, PhD
Chair, IRB
irb@ub.edu.bs
APPENDIX B: Sample Informed Consent Form

SAMPLE CONSENT LETTER-CHILD PARTICIPANT

September 25, 2010

Dear Parent or Guardian:

This semester, third grade students at your child’s school will have the chance to participate in a project on children’s writing development. The purpose of the project is to see whether teacher feedback and help with editing can lead over time to better student writing. The results of this project may help teachers learn more about how to support children’s writing success. The project is supported by the Local Foundation and has been reviewed and approved by the school principal, your child’s teacher, and the Anytown School. The project is led by Ann Faculty, an elementary education professor at the University of The Bahamas (UB).

With your permission, we would like to collect three samples of the writing your child does in class during the months of February, March, and April. The writing we hope to collect will be regular assignments given by your child’s teacher. In addition, with your permission, we would like to ask your child several questions about how he/she plans writing assignments. This interview will last about 15-20 minutes and will take place in a quiet corner of your child’s classroom during the school day. Children usually find these interviews interesting, not stressful, but if your child is not comfortable with the interview, he/she is free not to participate. The person from our project who will work with your child is a UB graduate student with several years’ experience working with children in classrooms.

If you give permission for your child to participate in the project, he or she is free to decide not to continue participation at any time. Your child’s participation or non-participation in the project will have no effect on your child’s schoolwork. It is fine to give or refuse permission.

If you agree that your child can participate, we will not use your child’s name or the school or teacher’s name in any of our records. Your child’s name will be removed from the writing samples we collect, and a number code will be used instead. Writing samples and interview notes from the project will be kept in a locked cabinet in Ann Faculty’s office at UB.

If you have questions about the project or your child’s participation, please call Ann Faculty at (xxx) xxx- xxxx. You may also contact Dr. Pandora Johnson at UB’s Institutional Review Board at (242) 302-4310 if you have questions about your child’s rights as a participant in research.

(Please keep this top section for your records.)

Please tear off and return this section to your child’s teacher in the envelope provided.

☐ I give permission for my child, __________________________, to participate in the writing project conducted by Ann Faculty.

☐ I do not give permission for my child, __________________________ to participate in the writing project conducted by Ann Faculty.

_________________________  __________________________
(signature)                           (date)
SAMPLE CONSENT LETTER—ADULT PARTICIPANT

September 25, 2010

Dear Participant:

This spring, junior education majors at the University of The Bahamas (UB) will have the chance to participate in a survey on student career goals and undergraduate preparation to teach. The purpose of the project is to learn more about student perspectives on what helps prepare them to be effective teachers. The results of this project will be used to improve undergraduate coursework and advising in the Education Division at UB. The project is supported by UB’s Faculty Innovation Fund and is led by Ian Faculty, an elementary education professor at UB.

With your permission, you will participate in a survey questionnaire concerning your career plans and academic experiences as an undergraduate. This survey should take about 30 minutes to complete. In addition, you may be contacted for a 20-minute follow-up interview concerning your perception of more and less successful academic experiences you have had related to your preparation as a teacher. The interview would take place in an empty classroom on campus and your response would be recorded on audiotape. Students usually find these kinds of questionnaires and interviews interesting, but if you are not comfortable with the survey questions or interview, you are free not to participate or to skip any questions. The person who may interview you is a UB graduate student with experience in undergraduate advising and career guidance.

If you give permission to participate, you are free to decide not to continue participation at any time. Your participation or non-participation in the project will have no effect on your status in the programme at UB. It is fine to give or refuse permission.

If you agree to participate, we will not use your name or identifying information in any of our records. A number code will be used for your responses. Questionnaires, interview tapes, and interview notes from the project will be kept in a locked cabinet in Ian Faculty’s office at UB.

If you have questions about the project or your participation, please call Ian Faculty at (xxx) xxx-xxxx. You may also contact Dr. Pandora Johnson at UB’s Institutional Review Board at (242) 302-4310 if you have questions about your rights as a participant in research.

(Please keep this top section for your records.)

Please tear off and return the bottom section and return in the envelope provided.

☐ I agree to participate in the student questionnaire and interview conducted by Ian Faculty.

☐ I do not agree to participate in the student questionnaire and interview conducted by Ian Faculty.

______________________________________  ____________________________
(signature)                                (date)
APPENDIX C: IRB Determination Form
IRB DETERMINATION FORM – For IRB Use only

IRB number: __________________ Date of IRB Submission: ____________

Title of study: __________________________________________________________

Name of Principal Investigator(s): _________________________________________

Department: ___________________________________________________________

☐ New Proposal    ☐ Re-Approval    ☐ Notification of Changes to Previous Approved Project

“Exempt” Research. Action taken:
☐ Approved as submitted    ☐ Approved pending    ☐ Requires “Expedited Review”
☐ Requires “Full Review”    ☐ Disapproved

“Expedited Review.” Action taken:
☐ Approved as submitted    ☐ Approval withheld pending revisions    ☐ Requires “Full Review”
☐ Disapproved

“Full Review.” Action taken:
☐ Approved as submitted    ☐ Approval withheld pending revisions    ☐ Disapproved

Re-Approval. Action taken:
☐ Approved as submitted    ☐ Approval withheld pending revisions    ☐ Disapproved

Research Requiring Changes to Previously Approved Project. Action taken:
☐ Approved as submitted    ☐ Approval withheld pending revisions    ☐ Disapproved

If disapproved or revisions required, reasons for decision:

Required follow-up:

IRB Chairperson’s Signature: ____________________________ Date: __________

IRB Members’ Signatures:

__________________________________________ Date: __________

__________________________________________ Date: __________

__________________________________________ Date: __________

__________________________________________ Date: __________

__________________________________________ Date: __________

University of The Bahamas IRB Guidelines (As of February 2017)
Adapted with permission of Wheelock College, Boston, MA
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APPENDIX D: LEVELS OF IRB REVIEW

LEVELS OF IRB REVIEW

The IRB Chair will assign each research proposal to one of three categories: “Exempt Status,” “Expedited Review,” or “Full Review.” “Exempt Status” and “Expedited Review” proposals will be reviewed upon submission and a decision made in no longer than two weeks. “Full Reviews” require a meeting of the full IRB and usually will need three to four weeks for decision.

Guidelines for proposal submission are the same regardless of the level of review.

“Exempt Status”

NOTE: Research involving children always requires full IRB review, consequently “Exempt Status” never applies.

The Chair and one other member of the IRB may determine, based on the requirements of 45 CFR 46.101(b), that a research proposal is exempt from review by the full Institutional Review Board. Research activities in which adult human participants are involved only in one or more of the following categories are exempt from review:

(1) Research conducted in established or commonly accepted educational settings and 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.\(^7\)

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior unless:
   • information obtained is recorded in such a manner that human participants can be identified directly or through identifiers linked to the participants; and,
   • any disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or could be damaging to the participants’ financial standing, employability, or reputation.\(^8\)

Educational tests, surveys, interviews, or observations of public behavior of human participants who are elected or appointed public officials or candidates for public office are not exempt. Federal regulations may require that the confidentiality of personally identifiable data be maintained throughout the research, if such a requirement exists, the research is not exempt.\(^9\)

(3) 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

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\(^7\) Regulation 45 CFR 46.101(b)(1)
\(^8\) Regulation 45 CFR 46.101(b)(2)
\(^9\) Regulation 45 CFR 46.101(b)(3)
information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.\(^{10}\)

If research does not satisfy the Guidelines for “Exempt Status,” the full IRB will meet to review the proposal.

“Expedited Review”

If time is of the essence, researchers may request that the Institutional Review Board conduct an “Expedited Review” before the next regularly scheduled IRB meeting. “Expedited Review” procedures may be used to review when:

1. some or all of the research appears on the list included in a Notice in the Federal Register\(^ {11}\) as approved for “Expedited Review” if found by the IRB to involve no more than minimal risk; or,

2. there are only minor changes in previously approved research during the period (of one year or less) for which the approval is authorized.

Minimal risk is present when “the probability and magnitude of harm or discomfort anticipated in 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.”

An “Expedited Review” may be conducted by either the IRB Chair or one or more experienced reviewers designated by the IRB Chair. Approval is granted through the same procedures as used in a “Full Review.” All other IRB members will be kept apprise of research proposals approved under an “Expedited Review.”

If the proposed research does not satisfy the Guidelines for “Expedited Review,” the full IRB will meet to review the proposal.

“Full Review”

If the proposed research does not satisfy the criteria for either “Exempt Status” or “Expedited Review,” the proposal must reviewed by the entire IRB.

Any US federally funded project must be reviewed by the entire IRB. One copy of the application or proposal being submitted to the federal funding agency must accompany the IRB proposal submitted to the UB IRB. In addition, Principal Investigators must provide documentation that all investigators on a US federally funded project have completed the federally mandated human participants’ protection education.

The IRB consists of no fewer than five (5) members. IRB members have diverse backgrounds to

\(^{10}\) Regulation 45 CFR 46.101(4)

\(^{11}\) The list of research that may be approved via “Expedited Review” can be found at [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/) by clicking on the link for “Expedited Review Categories.”
promote complete and adequate review of research activities. The IRB includes at least one (1) member whose primary area of interest is in scientific disciplines and at least one (1) member whose primary interests are in nonscientific disciplines. The IRB includes one (1) member who is not otherwise affiliated with the University.

The IRB may invite individuals with competence in special areas to assist with its review. Particularly, if the proposed research involves a vulnerable category of participants (e.g. children, prisoners, pregnant women, handicapped or mentally disabled persons), the IRB will consider including a person knowledgeable and experienced in working with these participants.

To issue a decision, a majority of IRB members must be present, including one (1) member whose primary discipline is in nonscientific areas. For research to be approved, it must receive the approval of a majority of IRB members present at the meeting.
APPENDIX E: Glossary

GLOSSARY

BELMONT REPORT: A statement of basic ethical principles governing research involving human participants issued in 1978 by the National Commission for the Protection of Human Participants.

BENEFICENCE: An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

BENEFIT: A valued or desired outcome; an advantage.

CHILDREN: Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted. [45 CFR 46.401(a).] Persons under eighteen (18) years of age are considered children in The Bahamas.

COMPENSATION: Payment or medical care provided to participants injured in research; does not refer to payment for participation in research (remuneration).

COMPETENCE: A legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: INCOMPETENCE.)

CONFIDENTIALITY: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

CONSENT: See INFORMED CONSENT

DATA AND SAFETY MONITORING BOARD: A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another) that would warrant modification or termination of the trial or notification of participants about new information that might effect their willingness to continue in the trial.

DEBRIEFING: Giving participants previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

DECLARATION OF HELSINKI: A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.
EMANCIPATED MINOR: A legal status conferred upon persons who have not yet attained the age of legal competency as defined by US law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation. (See also: MATURE MINOR.)

EQUITABLE: Fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed. [see 45 C.F.R. 46.111(3).]

EXPEDITED REVIEW: Review of proposed research by the IRB Chair or one or more experienced reviewers designated by the IRB Chair. The same Guidelines for review as used in a Full Board Review apply. Expedited Review is allowed only in limited circumstances where the research involves limited risk or is a minimal change to a previously approved research project.

FULL BOARD REVIEW: Review of proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting. [see 45 C.F.R. 46.108.]

HUMAN PARTICIPANTS: Individuals whose physiological or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human participants are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information. [45 C.F.R. 46.102(f).]

INCOMPETENCE: Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity.

INFORMED CONSENT: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving Informed Consent, participants may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence. [see 45 C.F.R. 46.116.]

INSTITUTIONAL REVIEW BOARD: A specially constituted review body established or designated by an entity to protect the welfare of human participants recruited to participate in research. [45 C.F.R. 46.102(g); 46.108; 46.109.]

LEGALLY AUTHORIZED REPRESENTATIVE: A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human participants research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research. [45 C.F.R. 46.102(c).]

MATURE MINOR: Someone who has not reached adulthood (as defined by US law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. (See also: EMANCIPATED MINOR.)

NORMAL VOLUNTEERS: Volunteer participants who do not have the condition under study in a particular protocol, used as comparisons with participants who do have the condition. "Normal" may not mean
normal in all respects. For example, patients with broken bones may serve as normal volunteers in studies of cognitive development and the like. Similarly, patients with heart disease but without diabetes may be the "normal" in a study of diabetes complicated by heart disease.

**PRINCIPAL INVESTIGATOR:** The person or persons who are held responsible for meeting all UB IRB requirements.

**PRIVACY:** Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**PROTOCOL:** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**RESEARCH:** A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge. [45 C.F.R. 46.102(d).]

**RESPECT FOR PERSONS:** An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

**RISK:** The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

**SURVEYS:** Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.