Guidelines and Procedures for the Richard Bland College Protection of Human Subjects Committee (PHSC)

PHSC Membership:

The membership of the PHSC shall include at least one community representative, the Chief Academic Officer or his/her designated representative, and a minimum of three faculty members. At least one faculty member should have expertise in a non-scientific area. One member of the committee shall be elected Chair by majority vote of the members of the committee. The committee shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

A majority of the members of the PHSC, including at least one member who primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Final approval by the PHSC shall then require a two-thirds vote by members present. If the PHSC agrees that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of approval. A letter of approval will be sent to the investigator.

All members of the RBC PHSC must complete the National Institutes of Health (NIH) On-Line Educational Model located at: https://phrp.nihtraining.com/users/login.php. The certificate of completion for new committee members must be forwarded to the Chair of the PHSC.

PHSC Procedures:

1. All human subject research proposals will be electronically submitted for documentation and tracking. Researchers cannot exempt from review their own study or research. Similarly, individuals involved in the conduct and/or supervision of a research project cannot participate in its review, except to provide information to the PHSC.
2. Requests by external researchers (i.e., researchers not employed by Richard Bland College) for human subject research to be conducted at Richard Bland College must be reviewed and approved by the RBC PHSC.
3. The PHSC has the authority to approve or disapprove all research using human subjects. If the PHSC disapproves an application, reasons for this negative decision will be provided in writing to the principal investigator. If the researcher decides to modify the proposed research in such a way as to overcome the objections of the PHSC, the investigator may resubmit the proposal for consideration and/or have the Chair call a PHSC meeting during which the investigator may defend the proposal or the modifications.
4. Exercises which are an integral component of regular coursework require only the prior approval of the Chair of the PHSC.
5. Principal investigators must immediately report the PHSC any emergence of problems.
6. The PHSC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the PHSC's requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a

statement of the reasons for the PHSC's action, and shall be reported promptly to the investigator and appropriate institutional officials.

7. External researchers, adjunct faculty and visiting faculty members must name a faculty member as a Co-PI on protocols to obtain approval.

PHSC Criteria for Evaluating and Approving Proposals:

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonable be expected to result. In evaluating risks and benefits, the PHSC should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive, even if not participating in the research). The PHSC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the PHSC should take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. Informed consent will be appropriately documented.
5. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

Basic Elements of Informed Consent:

1. A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs, and, if so, what they consist of, or where further information may be obtained.

7. An explanation of whom to contact for answers to pertinent questions about the research and the research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary and the subject may discontinue participation without penalty.
9. A statement that "this project was approved by Richard Bland College Protection of Human Subjects Committee."

Exemptions:

The investigator should indicate the number of the category under which an exemption is claimed on the application protocol. The determination as to whether a research project is exempt will be made by the committee.

1. Research conducted in established or commonly accepted educational settings, involving normal education 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.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior) unless information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly through identifiers linked to the subjects and any disclosure of the human subjects' responses outside the research could reasonable place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.
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 information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subject.

Instruction for Submitting a Human Subjects Proposal:

According to 45 CFR 46, of the Code of Federal Regulations, the U.S. Department of Health and Human Services has mandated that research that involves human subjects must be approved by an Institutional Review Board to ensure the safety and the appropriate use of humans as subjects in research studies. ***ALL*** protocols involving human subjects must be submitted to the Protection of Human Subjects Committee at Richard Bland College for exemption or approval.

Based upon the guidelines provided by the DHHS, the RBC Protection of Human Subjects Committee will either 1) exempt the protocol from formal review or require that it undergo either 2) expedited review by the Chair or 3) review by the full committee during a convened meeting.

A properly completed protocol will include the following:

1. A brief rationale for the study
2. Full procedures
3. Description of the participants
4. Copy of all tests, questionnaires, all interview questions, the informed consent form, a statement about length of data retention and destruction, and other pertinent information

5. If applicable, a request for exemption and the appropriate number and reason for the exemption

Reviews should be completed within 3-4 weeks. Written notification of the PHSC's decision will be sent to the principal investigator.