Elkins College Academic Honesty Policy; allegations against faculty will be addressed through the Faculty Handbook.

5.8.3 Human Subject Research (Institutional Review Board)

As mandated by both federal law and national policies, Davis & Elkins College maintains an Institutional Review Board (IRB) for reviewing research proposed to be conducted by members of the College or involving members of the College as human research subjects. The primary purpose of this review board is to protect the rights of human subjects.

I. The Responsibilities of the IRB

1. Review research proposals and/or classroom research studies involving human subjects and to mandate revision (as needed).
2. Maintain and disseminate guidelines for staff, faculty, and students who wish to conduct research with human subjects.
3. Review all proposed research studies involving human subjects to assure compliance with appropriate statutes and standards of care.
4. Monitor proposed studies to ensure compliance with the principles of ethical research.
5. Monitor ongoing studies to ensure compliance with established policies, procedures, and applicable statues.

II. Composition and Responsibilities of the IRB

The committee will be composed of three faculty members, a student, the Director of Institutional Research, the Vice President for Academic Affairs, and a community member who is not employed at the College and is not a student at the College. Appointments to this committee and a chair will be named by the President in consultation with the Vice President for Academic Affairs.

The full board will meet two times a semester (or as necessary) to review proposals. Meeting dates shall be communicated at least two weeks prior to each meeting.

A quorum of more than half of the Review Board membership must be present for the consideration of any proposal or other relevant matters. A majority vote of board members present is necessary for approval of full reviews (explained below) as well as for actions unrelated to proposals. A principal investigator may, at his or her own discretion or at the IRB's request, attend the meeting during which his or her proposal(s) is considered. The chair of the IRB shall provide written notification of the Review Board's actions. This notification shall be sent to the principal investigator when the IRB rules on a proposal. All proposals and a record of IRB actions are maintained in the Office of Institutional Research.

III. Purpose

Any faculty, staff, or student conducting research with human subjects must devote attention to the potential risks to which those subjects may be exposed. The researcher must identify threats to the rights or well-being of persons (or groups of persons) who participate in studies conducted under the auspices of the College. Studies that present low risks to the human subjects do not need

be reviewed. Examples of research that would ordinarily involve low risk and, thus, not require review would include:

1. Recording of data from subjects 18 years or older using non-invasive procedures (e.g., survey research, observation and/or participant observation).
2. Anonymous voice recordings for research purposes.
3. Participation observation in a public venue such as worship service or other community gathering place.
4. Study of existing data, documents, or records.

IV. Definition of "Research"

Research is defined in the Code of Federal Regulations as "a systematic investigation designed to develop and contribute to generalized knowledge". Further, research is any project that uses systematic methodology (quantitative, qualitative, mixed-methods, triangulation) to collect, analyze, and draw conclusions from data.

V. Review Categories

At Davis & Elkins College there are three categories of research involving human subjects:

Category 1: Exempt from IRB Review - Proposals that fall under the "exempt" category need only to file the "application for exempt" form. **Category 2: Full Board Review** – Proposals that fall under the "full board review" category need to file the "application for full board review" form.

Category 3: Classroom Research – Proposals that fall under the "expedited/classroom research" category need to file the "application for "classroom research" form.

Exempt from IRB Review

These research activities involve no more than minimal risk and may include classroom studies, surveys, observation of public behavior, the non-invasive collection of physiological data, and the analysis of existing data that involves human subjects. Research that includes both exempt and non-exempt categories is not exempt. More detailed information regarding exemptions is found on the Office for Human Research Protections website. Irrespective of whether a study is exempt from full review, it must meet accepted standards of protection of privacy and a subject's right to refuse participation without penalty.

A project is exempt if all the research activities belong in one or more of the following categories:

A. Research involving the collection or study of existing data including documents, records, and pathological or diagnostic specimens if:
    1. These sources are publicly available or
    2. The information is recorded by the investigator in such a manner than human subjects cannot be identified.

B. The research is conducted in established or commonly accepted educational setting and involves normal educational practices. This includes:
    1. Research on normal and special education instructional strategies.

2. Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management techniques.

C. Research on individual or group behavior, or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research does not involve stress to the subjects. This includes:

1. Cognitive, diagnostic, aptitude or achievement tests if the data are recorded so that subjects cannot be identified;

2. None of the investigator's current students may participate as subjects unless

- The study is conducted solely for the purpose of program assessment, or
- The study is a class assignment whose sole purpose is to enhance learning.

D. Research involves the observation of public behavior if:

1. The behavior does not place the subject at criminal or civil risk.

2. The behavior does not deal with sensitive or personal behavior.

E. Research involving only surveys or interviews if the project does not deal with

1. Sensitive aspects of behavior or

2. Highly personal behavior of the subjects themselves.

F. Research involving only surveys and interviews with the public, appointed or elected officials.

G. Research involving only taste and food quality evaluations.

H. Recording data from subjects 18 years of age and older, using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance, and does not involve input of matter or significant amounts of energy to the subject, or an invasion of the subject's privacy. It also includes such procedures as weighing, measurement of sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, and use of diagnostic electromagnetic radiation outside the visible range (for example, X-ray and microwaves).

Proposals that fall under the "exempt" category need to file the "application for exemption" form and the "research involving stored data" form.

Full Board Review

A full board review is required for research involving risk of physical and/or psychological harm greater than that encountered in daily living or during routine examinations or tests. Research involving experimental medication protocols or research involving potentially harmful deception requires full board review.

Proposals that fall under the "full board review" category need to file the "application for full board review" form and the "research involving stored data" form.

Classroom Research

Classroom research projects may be provisionally approved by the IRB committee. Faculty who anticipate students engaging in research as a class requirement need to file the "application for classroom research" form and the "research involved stored data" form.

If the IRB determines that a particular study should be reviewed under a different category, the principal investigator will be notified and may be asked to provide additional documentation.

VI. Monitoring Authorized Research Proposals

A Principle Investigator conducting research involving human subject must at all times:

1. Act in accordance with the terms of the authorized research proposal (including any revisions or conditions specified by the IRB when approving the proposal);
2. Act consistently with the Key Ethical Principles set forth below;
3. Comply with federal, state and local laws and regulations, as well as College policies and procedures;
4. Permit the IRB to observe, or have a third party observe on its behalf, the conduct of the research; and
5. Permit the IRB to audit, or have a third-party audit on its behalf, the research facilities, files, and progress reports.

A Principal Investigator must promptly notify the IRB of any: material change in circumstances occurring after the approval of a research proposal; or inaccuracy, of which it has since become aware, in any information provided to the IRB in support of the authorized research proposal. Additionally, a Principal Investigator must promptly notify the IRB of any suspension or premature termination of its research, and of the reasons for that suspension or termination. Finally, a Principal Investigator must immediately restrict, suspend, or terminate research where it is directed by the IRB to do so.

In carrying out an approved research project, a Principal Investigator must submit to the IRB:

1. Progress reports including written summaries of the progress of the research, as often as the IRB may specify;
2. A safety report immediately upon the occurrence of any serious adverse event; and
3. A final report upon the completion of the research, to be submitted no later than 90 days following the date of completion.

VII. Key Ethical Principles

Human Subjects Research must conform to generally accepted international principles and values of ethical conduct in research. In particular, research must be:

1. Justifiable by its potential benefits, including (but not limited to) its contribution to knowledge, improving social welfare and individual wellbeing;
2. Designed or developed using methods appropriate to achieving the aims of the research proposal;

3. Based on a thorough study of the literature and where appropriate preceded by adequate laboratory and/or animal studies;
4. Conducted with integrity and carried out with a commitment to search for knowledge;
5. Undertaken with a commitment to disseminating and communicating results, whether favorable or unfavorable, in ways that permit scrutiny and contribute to public knowledge and understanding;
6. Just, in that the selection, exclusion and inclusion of categories of subjects or donors and recruitment and distribution of benefits of participation is fair, the process is accurately described in its methods and results, and there is no exploitation of subjects or donors;
7. Respectful of the privacy, confidentiality and cultural sensitivities of the subjects or donors and, where relevant, their communities; respectful of the right of subjects and donors to make their own decisions;
8. Where subjects or donors are unable to make their own decisions, or have diminished capacity to do so, designed to empower them where possible and to provide for their protection as necessary; and
9. Conducted in an impartial and transparent manner unless there are specific and justifiable reasons preventing it.

VIII. Risk Assessment

Research can be ethically acceptable only if its potential benefits outweigh its risks, following an assessment which involves:

1. Identifying any risks;
2. Gauging their probability of occurrence and likely severity;
3. Assessing the extent to which they can be minimized;
4. Determining whether they are justified by the potential benefits of the research; and
5. Determining how they can be managed.

IX. Standards for Researchers

Research must always be conducted by competent Principal Investigators who:

1. Have qualifications, education, training and experience that is adequate to their degree of responsibility for the proper conduct of the research;
2. Are familiar with current policies relating to the research;
3. Are both independent and impartial;
4. Treat humans, the human body and human tissue with respect; and
5. Are aware of cultural or religious differences in the meaning and significance attached to the body or specific parts of it before approaching potential subjects or donors.

X. Informed Consent

A Principal Investigator must obtain the informed consent from each individual (or legally authorized representative) who is the subject of a research project requiring IRB review. A Principal Investigator must ensure that the informed consent of each subject is documented by the use of a written Consent Form approved by the IRB. The Consent Form must either: set out in full the Elements of Informed Consent (see below); or truthfully state that the Elements of Informed Consent have been presented orally to the subject (or his or her legally authorized representative). The Consent Form must be written in terms that can be readily understood by subjects participating in the research. The Consent Form must be signed and dated by the subject (or the subject's legally authorized representative) and by the Investigator who obtained the consent. A signed and dated copy of the Consent Form must be given to the subject, or to the subject's legally authorized representative if he or she has signed the Form.

Elements of Informed Consent: The following are matters that must be communicated to a subject before Informed Consent is given:

1. A statement of the purpose of the Human Subjects Research, the expected duration of the subject's participation, a description of any procedures to be followed, and an identification of any procedures that are experimental;
2. A description of any treatment included in the research, and the probability of random assignment to each treatment;
3. A description of any foreseeable risks and benefits to the subject;
4. If the research involves a risk of harm to the subject, an explanation of whether any compensation or medical treatment is available if injury occurs to the subject and if so, what that compensation or treatment will be;
5. A statement of the subject's responsibilities with respect to the research;
6. A statement describing how confidentiality will be maintained or private information identifying the subject will be dealt with;
7. A statement concerning the access to the subject's records that the IRB and any auditors will have for the verification of the procedures and data associated with the research;
8. The name and contact details of a person the subject may contact for further information regarding the research, a statement of the subject's rights, and the name and contact details of a person the subject should contact in the event of injury arising in conjunction with the research; and
9. A statement that the subject's participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may stop participating at any time without penalty or loss of benefits to which the participant is entitled.

To the extent that is relevant, the Elements of Informed Consent must also include: a statement addressing any cultural or religious concerns of the subject; a description of any foreseeable risks to an unborn fetus carried by the subject or to an infant being nursed by the subject; a statement that the research may involve risks to the subject (or an embryo or fetus carried by the subject, if the subject is or may become pregnant) that are currently unforeseeable; a statement of any

anticipated circumstances under which the subject's participation in the research may be terminated by the Investigator without the subject's consent; a statement of any costs to the subject that may result from participation in the research; a statement of the consequences of a subject's decision to withdraw from the research and a description of the procedures for an orderly termination of participation by the subject; and a statement that any significant new findings developed during the course of the research, if they may relate to the subject's willingness to continue participation, will be provided to the subject.

Vulnerable Subjects: A Principal Investigator who seeks to obtain informed consent from vulnerable individuals, including (but not limited to): those with impaired mental capacity; children; those who do not speak English; and those who are illiterate, must provide additional elements of protection, both with regard to obtaining and documenting informed consent, where that is necessary for the welfare of the subject. In the case of vulnerable subjects, consent is typically obtained from parent(s) or legal guardian(s). However, an understandable explanation of the research procedures should also be given to the minors or other vulnerable participants (populations such as pregnant women, prisoners, those who lack the capacity to consent, non-English speaking individuals, etc.) for whom consent has been obtained, and they should be given the chance to volunteer to participate in the proposed activity. This is called "assent." Their wishes determine their participation.

XI. Suspension or Early Termination of Approved Research

The IRB must promptly suspend or terminate research where:

1. It becomes (or should be) apparent to the IRB that the risks to subjects are greater than were anticipated at the time at which the research proposal was approved, to the extent that they are no longer justified by the benefits arising from the research; or
2. The research causes unexpected serious harm to any one or more subjects.

The Principle Investigator will promptly notify the subject of the suspension or termination.

XII. Internet-Based Human Subject Research

All Internet-based research studies must:

1. Incorporate the principles of voluntary participation and informed consent;
2. Maintain the confidentiality of information obtained from or about human subjects; and
3. Appropriately address possible risks to participants, including psychosocial stress and related risks.

Internet-based research may not be suitable for studies involving greater than minimal risk, particularly where the research involves vulnerable populations or data that:

1. Places subjects at risk of criminal or civil liability;
2. Could damage subjects' financial standing, employability, insurability, or reputation; or
3. Places subjects at risk for identity theft.

Exceptions to the minimal-risk standard may be made at the discretion of the IRB, but may involve additional consent requirements as defined below.

Benefits and Disadvantages of Internet-Based Research: Many investigators are turning to Internet-based research as a fast, simple and inexpensive method of reaching potential participants. Increasing segments of the population are gaining access to the Internet each day, and Internet use in the privacy of one's own home may be viewed as a less intrusive research method, particularly for sensitive subjects.

However, there are several methodological drawbacks to using the Internet for data collection. The population of respondents may not represent a random sample from the true population of interest, hindering the investigator's ability to generalize results to broader populations. Additionally, it may be difficult to monitor and exclude multiple responses from the same participant or, in the case of responses using accuracy and reaction time, to determine whether participants are fully focusing on the task at hand. Investigators must understand that each Internet-based communication carries the risk of a breach of confidentiality. Even when data are collected without names, web sites or email programs may still be capable of collecting identifiers. Accordingly, investigators should keep in mind that they may be unable to guarantee anonymous collection of data. Finally, investigators must remember that admonishing participants that they must meet any demographic criteria, including a requirement to be 18 years of age to participate, does not guarantee compliance. Researchers are advised to take steps to authenticate participants. For example, investigators can provide each study participant (in person or by postal mail) with a Personal Identification Number (PIN) to be used for authentication in subsequent Internet-based data collection.

Institutional Review Board Review of Internet-Based Research Materials: The IRB must review and approve all materials that will be presented to potential participants, including:

1. Recruitment ads or invitation to participate;
2. Informed consent elements;
3. Introduction and "Thank You" pages;
4. Survey instructions and "Pop-up" help;
5. Survey questions and response choices;
6. Graphics, audio, video content;
7. Links to other web sites/content; and
8. Any other relevant materials.
9. *Recruitment:* Internet-based procedures for advertising a study and recruiting potential participants must follow the IRB guidelines for recruitment that apply to any traditional media, such as newspapers and bulletin boards. Additionally, advertising and recruitment efforts must comply with the College's information technology policies.
10. *Informed Consent Process for Internet-Based Research:* Typically, Internet-based research involving minimal risk to participants does not necessitate hard-copy documentation of consent. Instead, a variation of the following statement must be visible on the screen prior to entering the survey: "*Confidentiality will be maintained to the degree permitted by the technology used. Your participation in this online survey involves risks similar to a person's*

everyday use of the Internet. By clicking "submit" upon completion of the survey, you are granting consent for your responses to be included in the research study."

Internet-Based Research Involving Minors: Investigators are not permitted to collect personal information from a child without posting notices about how the information will be used and without obtaining parental permission. Written permission must be obtained via postal mail or fax. A face-to-face interview must be conducted to obtain parental consent for studies with minors that involve more than minimal risk.

Internet-Based Research Data Collection: Any data collected from human participants through the Internet must be transmitted in encrypted format, using the highest level of encryption that is reasonable within limits of availability and feasibility. Encryption helps to ensure that any data intercepted during transmission cannot be decoded, and that individual responses cannot be traced back to an individual respondent. Investigators are cautioned that encryption standards vary from country to country.

Internet-based survey instruments must be formatted in a way that will allow participants to skip questions if they wish or provide a response such as "I choose not to answer." Also, at the end of the survey, there should be two buttons: one to allow participants to discard the data and the other to submit it for inclusion in the study. Finally, if applicable, online surveys must include mechanisms for withdrawal. For example, if a participant decides to withdraw, there should be a mechanism for identifying the responses of a participant for the purposes of discarding those responses.

Research in Online Communities: Conducting research in online communities, such as chat rooms, blogs, social sites, and gaming sites, requires investigators to respect the privacy and right to consent of members of the communities. Joining an online community for the purpose of surreptitiously collecting information and quotes for a research study is unethical and would not be approved by the IRB. Instead, an investigator may set up his or her own chat room. Each person who joins the chat room must be greeted with a statement about the research study as well as a statement of informed consent, and must be offered the opportunity to exit the chat room if they do not wish to participate.

Internet-Based Research Software and Server Guidelines: For minimal-risk studies that do not involve the collection of sensitive data, online software and survey tools may be used, provided they meet the following guidelines:

1. SSL (Secure Sockets Layer) encryption is available;
2. At the completion of the survey, there should be two buttons: one to allow participants to discard the data and the other to submit it for inclusion in the study;
3. The software company has signed confidentiality agreements preventing them from improperly accessing or disclosing the information contained in their databases;
4. The system is capable of masking IP addresses and other identifying information from the investigator.

For high-risk studies that involve the collection of sensitive data, the IRB recommends that surveys be housed on a Davis & Elkins College server. The server will be administered by the Davis & Elkins College Information Resources staff. In accordance with College policy, access to the

server is limited to key project personnel and the server will receive frequent, regularly scheduled security audits.

Internet-Based Research Data Storage and Disposal: If a server is used for data storage, personal identifying information should be kept separate from data, and data should be stored in encrypted format. Proper data destruction methods and schedules must also be used to ensure that no data can be recovered from obsolete electronic media. All data storage and destruction plans must comply with the Record Retention Policy and Schedule.

XIII. Confidentiality

A Principal Investigator must not disclose any personal information obtained for the purposes of Human Subjects Research without the express consent of the subjects or donor to whom it relates (or his or her legally authorized representative), except where: disclosure is necessary to eliminate any apparent immediate risk of harm to the donor or to any other person; and the disclosure is the minimum necessary for the purpose of eliminating such harm.

If personal information relating to a subject or donor is, or is likely to be, disclosed without consent, a Principal Investigator must immediately inform that subject or donor (or his or her legally authorized representative): of the disclosure and of its purpose and extent; and that any person given access to the information will be required by the researcher to be subject to a duty of confidentiality, and he or she must ensure that any 3rd parties to whom the information is disclosed will be subject to a legally binding duty of confidentiality.

IV. Data and Record Keeping

A Principal Investigator must ensure that all information related to IRB research is recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. All documentation and records must be retained by the Investigator for the amount of time specified in the Record Retention Policy and Schedule in the *Davis & Elkins College Policy Manual* Volume III; and must be made accessible by the Investigator to the IRB for the purpose of auditing and review. A Principal Investigator must ensure that its security policies and procedures are sufficient to prevent any breach of confidentiality in respect of information relating to research.

5.8.4 Humane Care and Use of Laboratory Animals Policy

Davis & Elkins College, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. Applicability

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

"Institution" includes the following branches and major components of Davis & Elkins College: Department of Biology and Environmental Science