Determining Your Level of Review

Thank you for your interest in submitting an Institutional Review Board Application.

First, we will determine your level of review.

- Level I: Exempt (no foreseeable risk)
- Level II: Expedited Review (minimal risk)
- Level III: Full Board Review (more than minimal risk and protected subjects)

You will need to document the level of review required on your IRB Application. Please take a moment to carefully consider the following checklists and follow the corresponding instructions.

Exempt Review Checklist, Part A

Please check all of the following item(s) that apply to your proposed research:

- ☐ The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

- ☐ The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

- ☐ The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

- ☐ The research does not involve subjects under the age of 18.

- ☐ The research does not involve deception.

- ☐ The procedures of this research are generally free of foreseeable risk to the subject.

- ☐ The research does not require a waiver from informed consent procedures.

If you selected all items, go to **Exempt Review Checklist, Part B**.

If you selected all items *except* "The research does not involve subjects under the age of 18", go to **Exempt Review Checklist, Part B (*with subjects under age 18*).**

If one or more items are unchecked, go to **Expedited Review.**

Exempt Review Checklist, Part B

Please check all of the following items that apply to your proposed research:

- ☐ Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

- ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is Exempt, whether or not data collection is anonymous.

- ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

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

- ☐ Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If you checked at least one of these items, the project is designated **Exempt. Proceed with your IRB Application.**

If no items are selected, go to **Expedited Review.**

Exempt Review Checklist, Part B (*with subjects under age 18*)

Please check all of the following items that apply to your proposed research:

- ☐ Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

- ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is Exempt, whether or not data collection is anonymous.*

  *If this item is selected, go to **Expedited Review Checklist, Part A**

- ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

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

- ☐ Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- ☐ Research includes currently enrolled as full-time college students.

If you selected at least one item (except for item 2*), the project is designated **Exempt. Proceed with IRB Application.**

Expedited Review Checklist, Part A

Please check all of the following item(s) that apply to your proposed research:

- ☐ The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

- ☐ The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

- ☐ The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

- ☐ The procedures of this research present no more than minimal risk to the subject. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

If you selected all items, go to **Expedited Review Checklist, Part B**

If one or more items is unchecked, go to **Full Committee Review**

Expedited Review Checklist, Part B

Please select all of the following item(s) that apply to your proposed research:

- ☐ Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or-videotapes, names will be recorded, even if they are not directly associated with the data).

- ☐ Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.); b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, Doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects.

- ☐ Collection of data from voice, video, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- ☐ Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows:
    - Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;

    - Involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

- ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. Although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g.,

use will be made of audio or videotapes, names will be recorded, even if they are not directly associated with the data).

- ☐ Research that involves deception. Deception must be scientifically justified and de-briefing procedures must be outlined in detail.

- ☐ Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.

- ☐ Research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where the research remains active only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; (d) where no subjects have been enrolled and no additional risks have been identified.

If you selected at least one of these items, the project is designated **Expedited Review. Proceed with IRB Application.**

If no items are selected, go to **Full Committee Review**

Full Committee Review Checklist

Please check all of the following item(s) that apply to your proposed research:

- ☐ The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.

- ☐ The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- ☐ The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

- ☐ The procedures of the research involve more than minimal risk to the subject (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
- ☐ Any research which does not fall into any of the categories explicitly identified as qualifying for Exempt or Expedited status.

- ☐ Any research being proposed by investigators outside Hampden-Sydney College.

If you selected at least one of these items, the project is designated as **Full Committee Review. Proceed with IRB Application.**