IRB Form 2

Application for Review of Human Subjects Research at Lehigh Carbon Community College

Before performing Human Subjects Research at Lehigh Carbon Community College you must read and understand Lehigh Carbon Community College's Guidelines for Human Subjects Research.

Please submit 2 copies of the following to the IRB Chair.

- A copy of this document with the information about the principal investigator and research project filled out and the check lists completed.
- A brief description of your research project.
- A description of the aspects of the research involving Human Subjects.
- A copy of any consent forms. These forms must have an expiration date of no more than one year from the beginning of the project.

If the project goes on for more than one year, a new application must be submitted.

Name of Principal Investigator: _____

Title of Principal Investigator: _____

Title of Research Project: _____

Duration of Research Project: _____

Signature of Principal Investigator: _____

Date: _____

If this is student research it requires a faculty or staff sponsor.

Name of Sponsor: _____

Title of Sponsor: _____

Signature of Sponsor: _____

Date: _____

Complete the following checklists to determine if you believe that your research should qualify for expedited review:

This research does qualify for expedited review ____

This research does **not** qualify for expedited review ____

Expedited Review

Part A (all items must apply) Put a check mark near all items that apply to your research.

__ 1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

__2. The research does not involve children as subjects or, if it does involve children as subjects, the research can be dealt with via expedited review as specified in Part B 4 b, below.

__3. 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.

__ 4. 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).

__ 5. 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.)

Part B (at least one item should apply) Put a check mark near all items that apply to your research.

__ 1. 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.* [NB: 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-video-tapes, names will be recorded, even if they are not directly associated with the data).]

__ 2. 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.

__ 3. 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.

__ 4. Research on *individual* or *group characteristics* or *behavior* (including but not limited to research involving *perception, cognition, surveys, interviews,* and *focus groups*) as follows:

a) 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;

b) *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.

__ 5. Research involving the *use of educational tests* (cognitive, diagnostic, aptitude, achievement), *survey procedures, interview procedures,* or *observation of public behavior*. [NB: 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).]

__ 6. Research that involves deception. [NB: Deception must be scientifically justified and de-briefing procedures must be outlined in detail.]

__ 7. 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.

__ 8. Research *previously approved by the 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.

Full Committee Review

If ANY of these apply. Put a check mark near all items that apply to your research.

__ 1. The research involves *prisoners, fetuses, pregnant women,* the *seriously ill,* or *mentally* or *cognitively compromised adults* as subjects.

__ 2. 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.*

__ 3. The research involves the *collection of information regarding sensitive aspects* of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

__ 4. 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).

__ 5. Any research which does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

__6. The research involves *children under the age of 18* as subjects.