Instructions for Completing the LRB Recommendation Form

I. Function and Responsibility of the Local Review Board (LRB): LRBs assist the university Institutional Review Board (IRB) in their review of the methodological, field specific science, and ethical aspects of research involving human subjects. In addition, the LRBs provide a peer-review service for researchers and local oversight of the conduct of the research.

II. LRB Member Training: Documentation of LRB members’ training through the CITI program at the LRB learner group level must be on file with the Office of Research Protections (ORP) in the Office of Research Services. Additional information about training is available on the IRB webpage at: [http://research.depaul.edu](http://research.depaul.edu).

III. Exempt Reviews: In order for a project to qualify for exempt review, it must meet the criteria for one or more of the six exemption categories and involve little to no risk (benign risk) overall. The research activities must fit within the narrow confines of the exempt categories. The categories underlined/bolded below represent the majority of exempt research at DePaul:

- **Category 1**: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.

- **Category 2**: Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
  - Studies including prisoners may not be classified as exempt under this category, and research that involves surveys, interviews or observation of minors when the researchers interact with the child during the observation are not allowed under this category.
  - In essence, this category allows for the exemption of interview or survey research with non-prisoner adults and the research is benign (i.e., does not pose risks to financial standing/reputation/employability or of civil/criminal liability or other psychological, physical, or social risks to the subject).

- **Category 3**: Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 of this section, if: (i) the human participants are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- **Category 4**: 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 a manner that participants cannot be identified, directly or through identifiers linked to the participants.

The following chart summarizes the type of review that different types of archival research should receive, since not all research with archival materials is exempt:
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<tr>
<th>Non-Reviewable</th>
<th>Exempt Review</th>
<th>Expedited/Full Board Review</th>
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<tbody>
<tr>
<td>Work with permanently deidentified/uncoded data (at the time of receipt by the researcher).</td>
<td>Work with existing data extracted from a private source when the researcher will not extract codes or identifiers, so that the research records contain only anonymous data.</td>
<td>Work with data from a private source when the researcher will receive/extract the data in an identifiable/coded format, even if the researcher will later deidentify the data.</td>
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- **Category 5:** Research and demonstration projects that are conducted by, or participant to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in, or alternatives to, those programs; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- **Category 6:** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

IV. Expedited Reviews: In order for a project to qualify for expedited review, it must pose no more than minimal risk, and it must meet the criteria for one or more of the initial review expedited categories. Any activity that does not fit into the expedited categories, but which may involve minimal risk, requires convened IRB review. The following **underlined/bolded** categories describe the majority of expedited research at DePaul:

- **Category 1:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.); (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (i) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week or (ii) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of
exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient
care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax
or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid
obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental
plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic
scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum
collected after saline mist nebulization.

- **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or
sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to
evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review,
including studies of cleared medical devices for new indications.) Examples: (i) 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 participant or an invasion of the participant’s privacy, (ii) weighing or testing sensory
acuity, (iii) magnetic resonance imaging, (iv) electrocardiography, electroencephalography,
thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic
infrared imaging, Doppler blood flow, and echocardiography, and (v) moderate exercise, muscular
strength testing, body composition assessment, and flexibility testing where appropriate given the age,
weight, and health of the individual.

- **Category 5:** Research involving materials (data, documents, records, or specimens) that have been
collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

- **Category 6:** Collection of data from voice, video, digital, or image recordings made for research
purposes.

- **Category 7:** Research on group characteristics or behavior (including, but not limited to, research on
perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and
social behavior) or research employing survey, interview, oral history, focus group, program evaluation,
human factors evaluation, or quality assurance methodologies.

V. The completed LRB forms should be forwarded to the Office of Research Protections (ORP) in the
Office of Research Services by either emailing the electronically signed PDF version to
ORP@depaul.edu or scanning the signed document and sending it via email to ORP@depaul.edu. You
no longer have to send this completed form in hard copy via campus mail. For exempt studies only two
LRB member signatures are required. The LRB member reviewers cannot be listed as personnel or
faculty sponsor on the application. Being a member of a student’s thesis committee does not eliminate
the individual from being a reviewer on the protocol.