Instructions for Form: Application for Claim of Exemption

In order to decide whether your activity involves research that may be reviewed and approved at the exempt level, review the following information.

1. Does the proposed activity meet the definition of research as defined in 45 CFR 46.102(d)?

46.102 (d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

- A systematic investigation is one that uses a systematic approach, such as scientific methods, to collect and analyze data
- Generalizable knowledge is knowledge expressed in theories, principles, and statements of relationships that can be widely applied to others experiences and the intent is to disseminate or apply to persons outside the individual or group involved in the activity.
- Ways knowledge can be generalized include:
  - When the results of the activity will contribute to the established body of knowledge
  - Publication, presentation or other distribution of the results to inform the field of study
  - The primary beneficiaries of the activity are other researchers, scholars, and practitioners in the same field
  - The results are to applied to a population larger or beyond the original study population
  - The results are intended to be replicated in other settings
  - Web based publication for professional purposes

☐ Yes ☐ No

- If yes, go to question 2.
- If no, your activity is not research, is non-reviewable, and does not require IRB review and approval. You may obtain an official determination that your activity is non-reviewable from our office. Contact ORP@depaul.edu for additional information on obtaining a non-reviewable determination.

2. Does the proposed research activity involve human subjects?

46.102(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

☐ Yes ☐ No

- If yes, go to question 3.
- If no, your activity does not involve human subject, is non-reviewable, and does not require IRB review and approval. You may obtain an official determination that your activity is non-reviewable from our office. Contact ORP@depaul.edu for additional information on obtaining a non-reviewable determination.

3. Does the research fit solely in one or more of the categories for exempt research listed below? Review the tips below to ensure your research meets the exemption criteria.

☐ Yes ☐ No

- If yes, complete the Form: Application for Claim of Exemption.
- If no, your research may be eligible for expedited review, but you must complete the expedited review form.

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

- This category allows for the recruitment and enrollment of children.
- The practices being studied must be normal educational practices and should not involve the evaluation of radical new instructional strategies or the use of randomization of subjects to different instructional methods, if one of the methods is a non-standard method.
- Physical education research that involves altering exercise activity significantly would not be exempt, as there may be the risk of injury.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses 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.
• Children may be involved in educational testing. However, in order to be exempt children may not be involved in survey or interview research or observations of public behavior when the investigator is involved in the activity being observed.

• If disclosure outside of the research could result in criminal or civil liability, damage to the financial standing, or employability, or reputation of the subject AND the information is recorded in a way that the subject could be identified or linked to the information (directly or indirectly), the research cannot be exempt.

• Research where the data is sensitive, but is collected anonymously thereby eliminating the possibility of disclosure causing any of the risks noted above, is generally exempt. However, if there is the potential for the subject to become upset or uncomfortable when completing the survey, even if the survey is collected anonymously, the research may not be exempt and may require expedited review. In these cases the IRB may also require that the research materials include a mechanism to provide resources to the subjects for getting help or support if they are upset.

• Surveys that are limited to just a survey are clearly exempt. Research activities that include manipulation of the subject’s mood, environment, psychological state, or emotion before or during asking them to complete the survey would not be eligible for exemption as they involve an intervention plus a survey.

• Research involving minor deception (i.e. not explaining the real purpose of the study and what the study involves) and that fully meets the exemption criteria may be exempt. However, most research that involves deception requires expedited review and an alteration of consent.

• Research that involves cognitive and psychological testing is not usually exempt, especially if it is psychologically invasive in nature and could potentially cause discomfort or distress.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects 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.

• This category is an extension of category 2 and should only be applied when the research will not meet the criteria for category 2.

• Identifiers may be kept as public officials have a lesser expectation of privacy and confidentiality as compared to the average person. However, the rights of the public officials as subjects should still be protected, as appropriate to the research.

(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 such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

• “Existing” means that all data, documents, records, etc. must already exist now at the time you are proposing the study. If data sources that are private and individually identifiable will be collected prospectively after you propose the research by the source or owner, this would disqualify the research from exemption.
If the research involves the collection of data from medical, clinical records, or other privately held records, the data must be recorded without any identifiers in order to be exempt. Additionally, if the data is held in medical records, the researcher must comply with the HIPAA Privacy Rule, which may require a HIPAA waiver of authorization from the Covered Entity to whom the records belong.

(5) Research and demonstration projects which are conducted by or subject 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 procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

This category allows research on public benefit or service programs, such as Welfare, Medicaid, Unemployment, or Social Security. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under Social Security Act) or service (e.g., social, supportive, or nutritional services as provided under the Older Americans Act).

The data may be routinely compiled by the offices administering the service program for analysis, but it may be considered private by the subject. Therefore, appropriate protections must be in place to protect the confidentiality of the data.

The research or demonstration project must be conducted pursuant to specific federal statutory authority.

There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB), because if there were such a requirement, expedited review would be required.

The project must not involve significant physical invasions or intrusions upon the privacy of participants.

(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 and 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.

These studies must be limited to taste and food evaluation studies and cannot involve consumption by the subject of any type or volume of food that has the potential to cause risks such as indigestion or vitamin deficiencies.

The food consumed should be in reasonable amounts over a reasonable time frame.

Studies that involve the consumption of alcohol, vitamins, or supplements, such as protein powder, creatine, and glucosamine chondroitin sulfate, would not qualify for exemption.

APPLICATION COMPLETION

Indicate the date you completed the form, or the date you revised the form to address the IRB’s request for revisions.

Indicate which exemption category or categories applies to your research.
Complete the requested information for the Principal Investigator (PI) for the research. Status refers to whether you are faculty, staff, an undergraduate student, or a graduate student. Title refers to your title, such as Assistant Professor, Associate Professor, Research Assistant, Post Doctoral Fellow. The PI must be a DePaul faculty, student, or staff member. For collaborative research, the DePaul PI is the person at DePaul conducting the research activity that engages DePaul in the research. The non-DePaul collaborator would be listed on the Form: Co-investigator and Key Research Personnel.

For students, staff members in a position functioning as a training position, or research fellows, there must be a Faculty Sponsor listed on the application. The faculty sponsor is the person supervising and mentoring the PI and has ultimate responsibility for the ethical conduct of the research.

Any additional co-investigators or key research personnel should be listed on the Form: Co-investigators and Key Research Personnel.

The PI of the research protocol is responsible for ensuring that all personnel listed on the application and personnel form have completed human subjects training. Although the protocol application materials may be submitted to the IRB with training pending, final approval for the research cannot be provided until everyone has completed training. We do not require hard copies of documentation of training, as we can verify training directly in the CITI program for DePaul faculty, staff, and students. For non-DePaul collaborators, we do require documentation of training from their local institution. If they are not at an academic institution they may complete the training requirement in the CITI program after affiliating themselves with DePaul.

**Section I- Project Information** - Indicate the title of the research protocol. Indicate the proposed starting and stop dates for the research. These dates are estimates and are used by the Research Protections at DePaul to contact the PI periodically for protocol status since exempt protocols do not require annual continuing review.

Indicate the type of research, faculty/staff, or student research with its subcategories.

**Section II- Funding** - Indicate whether or not the research is internally or externally funded. If you have applied for funding and the funding is pending, still list the potential funding source here. If the research is federally funded, you must provide a copy of the proposal submitted to the funding agency along with your other application materials.

If the research is funded provide the requested information about the funding source. Whenever possible, provide the grant or contract number provided by the funding agency. When the funding originates from another institution, provide that information by indicating that your collaborating investigator is the PI of the grant or contract. If there are multiple sources of funding, provide information on all sources. If necessary, attach additional sheets to provide similar information on all funding sources.

**Section III- Conflict of Interest**. Indicate whether or not you, or any of the listed research personnel for this protocol, have a financial conflict of interest, as defined by DePaul policy. Significant financial conflicts of interest must be reported to the Conflict of Interest Committee.

**Section IV-Performance Sites**: Indicate whether all or some of the research may take place at locations outside of DePaul University. Performance sites may or may not be engaged in the research. When a Performance site is engaged in the research and has an IRB, we would require a copy of the IRB approval memo from that site. For sites that are not engaged in the research (i.e. may just be recruitment sites, or provide room for a study
activity without being part of the conduct of the research), we would only require letters of collaboration or support. The letters should indicate what they are agreeing to for the research and should summarize their understanding of the research protocol as it pertains to the involvement of their site.

Section V- Research Objectives- Briefly state the objectives (purpose, aims, goals) of the research.

Section VI- Research Procedures and Target Populations- Indicate the number of subjects, the age range for the subjects, and the inclusion/exclusion criteria for the research subjects. Indicate whether you anticipate any vulnerable subjects will be included in the subject population. Provide a summary of the research methods, procedures, and informational process. Provide information about the recruitment materials or methods that will be utilized and explain how they will be used in the research.

Section VII- Confidentiality- Indicate whether or not the research procedures involve video or audio recordings. If yes, describe what protections are in place for those recordings. Remember that voice and video recordings are considered to be identifiable.

Indicate how the data will be recorded and how you will protect the confidentiality of the data while you are collecting it and once you have it recorded in your research records.

Section VIII-Payment, Compensation, Reimbursement- Indicate whether subjects will be compensated in any way for their research participation. Compensation includes drawings for gift cards, providing food and beverages, and reimbursement for transportation costs. If the study is not funded, explain where the money is coming from to provide the compensation.

Section IX-Use of Existing Data- Indicate whether any portion of the research involves the use of existing or archival identifiable data. Remember that using data that is in your possession from another study, but which remains identifiable, is a new use of this data and requires IRB approval for the additional use. In order to be exempt the data must be recorded with no identifiers, codes or links that allow you to link the data to an individual. Existing data that is completely de-identified at the time you receive or access it, would be non-reviewable by the IRB.

Section X-HIPAA- Indicate whether you will use, access, or disclose protected health information (PHI) for the purposes of this research. For example, if you are collecting data from medical or clinical records, you are using PHI. Provide details about the PHI and the source of the PHI.

Section XI-Assurances- Read the assurance statements and sign in the appropriate location. Remember that students, staff members in a position functioning as a training position, or research fellows require a faculty sponsor signature.

USE THIS CHECK LIST TO ENSURE COMPLETE APPLICATIONS:

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<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
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<td>The exemption application is completed and signed by the PI, and if applicable, the faculty sponsor.</td>
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<td>Recruitment materials (ads, verbal scripts, flyers, online postings or announcements) are attached</td>
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<td>Study measures (survey instruments, interview scripts) or data collection tools (document where data collected from private records is recorded) are attached.</td>
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<td>An information sheet or appropriate information process is included.</td>
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<td>Human subjects training has been completed for all research personnel via CITI, or</td>
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<td>under the collaborator’s own institution, or an alternative process is proposed to</td>
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<td>meet this requirement.</td>
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<td>Additional forms or information as needed has been provided, such as COI, HIPAA,</td>
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<td>additional funding source information, etc.</td>
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<td>If applicable, letters of collaboration and support are attached.</td>
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