

Instructions for Form: Application for Claim of Exemption

Note: These instructions reflect the revised regulations from 2018 with a compliance date of January 21, 2019. All research reviewed and approved on or after January 21, 2019 must comply with the revised regulations. Research protocols that were approved before January 21, 2019 may continue as approved or may be transitioned to the revised regulations. The decision to transition a research protocol to the revised regulations will be made on a protocol per protocol basis. Once a protocol is transitioned to the revised regulations, it cannot return to the pre-2018 (older) regulations.

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(l)?

46.102 (l) 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. For the purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

- 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(e) (1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with with the individual, and, uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) Interaction includes communication or interpersonal contact between investigator and subject.

(4) 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 that the individual can reasonably expect will not be made public (e.g., a medical record).

(5) Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) An Identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Yes No

- If yes, go to question 3.
- If no, your activity does not involve human subjects, 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 from 45 CFR 46.104 (d)? 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/full review form.

Note: The exemptions are applicable to subpart B (research with pregnant woman, fetuses, and neonates) as long as the conditions of the exemptions are met. The exemptions do not apply to research subject to subpart C (research with prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners. So if you enroll someone in the research and they then become a prisoner, you do not need to stop the research and gain approval for prisoner research. The exemptions at 1, 4, 5, 6, 7, and 8 can apply to subpart D research (research with children) as long as the conditions of the exemptions are met. The first two provisions of exemption 2 (i and ii), are applicable to subpart D research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. The third provision of exemption 2 (iii) may not be applied to research with children. Exemption 3 does not apply to research with children.

(1) Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and 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 as long as all the activities meet the conditions outlined in the category
- The practices being studied must be normal educational practices and should not involve the evaluation of radical new or experimental instructional strategies or the use of randomization of subjects to different instructional methods, if one of the methods is a non-standard or experimental method.
- Physical education research that involves altering exercise activity significantly would not be exempt, as there may be the risk of injury.
- This category of research can also include after school programs or online education, as well as the classroom setting, that are part of a normal educational setting.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111 (a)(7).
- Children may be involved in educational testing or observation of public behavior under this exemption only when the investigator(s) do not participate in the activities 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 may not be exempt, unless the privacy and confidentiality measures are in place and receive a limited IRB review of the privacy and confidentiality practices and determines they are appropriate protections in place to keep the research at the exempt level.
 - 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, knowledge, or emotion before or during asking them to complete the survey would not be eligible for exemption under this category as they involve an intervention plus a survey. However, some benign interventions may be exempt under category 3.
 - This exemption is not applicable to research that involves an intervention.
 - Research involving minor deception or non-full disclosure (i.e., not explaining the real purpose of the study or fully what being in the study involves) and that fully meets the exemption criteria may be exempt very likely under exempt category 3. However, some 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.
 - This category now allows for the collection of and recording of identifiable information (even if sensitive), provided that an IRB makes the determinations necessary under a limited IRB review.

Limited IRB review involves the IRB reviewing the protocol to ensure there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data.

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

(ii) For the purposes of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in the research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- This category is applicable to behavioral interventions only and is not applicable to biomedical research.
- A benign behavioral intervention must be brief in duration (although data collection may take longer). The intervention must be harmless, painless, and not physically invasive, so the intervention is not expected to cause physical or emotional harm. Additionally, the intervention must not be likely to have a significant adverse lasting impact on the subject and the investigator must have no reason to believe that the intervention will be offensive or embarrassing to subjects, and should take into consideration the subjects' population, the context of the research, the topic and other characteristics of the study.
- Subjects must prospectively agree to the intervention, but this simple and meaningful agreement to participate does not need to meet the full requirements of consent. DePaul uses the exempt information sheet.
- As noted for this exemption, if deception or non-full disclosure is used, the subject must be told that in the exempt information sheet so that they can fully agree to the deception or manipulation. This does not mean you have to tell them what the deception is or what the manipulation is, but it just means that they need to be told about the deception, manipulation (non-full disclosure) in a general way. For example, "You are not being told about the true purpose of the research (or all that is involved in participating in

the research), but will be told the full information after you complete the research.” This means that any research that involves deception/non-full disclosure will require a detailed debriefing process.

- This research is applicable to research with adults; it is not applicable to research with children.
- Research in this category does allow for the collection and recording of identifiable data, if the IRB conducts a limited IRB review. Limited IRB review involves the IRB reviewing the protocol to ensure there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data.

(4) Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publically available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 4 U.S.C. 552a, and if applicable, the information used in the research was collected subject to the Paperwork Reduction act of 1995, 44 U.S.C. 3501 et seq.

- The revised regulations no longer require that the data for this category need to be existing. So that means, for example, data or biospecimens that will be collected in the future could qualify for this exemption if the research meets the criteria.
- The revised regulations allow research to be exempt when the secondary use of identifiable private information is regulated under HIPAA as “healthcare operations,” “research,” or “public health.” Note: HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).
- This category of research may involve prisoners if their involvement is incidental and they are not the primary focus of the research. So for example, if you are looking at medical or other types of records and some of those records incidentally include some prisoners, the prisoners may be included in the research under this category. If this is a known possibility, though, you should mention that in the IRB application.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as section 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publically accessible Federal web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

- This category has been expanded under the revised regulations to include research that is supported by a federal department or agency (for example through a grant of funding).
- The IRB would need to know that the publication of the list or research protocols as required is planned or already published.

(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.

(7) Storage or maintenance for secondary research for which broad consent is required: storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

- This category is a new category under the revised regulations. It allows protocols that establish data banks or biospecimen banks that were previously reviewed at the expedited review level to be determined to be exempt.

- Secondary research refers to research with materials originally obtained for nonresearch purposes or for research other than the current research proposal.
- This exemption category can only be used when there is a broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials
- Limited IRB review involves the IRB reviewing the protocol to ensure there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data. Additionally, the IRB must ensure that broad consent exists for the use of the data or biospecimens.

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section: and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

- This category is a new category that covers the secondary research use of identifiable private information or identifiable biospecimens originally obtained for nonresearch purposes or for research other than the current protocol.
- Limited IRB review involves the IRB reviewing the protocol to ensure there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data. Additionally, the IRB must ensure that the research to be conducted is within the scope of the broad consent (which means the IRB must see a copy of the broad consent) and that the research plan does not include the return of individual research results to the subjects.

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. Then indicate if the sites working with you are engaged in the conduct of the research or are not engaged performance sites. 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 and a letter of collaboration. 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 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. So

for example, if you are recruiting from a specific employer, they are not engaged in the conduct of the research but may assist you by allowing you to come in and speak to the employees or they may forward and email to the employees. They might also provide you with space for an interview to survey completion.

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 (how and when the information sheet text is provided to subjects). For example, the information may be provided as part of a recruitment email, it may be a hard copy on paper, or it may be online as the first page or an online survey. In addition, if the research involves deception, non-full disclosure or manipulation, provide the details regarding that portion of the research. Please note that if the research involves deception, non-full disclosure or manipulation, the regulations now require that the subject be told in the information process before participating in the research about this fact. They do not need to be told the exact details, but need to be provided with enough information to understand that deception, non-full disclosure or manipulation is part of the research and that they will be provided with full information after participation, usually through a debriefing 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- Privacy and Confidentiality- Provide a summary of how the privacy of the subject is protected during the initial recruitment and contact process. 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 collected recorded. Indicate the types of research activities with identifiable information you will be conducting. Indicate the source of the information of biospecimens, how you obtain access, whether the record is private, and if the data is from a previous IRB approved protocol, provide that number. Explain how you will protect the confidentiality of the data while you are collecting it and once you have it recorded in your research records. Explain how the information will be shared amongst the research team and outside the research team, if applicable.

This section has been expanded so that the IRB can conduct the newly required limited IRB review for some exempt activities. In a limited IRB review, the IRB must make a determination that the privacy and confidentiality measures in place in the protocol are appropriate and sufficient to protect the subject and thus allowing the exemption determination.

Section VIII – Broad Consent –

Note: When research involves the exemption categories 7 or 8, broad consent is required. Broad consent is a new type of informed consent provided under the revised Federal regulations for human subjects, which pertains to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either studies other than the current secondary research study proposal, or materials that are collected for nonresearch purposes, such as materials that are left over from routine clinical diagnosis or treatments. Broad consent does not apply to research that collects information or biospecimens from

individuals through direct interaction or intervention specifically for the purpose of the research, i.e., a research plan that includes prospective collection of blood or saliva or identifiable information.

Broad consent does not require all the elements of consent required in a standard consent, but does require some of the basic elements, including disclosing reasonable and foreseeable risks; reasonably expected benefits to subjects or others; confidentiality safeguards; and that participation is voluntary and may be discontinued without penalty.

There are also new elements of consent under the revised regulations that would be required in broad consent. These are: when appropriate, a statement about commercial profit and whether subjects will or will not share in it; and when appropriate, whether research might include whole genome sequencing. The basic and additional elements of consent that are required for broad consent are outlined in 45 CFR 46.116(d)(1).

Broad consent must also comply with most of the general elements of informed consent outlined at 45 CFR 46.116 (a). These include: obtaining informed consent before involving a human subject in a research activity; only seeking informed consent under circumstances that provide the prospective subject sufficient opportunity to discuss and consider whether or not to participate; providing information to potential subjects in a way that is understandable to the subjects; providing prospective subjects with all of the information that a reasonable person would want to have in order to make an informed decision about participation; and not including certain types of exculpatory language in the informed consent.

There are elements unique to broad consent that can be found in 45 CFR 46.116 (d)(2)-(7). For example, there needs to be a general description of the types of research that may be done, with sufficient information that a reasonable person would expect the broad consent would permit the types of research conducted. There needs to be a description of the identifiable private information or identifiable biospecimens that might be used, whether they might be shared, and which types of institutions or researchers may use the information or biospecimens for research. There needs to be a description of the period of time the materials may be stored, maintained, or used. Information needs to be provided about who to contact related to subject rights, storage and use of the materials and research-related harm. As applicable, broad consent also needs to include a statement that subjects will not be informed about specific studies and that they might have chosen not to consent to some of these studies. As applicable, broad consent needs to include a statement that clinically relevant research results might not be disclosed to the subject. Finally, broad consent needs to include an explanation of whom to contact for answers to questions about subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm. If broad consent is requested, then all the elements that are described for broad consent under section 116(d) of the revised Federal regulations must be included. None of the elements can be altered or waived (omitted).

Broad consent can be obtained when standard informed consent is obtained for the original or initial primary research when investigators are interacting or intervening with the subjects, and collecting the samples or information. If a subject was asked and refused to provide broad consent, the IRB cannot waive informed consent to use the subject's identifiable private information or identifiable biospecimens in a secondary study. This means that a researcher needs to have a mechanism for tracking who agreed and did not agree to the future use of their identifiable information or biospecimens. Please note that the use of an individual's materials in a nonidentifiable manner in secondary research continues to be permissible as not human subject research

If you indicated you will be asking for an exemption category 7 determination, provide the requested information about the broad consent process and provide a copy of the broad consent document.

If you indicated that you are requesting an exemption under category 8, provide the requested information about broad consent and provide a copy of the broad consent originally used at the time of the initial research. Then, indicate whether you plan to share research data with the subject.

Section IX-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 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:

The exemption application is completed and signed by the PI, and if applicable, the faculty sponsor.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Recruitment materials (ads, verbal scripts, flyers, online postings or announcements) are attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Study measures (survey instruments, interview scripts) or data collection tools (document where data collected from private records is recorded) are attached.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
An information sheet or appropriate information process is included.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If deception, manipulation, or non-full disclosure is used, the information sheet informs subjects about it.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
If the research involves a benign intervention under category 3 exemption, the intervention is explained in a meaningful way so that the subject can provide agreement.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Human subjects training has been completed for all research personnel via CITI, or under the collaborator's own institution, or an alternative process is proposed to meet this requirement.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Additional forms or information as needed has been provided, such as COI, HIPAA, additional funding source information, etc.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
If applicable, letters of collaboration and support are attached.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
If federally funded, the grant submitted to the funding is attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
If applicable, copies of collaborative IRB approval memos are attached.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA