Instructions for Form: Application for Initial Expedited or Full (Convened) IRB Review

The Initial Expedited or Full (Convened) IRB Application is used when your human subject research activity does not meet the criteria for an exemption determination, because it involves some risk to the research subjects or does not meet the criteria for one or more of the exempt categories. Similar to exempt research, when research requires expedited or full review, the IRB begins the review process by asking whether the activity involves research and then whether the research involves human subjects.

In order to decide whether your activity involves research or human subjects, 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.
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> For the purposes of this part, the following activities are deemed not to be research:
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> (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 as defined by 45 CFR 46.102 (e) (1)?

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 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 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 meet the definition of minimal risk **and** fit solely in one or more of the categories for expedited review listed below?
   Please note that research that specifically targets prisoners as subjects, versus incidental inclusion, cannot be reviewed under expedited review procedures even when minimal risk is involved. Under the revised regulations, incidental inclusion of prisoners may be possible at the expedited or exempt level. If an enrolled subject becomes a prisoner while on the study, you do not need to stop the research and get it approved under subpart C. The definition of minimal risk for prisoner research differs slightly from the definition of research overall included below.
   Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

   ☐ Yes ☐ No

   - If yes, complete this Form: Application for Initial Expedited or Full (Convened) IRB Review and **indicate** you are submitting the research for expedited review at the beginning of the form, unless you are targeting prisoners as research subjects. If you are enrolling prisoners, you should choose Full (convened) review.
   - If no, your research is not eligible for expedited review, and must be reviewed at the full (convened) level. Indicate you are submitting the research for full (convened) review at the beginning of the form.

EXPEDITED REVIEW CATEGORIES:

(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.

- For example, you might conduct a retrospective study of how patients responded to a certain drug or several drugs or look at success rates for certain comparable medical devices. The study might elicit new information about the drug or device without changing treatment courses of the subjects, and therefore would meet the minimal risk criteria.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, 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

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, 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.

- In using this category it is important to pay attention to the volume and time frames noted for the blood that is allowed to remain in the minimal risk realm. The rationale for the two sub categories is that persons who are younger, unhealthy, or under a certain body weight may not be able to be subjected to the same timing of blood draws or to a similar amount of blood being drawn as a healthy person weighing over 110 pounds. So for example, someone undergoing chemotherapy, which may cause anemia or a low white blood cell count may not be able to reasonably be subjected to the same blood draw regimen as a healthy person without additional risk.

(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) uncannulated 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.

- The examples here are pretty explicit, but are examples and not an all-inclusive list.

(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: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- Note the exclusion of any procedures that involve the use of x-ray irradiation.
- Note that research involving moderate exercise may be reviewed at the expedited level, as long as the age, weight, and health of the individual is taken into account. So for example, a protocol that asks college students to speed walk or run a mile very likely would involve minimal risk and could be reviewed under expedited review procedures. However, a study that involves establishing an exercise routine in the elderly, with over weight persons, or persons with a sedentary lifestyle might involve greater than minimal risk for these populations.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

There are two additional categories (8) and (9) that are only to submissions under continuing review and are not applicable to protocols undergoing initial review.

APPLICATION COMPLETION

Indicate the date you completed the form, or the date you revised the form to address the IRB's request for revisions or because of an amendment. The version date of the form helps you and the IRB track which version is the most current one and as well as all the versions of the document as it is changed over the life of the protocol.

Item i: Indicate whether you are submitting the protocol for expedited review (minimal risk research that fits into one or more of the expedited categories) or for full (convened) review (research that involves greater than minimal risk or which might be minimal risk, but does not fit into one or more of the expedited categories). All research specifically targeting prisoners as subjects must be reviewed by the convened IRB.

Item i. 1.: Provide justification for why your research involves minimal risk, if you are submitting the research for expedited review. The definition of minimal risk has been provided in the form for your reference.

2. The list of expedited categories has been provided and you should check which ones apply to your research. The research does not have to fit into just one category, but may involve several categories. For example, a study may involve interviews that will be recorded, collecting saliva and blood samples, and the use of private records, which would mean the study involves categories 2, 3, 5, 6, and 7.

Item ii: **FOR Protocols Previously Approved as Development Only:** Under the regulations at 45 CFR 46. 118, the IRB may make the determination that although human subject research might be funded under that grant funding mechanism, the protocol for the human subject research portion of the project is under development and does not require IRB approval at this time. The regulatory citation is below:

> **46.118 Applications and proposals lacking definite plans for involvement of human subjects.**
>
> Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under §46.101 (i) exempted under §46.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

When the IRB makes this determination, the ORS staff creates a protocol file and assigns the development only protocol a protocol number for tracking purposes. Then, when the PI has completed the developmental process and is ready to conduct the human subject research portion of the grant-funded work, he/she must submit an IRB protocol application for the correct level of review (usually expedited or full). The research will keep the same protocol number, but will be referred to the correct level of review. Although this process may refer to a minimal number of studies, this question does help the IRB track the progress of studies that were approved under the development only process.

If you respond yes to this question, then provide the protocol number you were assigned for the Development Only approval. This will prevent us from opening a new protocol for this study and ensure we close out the development only portion of the research.

Principal Investigator and Faculty Sponsor Information

Complete the requested information for the Principal Investigator (PI) for the research. *Principal* means the **one** lead person ultimately responsible for the conduct of the research. There can be only one Principal Investigator (PI) on a protocol. Status refers to whether you are faculty, staff, an undergraduate student, or a graduate student. You should be able to choose your status from a drop-down list of choices. Title refers to your title, such as Assistant Professor, Associate Professor, Research Assistant, and Post-Doctoral Fellow. Under DePaul IRB policy, the PI of the protocol must be a DePaul faculty, student, or staff member, if the research is conducted at DePaul or is engaging DePaul in the research. Persons not affiliated with DePaul may be PIs only when the Director of Research Compliance has approved this exception to the rule and a written agreement is in place between DePaul's Office of Research Services and the unaffiliated PI. For collaborative research with researchers at other institutions, the DePaul PI is the person at DePaul conducting the research activity that engages DePaul in the research and who will be the leader for the DePaul activities. The non-DePaul collaborator would be listed on the separate document called Form: Co-investigator and Key Research Personnel. Please note we ask for completed degree, not the degree program in which the PI may be enrolled in now.

For students (undergraduate or graduate), 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 oversight of the research. The person completing the form should complete all the required information about the Faculty Sponsor. Part time or adjunct faculty may be faculty sponsors, if they have the requisite knowledge of the DePaul policies for human subject research and the federal regulations governing human subject research. If there is no Faculty Sponsor on the research, leave this section blank.

- Any additional co-investigators or key research personnel should be listed on the separate Form: Co-investigators and Key Research Personnel. This form may also be used over the life of the protocol to change, add, or remove personnel or change the Faculty Sponsor.

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. There is no cost associated with completing the required training for individuals. DePaul purchases access to the training program for the institution.

Section I- Project Information:

1. Indicate the title of the research protocol. When creating the title keep in mind that we do not want two protocols for the same PI to have the same title, as this causes confusion. Please create a unique title for each protocol. If your research is funded, the title of the IRB protocol does not need to match your grant title, as we ask for the grant title separately and one grant may fund multiple IRB protocols.
2. Indicate the type of research: faculty, staff or student. And clarify the type of student research. This helps us understand the reason for conducting the research.

Section II- Project Funding Information:

1. Indicate whether or not the research is intramural/internally or extramural/externally funded. If you have applied for funding and the funding is in the process of being awarded (is pending), still list the potential funding source here. If you are uncertain whether or not you will get funding, then you can wait to add the funding source to the protocol at a later date via an amendment. However, keep in mind that consent documents may need to be revised to reflect the funding agency. **Under the revised regulations, the IRB no longer is required to review the Federal grant supporting your research. However, the IRB can still request to do so, if it desires.**
2. Provide the requested information about whether the grant funding mechanism is internal or external and the sub-category for these two types of funding mechanisms. If there is more than one source or type of funding, you may click on more than one box to accurately provide funding information.
3. 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 and the name of his/her institution. If there are multiple sources of funding, provide information on all sources. You may add additional lines to the form to provide the requested information for multiple sources of funding.

Section III- Conflict of Interest: Indicate whether or not you, or any of the research personnel listed as co-investigators or key research personnel for this protocol, have a financial conflict of interest, as defined by the noted DePaul policies. Significant financial conflicts of interest must be reported to the Conflict of Interest Committee, as per the indicated DePaul policies. The IRB must understand any potential financial or personal conflicts of interest that might impact the research subjects enrolled in the research. So, if there is a potential conflict of interest, the IRB must review the conflict management plan. The IRB may request additional actions above and beyond the conflict management plan, such as requiring language be added to the consent document.

Section IV-Performance Sites (Engaged and Non-engaged):

1. Indicate whether all or some of the research may take place at locations outside of DePaul University. If yes, then indicate the names of the non-DePaul engaged performance sites and briefly explain the role of each performance site (i.e., what each collaborator or performance site will do as part of conducting the

research). A Performance site is a location where the research is conducted, where data are gathered from subjects or records, where subjects are recruited for the research, and/or where subjects provide consent for research participation. These sites are considered performance sites whether or not the research activities are funded or unfunded. So for example, if your co-investigator is from another university and they are conducting any of the research procedures, their institution would be a performance site.

Performance sites may or may not be engaged in the conduct of the research. When a Performance site is engaged in the research and has an IRB, we would require a copy of the IRB approval letter from that site or we may be willing to sign an IRB Authorization Agreement (Reliance Agreement) with the other institution. If the performance site is a location or organization that does not have its own IRB, a letter of collaboration may be accepted instead of an IRB approval. A letter of collaboration usually states that the co-investigator or collaborator supports the research and outlines what they are doing in support of the research. If the research is externally funded, you may submit the letters of collaboration included in the grant proposal submitted to the funding agency. Usually letters of collaboration are provided on letterhead.

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 do to help you conduct the research and should summarize their understanding of the research protocol as it pertains to the involvement of their site. Provide the name of the site or organization and a brief explanation of their role in the research. Then indicate whether or not letters of support are attached to the application or pending at the time of submission. Letters of support may be provided on letterhead or may be emails clearly indicating they originate from that outside organization.

Section V- Background: Provide information about other research of your own or in the literature that provides the foundation or rationale for you to conduct the current research. Provide enough information for the IRB to understand your research in the context of what is already known about the topic and why additional research on the topic is needed. Provide any information you feel would be helpful to the IRB or someone who is not an expert in your field to understand your research.

Section VI-Research Objectives (purpose, aims, or goals):

1. Briefly, state the objectives (purpose, aims, or goals) of the research. There may be one aim or several, but the aims should be streamlined, organized and succinct.
2. Indicate whether or not you are conducting community-based participatory research (see the link provided in the form for more information about this type of research). Then indicate your plans for involving the community in the project and how you will train participatory members and how research results might be disseminated within the community.

Section VII- Target Study Population(s):

1. a. Indicate the total number of subjects you want the IRB to approve for you to enroll in the research. Enrolled means that the subject has provided consent and/or you have collected some information from them or you have collected data about a subject under a waiver of informed consent (such as record

research- one record is equal to one subject). This total number will be the maximum you will be approved to enroll or include in your research and will be documented in your IRB protocol approval letter. If you need a larger number of subjects after you receive initial approval from the IRB, then you will need to submit an amendment requesting an increase in subject number.

b. Provide an estimate of the gender breakdown for your research. We have included an 'other' category to address the need for including transgender persons. You will not be held to this number, but providing this information helps the IRB understand the projected gender balance and aids in ensuring that subject selection is equitable. Under the IRB regulations, subject recruitment and enrollment should be equitable, meaning fair and available to everyone without bias. So for example, if you are conducting research with the general public and you reported an anticipated gender breakdown of 90 females and 10 males, the IRB would be concerned regarding why the gender distribution would not be more of a 50/50 distribution for males and females. Sometimes it will make sense in the context of the research why there might be more males than females or vice versa. For example, if you are recruiting from a profession that predominantly is represented by one gender over another, the gender distribution may be unequal.

c. If you have multiple groups of subjects, such as students, teachers, parents, etc., provide a brief explanation of the number of each you plan to enroll. Providing this information gives the IRB a better understanding of your research and whether projected sub-group numbers may allow you to gather statistically significant data for each sub-group, which impacts the validity of the research plan.

2. a) Indicate the age ranges for your research subjects. If there are multiple age ranges for the differing groups identified in item 1 above, indicate the age range for each group of subjects. For example, will all adults be age 18- 80, 18- 65, 30-40, etc.?

   b) Indicate why the age ranges were chosen specifically for your research. For example, you may be researching middle school children for a problem that is pertinent primarily to them and this may be the anticipated age range for these children.

3. Describe your inclusion criteria, including breaking this information out for different target populations you plan to enroll in the research. Inclusion criteria are those used to decide if a person is eligible to be in your research. You usually would tell them these criteria in recruitment materials and the consent process to confirm that they are truly in your target population. For example, must be age 18 or older, a parent of a child in middle school, and speak and understand English.

4. Describe the exclusion criteria. For simple studies these may be the opposite of the inclusion criteria. For more complicated studies exclusion criteria may involve excluding an entire gender as the study focuses on issues pertinent to only one gender. Usually there needs to be a good rationale for excluding entire populations of people, as the IRB needs to ensure that subject selection is equitable (fair). People should not be excluded based upon race, gender, ethnicity, or religion unless it is a justifiable exclusion based upon your research plan. For example, if you were studying opinions of persons who practice Hinduism, then excluding persons who practice other religions makes sense in the context of your research goals.

5. Provide a rationale for excluding any particular population from your research. This question allows you to explain why you would be excluding any type of population from your research. Again, this helps the IRB determine that your subject selection is fair and equitable and not based upon bias or unfair practices.

6. Indicate who will determine the potential subject meets the inclusion/exclusion criteria and the process for how this will be determined. For example, for online surveys the subjects will self-select in most cases based upon information provided in the recruitment and consent materials. For other types of studies the PI may determine the eligibility by screening subjects or performance site personnel may assist in helping to determine whether or not a particular person has the capacity to provide consent before they are approached by the study staff.

    a. Describe the process for monitoring the subjects during the course of the research to ensure that they still meet the eligibility criteria and how this determination will be documented. So for example, if a study follows subjects over an extended period of time, there should be a process by which you reaffirm the subject continues to meet the inclusion criteria as situations may change for that person over time. If this is not important to the research, then state so and explain why no longer meeting the initial inclusion criteria does not impact the subject's ability to continue in the research.
    b. Indicate what procedures will be followed should a subject no longer meet the inclusion criteria after they began the research. For example, if a subject no longer meets the inclusion criteria or now meets one of the exclusionary criteria, will they be withdrawn from the research? If so, you should explain how that process will work. If not, explain that they may just continue in the research.

7. Describe the procedures to assure the equitable selection of subjects. One of the IRB approval criteria under 45 CFR 46.111 is that subject selection is equitable (fair). To the best of the researchers ability, the selection of subjects should be fair and exclusion of subjects should not be based upon race, ethnicity, gender, or religion, unless germane to the research. Here we are asking you to provide your specific procedures for ensuring you and your research team conduct a fair and equitable subject selection process.

8. Indicate whether you anticipate any vulnerable populations will be specifically targeted for your subject population. The check list includes all the federally mandated populations that require some level of special consideration from the IRB and some local populations considered to be vulnerable by the DePaul IRB. Vulnerable populations are those that may be unduly influenced or coerced into being in the research. Depending upon the box or boxes checked additional questions will need to be addressed. For prisoners, minors, persons with impaired decision-making capacity, or economically or educationally disadvantaged persons, you will be asked some additional questions that address the specific regulatory citations and what the IRB needs to consider for these vulnerable populations. These questions will center on the consent process, selection, and coercion. For example, if based upon your research plan minors initially enrolled in the research using parent/legal guardian permission and assent

may turn 18 while still participating in the research, you should provide your plan for obtaining consent from the now adult subject once they turn 18. For children and prisoners, you will be asked to choose the regulatory category for the specific type of research you are conducting.

9. Provide a rationale for including any vulnerable populations in the research. For this question, the IRB needs an explanation of why you need these vulnerable subjects in your research. Sometimes, the research is addressing a topic that is directly pertinent to this population and the only way to learn something that may help this population in the future is to study the issue within that specific population. The IRB simply needs you to provide your protocol-specific rationale for including any targeted vulnerable populations.

Section VIII- Subject Recruitment and Privacy:

1. Indicate yes or no to whether you are utilizing recruitment materials. Almost all research that directly contacts subjects utilizes some form of recruitment materials.
    a. We have provided a list of commonly used recruitment materials. Check as many that may apply to your research methods. We have also provide an 'other' category should you be utilizing a recruitment item we have not listed. Keep in mind that all recruitment materials must be submitted to the IRB for review and approval. Each item should indicate what it is (e.g., initial email, follow-up email, social media posting, etc.) and should have a version date in the footer or header of the document. The IRB must see recruitment materials, such as flyers, in the final format so that any formatting or images can be reviewed. Please refer to our guidance document about recruitment Materials and Content Requirements for assistance in preparing your recruitment materials.
2. Provide the details of your recruitment plan, which includes how you will initially contact the subjects and any ongoing contact, such as screening or follow-up emails. Provide the IRB with the steps to your recruitment plan. Your recruitment plan should not invade the potential subject's privacy. For example, you should not be asking for a private email list to send the recruitment emails yourself. A subject may feel this is an invasion of their privacy.
3. Indicate if private records will be used to identify and initially recruit subjects. For example, sometimes organizations will use their private listserv or email lists to send out a recruitment item for the researchers.
    a. Indicate who owns and controls these private records and has provided permission for you to use these records in some way to recruit the research subjects.
4. Indicate whether the PI will be the only one conducting the recruitment process.
    a. If not, provide information regarding who will be conducting the recruitment process.

IX- Informed Consent Process:

1. Provide the details of the informed consent process including consent, parent/legal guardian permission, and assent when all processes are applicable to the research. Be sure to clearly differentiate between the differing processes. Parents or legal guardians who provide permission for their child are not providing consent for them. Parents may provide consent for themselves, if they are also subjects in the research. Similarly, minors (children) provide assent and not permission or consent. Sometimes when both the child and the parent will be research subjects in the same study, a combination document that obtains

both parent/legal guardian permission for the child and consent for the parent may be used. When this is the case, this section of the form should explain the plan to use a combination document.

- Under the revised regulations these are the general requirements of informed consent that must be met and included in your consent process plan:
    - Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
    - An investigator shall seek informed consent only under circumstances that provides the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
    - The information that is given to the subject or the legally authorized representative should be in language understandable to the subject or the legally authorized representative.
    - The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
    - Except for broad consent obtained in accordance with paragraph (d):
        1. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
        2. Informed consent as a whole must present information in sufficient detail relating to the research, must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
    - No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

2. Indicate whether you are requesting a waiver of the consent process or an alteration of the consent process. Please see the Request for a Waiver or Alteration of Informed Consent form for detailed information about these processes. A waiver of consent waives the entire process, such as when your research might be limited to record review and you have no contact with the people who the records are about. An alteration of consent is used frequently when you might alter one or more elements of consent, such as you would when using deception or incomplete disclosure of information in the research.
3. Indicate whether you are requesting a waiver of documentation of consent. Please see the Request for a Waiver of Documentation of Informed Consent form for detailed information about this process. A waiver of documentation involves obtaining consent (usually verbally or online), but just not obtaining a written signature.
4. Indicate whether the subject or the subject's parent/legal guardian or legally authorized representatives are anticipated to utilize English as a second language.

a. Indicate how you will ascertain or assess that the targeted subjects (or their legally authorized representative) have the ability to comprehend the information provided in English. Many people speak more than one language. Just because English may not be their first language does not mean that the subject may not be able to fully understand the information presented to them in English. However, the regulations require that the consent process is conducted in a language that the subject understands, so it is necessary that the researcher ensures this is the case be evaluating the potential needs of the target population for the research. The IRB must ensure that the consent is presented in a language that is understandable to the subject (or their legally authorized representative). So, from the researcher's perspective there should be a process for assessing what may be needed to assist the subject or the legally authorized representative in understanding the information provided.

5. Indicate if some or all of the subject or their legally authorized representatives are anticipated to be non-English speaking. The form provides the regulatory requirements for obtaining consent under 45 CFR 16.116 when people are not English speaking. These are the only two options: 1) a fully translated consent document, 2) the use of a short form process. **On the fly translations of consent materials are not allowed.**
    - Provide the details regarding how consent will be obtained from non-English speaking subjects or their legally authorized representative.
    - Indicate who will be translating the consent documents and their qualifications to do so. Just because someone grew up speaking a language does not necessarily mean they have the required expertise to translate written documents of a scientific nature or which utilize specialized vocabulary. See the note about back translations of the translated document.
    - Describe the process for initial communication and how information is communicated to potential subjects in a manner appropriate to their culture, country of origin, or in language that they understand. Also, explain the ongoing communication process during the study. If the research involves a great deal of interaction and ongoing communication, it is not enough to just have a translated consent document presented and signed at the beginning of the research. The PI and the research team need to be able to effectively communicate with the subject for the duration of the research. Sometimes, if the research team does not have the necessary resources to communicate with the potential subjects in another language throughout the research process, it is not feasible to recruit and enroll subjects who do not speak or understand English.
    - Address whether or not the research will be conducted in an international setting.
        - Provide information about the background and culture of the setting that would impact the vulnerability of the subjects, the subject selection process, the recruitment process, the consent process, and potentially the risks to the subject to being in the research.
6. Indicate whether you anticipate some or all of the research subjects will be decisionally impaired at the beginning or at some point in the research.
    - If yes, indicate specific consent procedures for persons who are decisionally impaired and any tools or procedures that will be used during the initial assessment period to determine the subjects are able to provide consent for themselves. Sometimes it is appropriate to utilize an independent assessor to determine whether the subject is mentally capable of providing consent. Explain any use of advanced directives. An advanced directive is an agreement that should an individual become incapable of making decisions for themselves at some point in the research

process, they appoint a specific person to make decisions for them. This information can be incorporated into the consent document.

Section X - Research Protocol Summary/Plan of Work:

1. Here you will provide the details of your research. Carefully review the bullet points, which are meant to guide you in providing the IRB with the level of detail required for us to fully understand your research and the potential impact of the research on the research subjects. The bullet points cannot capture every possible detail the IRB may desire to know, as some information really depends upon the research design. However, reviewing the bullet points and ensuring you provide the information noted will go a long way towards ensuring the IRB has the information they need to approve your research. It helps to provide the research summary in a logical, chronological order that walks the IRB through your research process from initial recruitment and contact, the consent process, the data collection process, and the analysis of the data.

Section XI – Resources:

1. Provide a summary of the resources or facilities that may be needed to conduct your research. So for example, you might need a particular piece of equipment that belongs to the department or the college, or you might need to utilize space that is not under your individual control, or you may elicit the assistance of a social worker or counselor should subjects become upset due to participating in the research.

Section XII- Potential Risks:

1. Check the general categories of specialized risks in this section that may apply to your research.
2. List and describe the real and potential risks of the research being sure to list the risks to the differing populations you have in your research. So for example, if your research includes children and their parents, depending upon what you are asking the child and the parent to do, the actual risks to each of these groups may differ. The IRB is not asking you to come up with an exhaustive list of every possible risk, but is asking for risks that are <u>reasonably</u> foreseeable risks. Researchers do tend to underestimate the risks of their own research. Common risks related to social behavior or educational research are being upset or uncomfortable with questions being asked in interviews or surveys and risks related to a potential breach of confidentiality of the data should someone outside the research gain access to identifiable data. When working in certain populations, such as international settings, the potential personal risks need to be assessed in the context of the current political or social climate in that setting and as related to the topic being researched.
    a. Note: If deception or incomplete disclosure is part of the research design, you must request an alteration of consent and usually a debriefing process is included in the protocol, unless the debriefing process would present greater risk to the subject than not conducting the process. The initial consent process MUST tell the subject about the deception or non-full disclosure in a general way so that they can prospectively agree to participate and you must indicate that they will be told the details after research participation. The debriefing process would explain the deception or incomplete disclosure in detail. The debriefing process would explain the deception or incomplete disclosure and why it was necessary and usually offers the subject the opportunity to withdraw their data from the research. The debriefing materials must be IRB approved.)

3. Describe your procedures that have been put in place to minimize the specific risks noted above in item 2. So for example if one of the risks is a breach of confidentiality of the data, tell the IRB how you plan to minimize that risk (i.e., coding the data with ID numbers not linked to the individual subject). Other examples of ways to minimize the potential risks are to provide a resource list or information to receive help if upset or uncomfortable after being in the research, monitoring the subjects for adverse effects or events and the procedures taken should adverse effects be observed, using pseudonyms, or immediately de-identifying all data.

Section XIII- Potential Benefits:

1. Indicate if the research involves direct benefits. Not all research involves direct benefits to the subject, so 'No' may be an acceptable response to this question. Direct benefits are those that the individual may receive, such as increased knowledge on a topic from a training or educational session, positive effects of an intervention, free health screening, or diagnosis of a condition.
    a. If 'Yes' is chosen, then describe in detail the direct benefits. Please note that any direct benefits noted here should match the consent document language pertaining to direct benefits. If you check no direct benefits for this question, then the consent should clearly indicate there are no direct benefits to you for being in the research.
2. Indicate whether the research involves indirect benefits.
    a. If yes, then describe them. Keep in mind that the majority of social, behavioral, and educational research involves indirect benefits to society or a field of study based upon the knowledge gained during the research about a specific topic. The benefits are potential and down-stream from the research and cannot be guaranteed to impact the individual subject directly. Almost all human subject research should have an indirect benefit as generalizing the information is usually one of the goals of research. However, a researcher should be careful to not overstate the potential benefits.
3. Indicate why the risks of the research are justified by the potential benefits. This is sometimes called the risk/benefit analysis. The overall benefits to the research should outweigh the risks. So for example, the indirect benefits of the knowledge gained about a topic may outweigh the very minimal risk of a breach of confidentiality of the data collected in an online survey, particularly when the survey data is not directly linked back to the subject. However, the risk of a physical injury may not be balanced by an indirect benefit of the knowledge gained about a topic, particularly if the chance of the injury is high and the potential type of injury is severe or permanent.

Section XIV- Available Alternatives:

1. Describe any alternative treatments, interventions, procedures, or therapies that might be available to subjects who choose not to participate in the research. So for example, if the research involves an intervention, is there another intervention that might be just as good? Another example, might include when the research involves a particular educational or training opportunity, could the subjects obtain this education or training by not participating in the research?

Section XV – Confidentiality:

1. Indicate whether you will audio or video record or photograph the research subjects.

a. Explain if and how subjects will be identified in these recorded materials and what measures will be in place to protect the data in these recordings, how long the recordings will be kept, and how and when they will be destroyed.
b. Indicate whether the recordings will be used for other activities besides research, such as creating an archive, using for student education and training, to create a documentary, etc.

2. Indicate where and how (in what format) the research data/records, specimens or biological samples will be stored and what measures are in place to protect the confidentiality of the research data, specimens, or biological samples from people not on the research team.
3. Indicate whether the data, specimens or biological samples will be stored such that subjects are identified directly or through indirect identifiers (e.g., codes, demographics, Social Security Number, IP address, record number) directly linked to the subjects.
    a. Then go on to describe your procedures for maintaining confidentiality of the data.
    b. Indicate if you will share the share identifiable data, specimens or biological samples with anyone else.
        i. Explain who you will be sharing identifiable data, specimens or biological samples with and justify the sharing of identifiable data, i.e., describe why or for what purpose you will share the data. Please note the informed consent confidentiality section should include this information, since the purpose of that section is to explain the limits on confidentiality to the research subject.
4. Describe how the data will be shared amongst the research team. In general, email is not a secure medium for sharing data that needs to be kept protected.
5. Indicate whether data will be shared in any manner outside of the research. For example, sometimes you are working with an organization and you will be supplying that organization with a report based upon the research. That would be an example of data sharing. However, to protect the subjects, you would only provide aggregate summary data in the report. Please note, if you share the data with anyone, including organizations you may be working with, this information must be included in the consent document confidentiality section. If your research is funded by NIH, you will need to comply with the NIH rules for data sharing and the subjects should be told about these required data sharing plans.
6. Indicate whether any research data or the fact that someone is a research subject in your study will become part of a permanent record, such as a medical record. Keep in mind that HIPAA actually has requirements regarding keeping accurate records of whose records were accessed for what purpose and depending upon the research, it may be necessary to actually indicate a particular person was part of a specific research study. For research that involves some form of medical encounter, there usually has to be a medical record entry created to document a visit. In which case, the visit and the fact a person was in the study may be documented, but not all research data is usually kept within the medical records.
7. Indicate how long you will keep your research data, specimens or biological samples. It is a common misconception that the IRB requires that you destroy your data at some point. Actually, the IRB does not require data destruction at the end of your research. It may be considered bad science to destroy your data. There is a trend towards data sharing and some federal funding sources may actually require you to post your summary data online for others to utilize for future research. The IRB just needs to know how the data will be used in order to ensure that the consent document is accurate regarding what the research subject can expect regarding the level of confidentiality of the data.

8. Indicate your retention plans for the IRB-related research records. The regulations require that you maintain these records for a minimum of three years after your research has been closed with the IRB. There is no requirement that you ever destroy these documents either. Examples of the records that must be retained include IRB submission materials, IRB approval letters, IRB approved documents, signed consent documents, etc.

Section XVI-Payment, Compensation, Reimbursement:

1. Indicate whether subjects will be compensated in any way, including given course credit, for their research participation. Compensation includes drawings for gift cards, providing food and beverages, and reimbursement for transportation costs.
    a. If yes, then provide information about the amount, schedule and method of payment. Keep in mind that this information must be clearly noted in the consent document payment section.
    b. Provide a description of the plan for prorating the payment or compensation. Payment or compensation should not be coercive, but also your plan cannot indicate they only get payment if they stay in the research. Research participation is voluntary and subjects should be compensated for partial completion of the research when it is appropriate to the research design, especially if the study is a longitudinal study (one with many visits or tasks over a prolonged period of time). Subjects do not need to be paid partial compensation for studies like a single online survey for which the subject only answered some questions. Partial payment is appropriate for studies such as when the subjects are being asked to complete baseline, 3 month, 6 month and 12 month activities, and it is possible a subject might only complete tasks at some of these time points. Additionally, you should think about whether it is appropriate to pay them at the time each task is completed versus holding all the money until they finish the research (which is coercive).

Section XVII – Costs to Subjects:

1. Indicate whether there will be costs of any kind to the subject that they will need to consider when thinking about whether or not to participate in the research.
    a. If yes, then explain what those costs will be. Information about costs to the research subject must be in the consent, parent/legal guardian permission, and assent documents in the cost section.
2. If the research involves a potential injury, indicate any plans to reimburse the subjects for any costs related to treatment or care for that injury. Again, this information must be clearly provided to the subject in the consent, parent/legal guardian permission, and potentially the assent document (depending upon the age range for the child). If this is not applicable to the research, check NA.

XVIII – Data and Safety Monitoring:

1. For studies that are federally funded and involve greater than minimal risk, you are required to have a Data and Safety Monitoring Plan. Provide the details about this plan. The information provided here for the IRB should agree with the information you provided to the funding agency in the grant application.
2. If the research protocol includes the use of Data and Safety Monitoring Board (DSMB), which is required of most clinical trials (including psychological intervention trials), indicate yes.
    a. Then provide the details regarding how the DSMB will operate (i.e., how often they will meet, who comprises the DSMB, what kind of report will be generated, etc.). Copies of DSMB reports

should be included with your Continuing Review Report each year. If the DSMB Report is not ready at that time, it must be submitted as an amendment as soon as it is available.

3. Indicate whether or not you will be obtaining a Certificate of Confidentiality to protect the confidentiality of the research data and ultimately the research subject. Keep in mind that the agencies that issue a Certificate of Confidentiality require IRB approval before the Certificate can be provided to you. They also require that very specific language be included in the consent document pertaining to voluntary disclosures of information (as mandated by state mandatory reporter laws). If for some reason the agency decides they cannot issue the Certificate, you must notify the IRB immediately and remove any reference to the Certificate from the consent document. The IRB will want to review the information you included in the online request for the Certificate of Confidentiality, so be sure to send the IRB a copy. Also, the IRB must get a final copy of the processed and approved Certificate for our files, as this document will have an expiration date that must be tracked. For information about the Certificate process and required information, go to: https://humansubjects.nih.gov/coc/index

For NIH funded studies, as of December 13, 2016, you no longer have to apply for a Certificate using the online system if you are collecting or using sensitive information. You will automatically be issued a Certificate in the terms and conditions of the grant award.

Section XIX -Subject Complaints, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Non-Compliance, and Adverse Events:

1. Describe the procedures for handling subject complaints or requests for information, particularly focused on how to address these events from the subject's perspective. Sometimes events require follow-up such as resolving an issue, providing referral to care, or reporting events to proper authorities (e.g., IRB, funding agency, OHRP, local agencies in the case of mandatory reporting laws, or school officials if a student is a risk to themselves or others).
2. Describe your procedures for recording and reporting UPIRSOs, subject complaints, non-compliance and Adverse Events to the IRB and other appropriate authorities (i.e., sponsor or funding agency, lead study site, etc.). The federal regulations have specific reporting criteria for reporting certain events to the IRB. You should also follow local policy for reporting events. Although, these types of events are less common for social, behavioral, and educational research, they do happen and should be planned for in your research plan.

Section XX-HIPAA:

1. 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. At this time, DePaul has few areas that are considered covered entities under HIPAA, so it will be more common for researchers to be utilizing PHI from other HIPAA covered entities. In which case, the HIPAA policies from that entity must be followed.
    a. If yes, provide a detailed explanation of the PHI being accessed and used for the research and identify the source of the PHI.

Section XXI- FERPA:

1. Indicate whether the research involves the use of FERPA protected information or data from school records.
    a. If so, provide specific information about the use of these records, such as who owns the records, which will provide the records or data, and the process for obtaining the information or data in compliance with FERPA. Please note: Using D2L or other DePaul records to obtain your student's email addresses in order to email them about your research or to collect information about them or examples of their school work without the student's express written permission to do so is a violation of FERPA. Under the FERPA rules, you must have a legitimate educational reason for accessing the record. Accessing the record for a research purpose is not considered a legitimate educational use. So, just because you have access to these private school records as part of your job, you are not entitled to then access these records for your research purposes. The same would be true if you are a teacher at an elementary, middle, or high school and your plan is to obtain information from school records in the school in which you work for a thesis or dissertation project at DePaul.

Section XXII-Assurances: Read the assurance statements and sign at the appropriate location. Remember that students, staff members in a position functioning as a training position, or research fellows require a Faculty Sponsor signature. The signatures are electronic signatures. Hard copies of this form are no longer required to be sent to the IRB.

USE THIS CHECK LIST TO ENSURE COMPLETE APPLICATIONS:

The expedited/full application is completed and signed by the PI, and if applicable, the Faculty Sponsor.	☐ Yes	☐ No	
Recruitment materials (ads, verbal scripts, flyers, online postings or announcements) are attached	☐ Yes	☐ No	☐ NA
Study measures (survey instruments, interview scripts) or data collection tools (document where data collected from private records is recorded) are attached.	☐ Yes	☐ No	☐ NA
The informed consent document or documents are attached unless the entire study is conducted under a waiver of informed consent.	☐ Yes	☐ No	☐ NA
If applicable, the parent/legal guardian permission document is attached.	☐ Yes	☐ No	☐ NA
If applicable, the assent document or documents are attached.	☐ Yes	☐ No	☐ 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.	☐ Yes	☐ No	
Additional forms or information as needed have been provided, such as COI, HIPAA, additional funding source information, etc.	☐ Yes	☐ No	☐ NA
If applicable, letters of collaboration and support are attached.	☐ Yes	☐ No	☐ NA
If applicable, copies of collaborative IRB approval memos are attached.	☐ Yes	☐ No	☐ NA