

New School Guidance for PI's Submitting to BRANY

BRANY PROTOCOL TEMPLATE – SBER - Revised 6/24/21

INSTRUCTIONS:

- You may use a different format, order, outline, or template provided the necessary information is included.
- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as “NA.”
- When applicable, for any items described in the sponsor’s research study plan (protocol), grant, contract, or other documents submitted with the application, you may reference the title and page numbers of these documents. If you reference page numbers, attach those pages to this document. Limit attached pages to those referenced in this document.
- When you write a research study plan (protocol), keep an electronic copy. You will need to modify this copy when making changes.
- **Assign a unique study (protocol) identifier and version date to this document and add it to this document’s footer. For example, Study Protocol # RH2021-101, Version dated 01-01-2021.** This enables those involved in the creation and review of the document to track the versions submitted versus subsequent modifications or updates that may be needed.

DELETE THIS INSTRUCTION SECTION FROM THE FINAL DOCUMENT

1) STUDY (PROTOCOL) TITLE

- Include the full study (protocol) title.

Study Name

2) OBJECTIVES

- Describe the purpose, specific aims, or objectives.

Please provide this information from Chapter 1 of your dissertation and be sure to be specific. If your research is not related to a doctoral dissertation, please take from your research proposal and summarize in this section.

3) BACKGROUND

- Describe the relevant prior experience and gaps in current knowledge.
- Describe any relevant preliminary data.
- Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how the study will add to existing knowledge.

Please provide a brief literature review, problem statement and significance of the research. Please be sure to identify how previous research studies have informed your research and explain how your study evolved including background in terms of the gap in the literature.

4) INCLUSION AND EXCLUSION CRITERIA

- Describe the criteria that define who will be included or excluded in your final study sample.

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- Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the below populations as subjects in your research unless you indicate this in your inclusion criteria.)
 - Adults unable to consent (individuals with impaired decision-making capacity)
 - Individuals who are not yet adults (infants, children, teenagers)
 - Pregnant women
 - Prisoners

You ONLY need to provide you exclusion and inclusion criteria. If the above populations are NOT involved in your study, you do NOT need to address these bullet points.

5) VULNERABLE POPULATIONS

- **Note:** Vulnerable populations are individuals who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. In addition to the vulnerable subject populations covered in the subparts of the federal regulations for human subject research), there are special classes of subjects including students, employees, and cognitively impaired individuals who may be vulnerable in terms of their research participation. Subjects are considered vulnerable when they are not respected as autonomous agents and/or their voluntariness is compromised.
- If the research involves **individuals who are vulnerable to coercion or undue influence**, describe additional safeguards included to protect their rights and welfare.
- If the research involves **cognitively impaired adults**, describe the additional safeguards included to protect their rights and welfare.
 - For individuals who may have impaired decision-making capacity there must be an assessment of the subject's capacity to consent to participate prior to enrolling the subject in the study. For all subjects in studies involving individuals with severe psychiatric illness (e.g., schizophrenia) affecting competency, **the assessment should be undertaken by a physician not associated with the study and whose professional training and credentials are suitable given the nature of the subject's illness and the nature of the study**. This physician must be completely independent from the study and the physician's name should not appear as an author on any published paper reporting on the study as that might lead to the appearance of a conflict. Factors to be considered in assessing capacity include: the prospective subject's medical condition, the voluntariness of the subject's consent in light of the subject's hospitalization or relationship with the physicians conducting the study, as well as the subject's ability to assess the information provided to him/her and make informed and knowing decisions. In the event the subject lacks capacity to consent to participate, an individual legally authorized to consent on behalf of the subject must give consent
 - Additional considerations for cognitively impaired adults may include:
 - Is there a washout period? If yes, are there appropriate rescues or other precautions in place? (Washout Period: A period during a clinical study when a participant is taken off a study drug or other medication to eliminate the effects of the treatment.)
 - Is there need for an independent clinical monitor?
- If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (**minors/children**), ensure that you have provided sufficient information regarding the safeguards in place to protect their rights and welfare.

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- If the research involves pregnant women and/or fetuses, describe the safeguards in place to protect their rights and welfare, and address the following:
 - State whether, where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
 - State the level of risk to the fetus:
 - Is the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?
 - If there is no such prospect of benefit, is the risk to the fetus not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means?
 - State whether any risk is the least possible for achieving the objectives of the research.
 - State whether the consent of the mother will be obtained.
 - State the level of risk to the pregnant woman:
 - Does the research hold out the prospect of direct benefit to the pregnant woman?
 - Does the research hold out the prospect of a direct benefit both to the pregnant woman and the fetus?
 - Does the research offer no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means?
 - If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the father must be obtained, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
 - State the risks, if any, to the neonate.
 - Confirm that no inducements, monetary or otherwise, will be offered to terminate a pregnancy.
 - Confirm that individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
 - Confirm that individuals engaged in the research will have no part in determining the viability of a neonate.

As an extension to question # 4, please identify any vulnerable populations and what steps you will be taking to protect these individuals. For the purposes of IRB, vulnerable populations are described as children, prisoners, pregnant women, etc., however, other quasi-vulnerable populations are anyone involved in a psychology study, (especially counseling) undocumented immigrants, students, employees, etc. In other words, a vulnerable population is anyone whereby additional protections are needed to ensure their protection. Likewise, if you do have such a population, please also describe the steps you are taking to ensure these participants are protected.

6) SETTING

- Describe the sites or locations where your research team will conduct the research.
- Identify where your research team will identify and recruit potential subjects.
- Identify the primary site where research procedures will be performed, as well as any secondary sites, if applicable.

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- Describe the composition and involvement of any community advisory board, if applicable.
- For research conducted outside of the organization and its affiliates describe:
 - Site-specific regulations or customs affecting the research for research outside the organization.
 - Local scientific and ethical review structure outside the organization.

Please describe where the study will take place. If you are doing a survey and it is only taking virtually, please reference this.

7) RESOURCES

- Describe the resources available to conduct the research: For example, as appropriate:
 - Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?
 - Describe the time that you will devote to conducting and completing the research.
 - Describe the number and qualifications of your staff, their experience in conducting research, their knowledge of the local study sites, culture, and society.
 - Describe the availability of medical or psychological resources that subjects might need because of an anticipated consequences of the human research.
 - Describe your process to ensure that all persons assisting with the research are adequately informed about the study plan (protocol), the research procedures, and their duties and functions.

For most people, this will be “n/a.” You will only answer this question if you have a grant. If so, please reference the grant/funding.

8) NUMBER OF SUBJECTS

- Indicate the total number of subjects to be accrued at your site.
- If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)
- For Multi-Site Research - indicate the total number of subjects to be accrued across all sites.

Please indicate the number of subjects you are recruiting. Almost all studies will NOT meet the definition of multi-site research as referenced above. If you are recruiting subjects at multiple places, please reference, however, this will NOT meet the definition of multi-site research as noted above.

9) MULTI-SITE RESEARCH

- If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:
 - All sites have the most current version of the study plan (protocol), consent document, and HIPAA authorization.
 - All required approvals have been obtained at each site (including approval by the site’s IRB of record).
 - All modifications have been communicated to sites and approved (including approval by the site’s IRB of record) before the modification is implemented.
 - All engaged participating sites will safeguard data as required by local information security policies.
 - All local site investigators conduct the study appropriately.

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- All non-compliance with the study plan (protocol) or applicable requirements will be reported in accordance with local policy.
- Describe the method for communicating to engaged participating sites:
 - Problems
 - Interim results
 - Closure of a study

Please write “n/a”

10) RECRUITMENT METHODS

- Describe when, where, and how potential subjects will be recruited.
- Describe the source of subjects.
- Describe the methods that will be used to identify potential subjects.
- Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)
- If there is a screening process, describe how individuals will be screened for eligibility.
- Describe the amount, timing, and method (cash, check, debit card) of any payments to subjects.
- For Multi-Site Research where subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Please describe how and where you will recruit subjects. If you are compensating your subjects, please talk about how you will do. Remember if you are compensating subjects, it is possible their answers will not be truly anonymous. Likewise, please provide ALL recruitment material as attachments including social media postings which should be provided as “pdf” files. The IRB needs to review all recruitment material. Also compensating subjects is always an option and should be reflective of how much time is being asked of the participants. Minimum wage per hour is a good starting point.

11) STUDY TIMELINES

- Describe:
 - The duration of an individual subject’s participation in the study.
 - The duration anticipated to enroll all study subjects.
 - The estimated date for the investigators to complete this study (complete primary analyses).

Please address two important parts here. First, roughly when will your study take place and how long it will take to enroll participants (recruitment process). Please take into consideration how long the IRB process will take so add some additional time. Second, please identify how much time you are asking of your subjects.

12) PROCEDURES INVOLVED

- Describe and explain the study design.
- Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.
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- Procedures performed to lessen the probability or magnitude of risks.
- All drugs and devices used in the research and the purpose of their use, and their regulatory approval status (if applicable).
- The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)
- What data will be collected including long-term follow-up.
- For HUD (Humanitarian Use Device) uses, provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.
- **Note:** Humanitarian Use Device (HUD): a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255)).

Unless you are doing clinical research which requires Clinicaltrials.gov registration, all others would answer "N/A."

13) SPECIMEN BANKING

- If specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how they will be accessed, and who will have access to the specimens.
- List the data to be stored or associated with each specimen.
- Describe the procedures to release specimens, including: the process to request a release, approvals required for release, who can obtain specimens, and the data to be provided with specimens.

N/A

14) DATA MANAGEMENT

14.1) Data Analysis

- Describe the data analysis plan, including any proposed statistical tests.

Please describe how you will analyze your data – both quantitative and qualitative. In other words, what programs will be using and what types of statistical or qualitative analysis will you be doing?

14.2) Study Endpoints

- Describe the variables that will be examined to assess whether study objectives have been met.

When you achieve, what "n" will your study stop. In other words, how many people do you need to recruit/enroll to be satisfied.

14.3) Data Quality

- Describe procedures that will be used for quality control of collected data.

Please state specifically – how and where your data will be stored. Will it be transferred and to whom? How will this data process take place?

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14.4) Confidentiality

- Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.
- Are the data **ANONYMOUS**? This means no personal identifying information is being collected or personal identifying information is in no way, at no time, connected or linked to the data.
- Are the data **DE-IDENTIFIED**? This means personal identifiers are accessed or collected and removed from the data; however, a link is retained between the personal identifiers and the data.
 - What information will be included in the data?
 - Where and how will data be stored?
 - How long will the data be stored?
 - Who will have access to the data?
 - Who is responsible for receipt or transmission of the data?
 - How will data be transported?
- For Multi-Site Research - describe the local procedures for maintenance of confidentiality.

Please identify the type of privacy you will be offering participants. In other words, will you be offered confidentiality, anonymity, or will the participants be identified? In most studies a researcher is offering confidentiality unless it is one time survey will no identifiers or follow-ups. (Demo questions do not present a risk to anonymity, however, a small homogeneous sample is possible. Likewise, in some studies you will be identifying the participants because of their role, status in society, or job – for example, public official.) It is not better or worse to offer anonymity v. confidentiality, it matters more what makes sense for your study. On the other hand, protecting the data can be even more important than the type of data privacy being offered.

14.5) Future Use of Data

- If data will be banked for future use, describe where the data will be stored, how long it will be stored, how it will be accessed, and who will have access to the data.
- Describe the procedures to release data, including: the process to request a release, approvals required for release, and who can obtain data.

Click or tap here to enter text.

15) PROTECTING THE PRIVACY OF SUBJECTS

Note: This does not refer to confidentiality of data. This refers to the measures taken to respect the subject's person, including the physical environment, and how research staff interact with the individual.

- Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or with whom they provide personal information.
- Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At

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ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

- Indicate how the research team is permitted to access any sources of information about the subjects. For example, if information will be obtained from a subject’s social media account, how does the research team gain access to that information?

If you have any thoughts of using the data in the future, please NOTE this in the consent form. If you do NOT provide the subjects with this information in advance, the alternative would be to go back and re-consent them prior to future use. Thus, the general rule is to mention future use if this is remotely being considered and most importantly HOW will data be used in the future. Also, how will the data be used – identified or de-identified.

16) ENSURING THE SAFETY OF SUBJECTS

- **This is required when research involves more than Minimal Risk to subjects.**
- The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
- Describe:
 - The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.
 - What data are reviewed, including safety data, untoward events, and efficacy data.
 - How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
 - The frequency of data collection, including when safety data collection starts.
 - Who will review the data?
 - The frequency or periodicity of review of cumulative data.
 - The statistical tests for analyzing the safety data to determine whether harm is occurring.
 - Any conditions that trigger an immediate suspension of the research.

For most studies, this would not be applicable, and you will provide further details in question 18. In such cases, please answer “n/a.” For any study in which the safety of the participants need to be considered, please address how this will be done.

17) WITHDRAWAL OF SUBJECTS

- Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.
- Describe any procedures for orderly termination.
- Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

In other words, please describe the steps you will take to exclude data from those who withdraw. It is possible in one-time anonymous studies that you can’t remove the participants and if this is the case, please state in the consent form.

18) RISKS TO SUBJECTS

- List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to participation in the research. Include the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks, and risks that might be associated with breaches of confidentiality.

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- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

All studies have potential risks to participants. With this said, most of these risks are very benign and are likely not going to occur. However, in the digital age, a breach of confidentiality is the number one concern for any study. A breach of confidentiality can happen if the data is compromised in any way. Therefore, this is always a risk. Other risks include political, economic, and social. If one is doing clinical risk, what steps will be taken to ensure the participants are not triggered by participating. Additionally, what steps would you take if that does occur? For current TNS students, referrals to the Counseling Center should be in the consent form. Additionally, for those who are NOT TNS students, referrals to non-profit and national counseling hotlines are required.

19) POTENTIAL BENEFITS TO SUBJECTS

- Describe the potential benefits that individual subjects may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits.
- Indicate if there is no direct benefit.

In almost all studies, there are no direct benefits to subjects. Thus, please answer accordingly.

20) COMMUNITY-BASED PARTICIPATORY RESEARCH

- Describe involvement of the community in the design and conduct of the research.
- **Note:** “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

If this applicable to your study, please answer accordingly. If this not applicable, please write “n/a.”

21) SHARING OF RESULTS WITH SUBJECTS

- Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be directly shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

In most cases, your study results will be publicly available because this is a dissertation, research article, etc. If you plan on sharing directly with participants, please state this.

22) PRIOR APPROVALS

- Describe any letters of support or approvals that must be obtained prior to commencing the research. (e.g., local IRBs, school, external site, funding agency, or laboratory).

Please state any approvals you may need from other parties. Please note that research being done in conjunction with another university requires approval by both institutions. Likewise,

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almost all sites (and especially schools) require that explicit permission is provided. Please use the site permission template provided on the TNS website. Most importantly for the permission to be valid, the language must be on site specific letterhead and signed by an institutional official with the proper authority.

23) COMPENSATION FOR RESEARCH-RELATED INJURY

- If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.
- Provide a copy of contract language, if any, relevant to compensation for research-related injury.

For most studies this will be “n/a”. If you believe it is different, please reach out the HRPP office.

24) ECONOMIC BURDEN TO SUBJECTS

- Describe any costs that subjects may be responsible for because of participation in the research.

For most studies this will be “n/a”. If you believe it is different, please reach out the HRPP office.

25) CONSENT PROCESS AND DOCUMENTATION

- Indicate whether you will you be obtaining consent, and if so describe:
 - Where will the consent process take place?
 - Any waiting period available between informing the prospective subject and obtaining the consent.
 - Any process to ensure ongoing consent.
 - The role of the individuals who will be listed in your IRB application as involved in the consent process.
 - The time that will be devoted to the consent discussion.
 - Steps that will be taken to minimize the possibility of coercion or undue influence.
 - Steps that will be taken to ensure the subjects’ understanding.
 - Whether and how consent of the subject will be documented in writing.
- If you will be documenting consent in writing, attach a consent document. If you will obtain consent, but not documenting consent in writing, attach a consent script.
- **Non-English-Speaking Subjects**
 - Indicate what language(s) other than English are understood by prospective subjects or representatives.
 - If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.
- **Waiver or Alteration of the Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**
 - **If:**
 1. *The research involves no more than minimal risk to the subjects;*
 2. *The research could not practicably be carried out without the requested waiver or alteration;*
 3. *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;*

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4. *The waiver or alteration will not adversely affect the rights and welfare of the subjects; and*
5. *Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation,*

Then, the IRB will generally approve a waiver of the requirement to obtain informed consent. **Provide sufficient information to justify that (1) - (5) above are true so the IRB can make these determinations.**

- **Waiver of Documentation of Consent (consent will be obtained, but not documented via a signed form)**
 - If your research (1) presents no more than minimal risk of harm to subjects and (2) involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. **Provide sufficient information to justify that (1) and (2) above are true so the IRB can make these determinations.**
- If the research involves a waiver the consent process for planned emergency research, please review BRANY IRB's Standard Operating Procedures Section III.8 to ensure you have provided sufficient information for the IRB to make these determinations.
- **Subjects who are not yet adults (infants, children, teenagers)**
 - Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)
 - You must be aware of which individuals in your state meet the definition of "children." (E.g., individuals under the age of 18 years.)
 - For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your study plan (protocol).
 - Describe whether parental permission will be obtained from:
 - Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
 - One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
 - Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.
 - Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
 - When assent of children is obtained describe whether and how it will be documented.
- **Cognitively Impaired Adults**
 - Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent

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document and does not routinely require assent documents and does not routinely require children to sign assent documents.

- **Adults Unable to Consent**

- List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
- You should be aware of which individuals in meet the definition of “legally authorized representative” in the jurisdiction where the research will occur.
- For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your study plan (protocol).
- A **non-therapeutic clinical trial** (i.e., a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written consent document.

For research that is **not subject to the requirements of the Department of Defense**, consent to participate in **non-therapeutic** research may be obtained from a **healthcare proxy authorized to consent for research** (or, if the proxy is silent with respect to research, it is acceptable for another legally authorized representative) if the following conditions are fulfilled:

- (a) The objectives of the trial cannot be met by means of a trial in subjects who can give consent personally.
- (b) The foreseeable risks to the subject are low.
- (c) The negative impact on the subject’s well-being is minimized and low.
- (d) The trial is not prohibited by law.
- (e) The opinion of the IRB is expressly sought on the inclusion of such subjects, and the written opinion covers this aspect.

Non-therapeutic trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

Consent to participate in **therapeutic research** may be obtained from a **healthcare proxy authorized to consent for research**. If the proxy is silent with respect to research, it is acceptable for a health care proxy (or other legally authorized representative) to sign the consent if:

- (a) There is potential benefit over standard treatment; and
- (b) Standard treatment is not being withheld; and
- (c) There is no alternative standard treatment; and
- (d) Enrollment in the study is in the best interest of the patient; and
- (e) Participation in the research would not be contrary to the known wishes of the patient

This policy should only be followed if consistent with the policy of the investigator’s institution. In the event an Institution’s policies are more stringent, the more stringent policies should be followed.

- Describe the process for assent of the subjects. Indicate whether:

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- Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent, and which will not.
 - If assent will not be obtained from some or all subjects, an explanation of why not.
 - Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.
- **HUD (Humanitarian Use Device) Uses**
 - For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Please consult the HRPP website for the most up-to-date consent forms. There is a good deal of logic and consideration of privacy that influences which consent form will be used. In most cases (and very simplistically) the rules are as follows:

- Information Sheets (web-based consent) should be used in all survey research.
- Information Sheet or Informed Consent can be used for interviews. If you are seeking to protect the privacy of an individual, an information sheet or informed consent (requesting a waiver of signed consent) may be appropriate. If you are interviewing someone via zoom, the consent form can be sent ahead of time and reviewed with the subject prior to beginning.
- Informed Consent – should be used in all studies whereby the participants’ names will be identifiable.
- Informed Consent – should be used in almost all clinical psychology studies.
- Non-English-Speaking Populations – When working with such populations, it is acceptable to use a “short form.” In ALL cases, whatever consent form is used, it must be translated.
- In all cases, the consent form should be written in a way in which participants can understand what you are asking from them. Please remember that the average American’s reading comprehension level is that of an 8th grader and lower for those who are not native English speakers.
- For other situations or questions, please consult the HRPP office for guidance.

On another note, please also describe how consent will be obtained. A consent form is required to be provided prior to a subject’s participation regardless of whether it is in-person, online, zoom, etc.

26) DRUGS OR DEVICES

- If applicable, if the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators. Include the regulatory approval status of drugs and devices and whether they will be used in accordance with their approved labeling.

For most studies this will be “n/a”. If you believe it is different, please reach out the HRPP office.

PROTOCOL NUMBER:

VERSION DATE: