**Institutional Review Board**

**Vulnerable Populations**

Information on this worksheet was taken from the CITI course “Populations in Research Requiring Additional Considerations and/or Protections.” This worksheet should be used to determine if the study uses any vulnerable populations and if so, what additional safeguards to consider using to protect them.

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| **Common Abuses in Human Research** | |
| Physical Control | Subjects who are physically forced to participate in research. This represents a complete lack of voluntariness. When subjects have no choice about whether or not to participate in research, and are under the complete physical control of the researchers |
| Coercion | The use of a credible threat of harm or force to control another person. This also represents a lack of voluntariness |
| Undue Influence | The misuse of a position of confidence or power to lead or influence others to make a decision they would not otherwise make |
| Manipulation | The deliberate design and management of conditions or information intended to lead subjects to make a decision they would not otherwise make. Examples of information manipulation are lying, withholding information, or exaggerating |

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| **Vulnerable Populations Requiring Additional Protections** | |
|  | Children and/or Wards |
|  | Pregnant Women and/or Human Fetuses |
|  | Neonates |
|  | Prisoners |
|  | Individuals with physical disabilities |
|  | Individuals with mental disabilities or cognitive impairments |
|  | Economically disadvantaged persons |
|  | Socially disadvantaged persons |
|  | Terminally ill or very sick individuals |
|  | Racial or ethnic minorities |
|  | Institutionalized persons (e.g., persons in correctional facilities, nursing homes, or mental health facilities) |
|  | Educationally Disadvantaged Persons |
|  | Individuals with Special Needs |
|  | Individuals with a Therapeutic Association or Affiliation with the Researcher |
|  | Students |
|  | Employees of the Researcher |
|  | Individuals with speech impairments |
|  | Illiterate |
|  | Non-English Speakers |
|  | Soldiers and Other Members of the Military |
|  | Immigrants |

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| **Situational Considerations for Vulnerability** | | |
|  | Cognitive or Communicative Vulnerability | |
|  |  | Capacity-related cognitive vulnerability: subjects to some extent lack capacity to make informed choices, e.g., young children or adults with cognitive impairments that affect decision making |
|  |  | Situational cognitive vulnerability: subjects do not lack capacity, but are in situations that do not allow them to exercise their capacities effectively. This might occur when a subject is distracted or during an emergency situation, such as an acute illness or injury |
|  |  | Communicative vulnerability: subjects do not lack capacity, but due to limited ability to communicate with the researchers are not able to exercise their capacities effectively. This might include subjects who speak or read different languages than researchers do, or subjects who have speech impairments or difficulty reading |
|  | Institutional Vulnerability, i.e., prospective subjects in research who are subject to the formal authority of others. These individuals have the cognitive capacity to consent but may not be able to make a truly voluntary choice, and may be unduly influenced (or coerced) to participate when they otherwise might not have done so. In these situations, informed consent may be compromised because it is not truly voluntary. Further, these individuals may be subject to exploitation because of their subordinate status. | |
|  | Deferential Vulnerability, i.e, the authority over the prospective subject is due to informal power relationships rather than formal hierarchies. The power relationship may be based on gender, race, or class inequalities, or they can be inequalities in knowledge (such as in the doctor-patient relationship). Like institutional vulnerability, deferential vulnerability increases the risk of harm that informed consent would be compromised because it is not fully voluntary | |
|  | Medical Vulnerability, i.e., when prospective subjects have serious health conditions for which there is no satisfactory standard treatments. Such subjects may not be able to adequately weigh the research’s risks and potential benefits, and informed consent would therefore be compromised by inadequate comprehension. Further, these subjects are at risk of exploitation because they may overestimate potential benefit. Medical vulnerability may be augmented by the therapeutic misconception when subjects blur the roles played by physician-researchers and fail to appreciate the difference between research and treatment | |
|  | Economic Vulnerability, i.e., when prospective subjects are disadvantaged in the distribution of social goods and services (income, housing, healthcare). Participation in research offers the possibility of payment or attainment of healthcare or other services that are otherwise not available, and induce persons to enroll in a research study when it might be against their better judgment and when otherwise they would not do so. These inducements to enroll threaten the voluntary nature of consent and raise the danger of exploitation | |
|  | Social Vulnerability, i.e., prospective subjects who belong to undervalued social groups may be subject to social vulnerability. The perception of these groups as less valuable to society could lead to reduced concern (by researchers) for risks and burdens on those groups, and increase the risk of exploitation | |
|  | Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc. | |
|  | Fear of negative consequences for not participating in the research (e.g., institutionalization, deportation, disclosure of stigmatizing behavior) | |
|  | Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research: Click or tap here to enter text. | |

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| **Additional Vulnerabilities** | | |
|  | Vulnerability due to critical illness | |
|  | Vulnerability due to terminal illness (research at the end-of-life) | |
|  | Vulnerability due to decisional impairment, which may include situational factors such as: | |
|  |  | Stigma |
|  |  | Lack of insufficient healthcare insurance coverage |
|  |  | Under-education |
|  |  | Discrimination |
|  |  | Institutionalization |
|  |  | Homelessness |
|  |  | Inadequate access to housing |
|  | Vulnerability due to physical disabilities or impairments | |
|  | Vulnerability due to economic disadvantage or social marginalization (e.g., race, religion, disease state) | |
|  | Vulnerability due to social hierarchy | |
|  | Sexual and Gender Minority Status | |
|  | Vulnerability due to uncertain immigration status and individuals involved in illegal activities | |

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| **Review or Research Design Considerations** | |
|  | Engage consultant in IRB review of the study |
|  | Use of a consent monitor |
|  | Translation of consent form and/or use of interpreter during consent process |
|  | Use of short-form consent form and process |
|  | Modify timing of consent process if possible (before or after stressful situation) |
|  | Alternative to participation in research to fulfill course requirement |
|  | Additional information in the informed consent form: Click or tap here to enter text. |
|  | Exclusion of the population if not required to achieve study objectives |
|  | Research should not have any role in decisions impacting subjects’ status (e.g., institutionalization, judicial determination of competence) |
|  | Treating physician (if member of the research team) should not participate in the consent process |
|  | Apply for Certificate of Confidentiality |
|  | Other: Click or tap here to enter text. |

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| **Questions to Consider: (check all that apply)** | | |
|  | Are subjects vulnerable | |
|  |  | Is there a power differential between researchers and subjects |
|  |  | Are there potential excessive motivating factors for subjects |
|  |  | Are there potential communication issues for subjects |
|  |  | Are there potential decisional issues for subjects |
|  |  | Is the recruitment process acceptable |
|  |  | Are advertisements acceptable |
|  |  | Are there economic issues that might affect the acceptability of payment arrangements |
|  | Is inclusion of vulnerable subjects appropriate | |
|  | Are vulnerable subjects adequately protected | |
|  |  | Does the research plan minimize the possibility of coercion, undue influence, manipulation, and exploitation |
|  |  | Does the research plan maximize the likelihood of valid informed consent |
|  |  | Is the consent process valid (i.e., understandable, comprehendible, and conducive to true voluntariness) |
|  |  | Are there reasonable accommodations provided for subjects who may be disabled |
|  |  | Is information presented to subjects in an understandable and accessible manner |
|  |  | Do subjects comprehend the research details and their rights as research subjects |
|  |  | Is the consent process conducive to true voluntariness |
|  |  | Who is involved in the consent process |
|  |  | Can the subject consent for him or herself |
|  |  | Do the vulnerabilities of the subjects require the additional protections of a research subject advocate |