Case Study Examples

Scenario 1: Excluding Individuals with Cognitive Impairment

Study Summary: This study aims to document upper limb muscle function among stroke patients in order to inform the development of a future motion assistive device. Individuals ages 65 and over who have been diagnosed with a stroke occurrence and have no cognitive impairment will be recruited. Individuals will be asked to move their arms and hands in different positions and interact with small handheld objects while being recorded with motion capture technology. This study is minimal risk.

Justification of Population: Muscle weakness and paralysis are some of the most common physical effects of stroke. These effects can have a significantly negative impact an individual's daily life activity. Therefore, the development of assistive device technology for individuals post-stroke is important for improving the lives of these individuals.

Capacity Assessment: Because Cognitive impairment and memory dysfunction are common symptoms that affect individuals who have suffered one or more strokes, it is necessary to assess the decision-making capacity of recruited individuals. The researchers propose to review the informed consent document with the subject and conduct an open-ended question and answer discussion of relevant information.

Consent/Assent Documentation: Individuals who demonstrate clear comprehension of the protocol and associated risks and benefits will be included and asked to sign the informed consent document. Individuals who do not meet these criteria will be excluded.

Scenario 2: Including Individuals with Cognitive Impairment

Study Summary: This study aims to explore the impact of the COVID-19 Pandemic on employment and job retention among individuals with Autism Spectrum Disorder (ASD) in Massachusetts. Individuals ages 18 and over with a diagnosis of ASD who live and work in Massachusetts will be recruited along with their parent or primary caregiver to complete a one-hour interview to discuss their thoughts on the employment situation before and during the COVID-19 pandemic. The study is deemed minimal risk but does pose potential reputational harm to an already marginalized population.

Justification of Population: The COVID-19 pandemic has resulted in a sudden and prolonged disruption to regular life and job opportunities. This change in routine can be particularly challenging for individuals with ASD who already have higher rates of unemployment compared to the general population. It is important to study what unique challenges this population faces in order to improve access to employment opportunities moving forward.

Capacity Assessment: As part of the recruitment strategy, individuals with a clinical diagnosis of ASD will be invited to participate along with their parent or primary caregiver. As part of the consent process, a researcher will administer a validated social cognition pre-screen with a pre-

determined composite score cutoff. The researcher assessing capacity, administering the pre-screen, and obtaining consent is Post-doctoral researcher who has conducted research with individuals diagnosed with ASD for the past 5 years.

Consent/Assent Documentation: Subjects who do not meet the pre-determined screening cutoff will provide assent form and require that their parent or primary caregiver sign the informed consent document. For subjects that score above the pre-determined cutoff, they will be asked to sign the informed consent document.

Scenario 3: Longitudinal Research

Study Summary: This longitudinal study aims to track the composition and levels of novel blood biomarkers in individuals diagnosed with mild to moderate Alzheimer's disease annually over a 4-year period. Individuals ages 55-90 will be recruited with their primary caregivers or, if applicable, Legally authorized Representative (LAR). At each annual visit, they will review consent procedures, complete a blood draw, neurological exam, and cognitive test battery. This study is minimal risk.

Justification of Population: Alzheimer's disease is one of the leading neurodegenerative diseases in the world. With no existing cure, researchers are working to discover novel methods to treat and prevent this disease. Identifying novel biomarkers is an important step toward to understanding of disease progression and the development of new targeted treatments.

Capacity Assessment: All possible subjects will be required to provide a note of clearance to participate from their primary care physician. A trained neuropsychologist with expertise working with Alzheimer’s patients will review the informed consent document with the subject and conduct an open-ended question and answer discussion of relevant information. The neuropsychologist will also administer two validated cognitive assessments with a pre-determined cut-off for inclusion. These procedures will be repeated annually. In cases where capacity has changed, the subjects primary care physician may be consulted.

Consent/Assent Documentation: If a subject is found capable of fully providing informed consent, they will be asked to sign the informed consent document. If an individual has demonstrated limited capacity to consent, their primary caregiver or LAR will sign the informed consent document and the subject will provide assent. Due to the longitudinal nature of this project, continual monitoring of the subject's capacity is required. At each annual visit, a clinician will assess the subject's capacity and, if necessary, obtain re-consent and assent.