Grand Valley State University Institutional Review Board (IRB)	
G-10: Working with Older Adult Participants	
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Conducting research within the older adult population may involve specific challenges. While "older adult" is commonly defined as an individual aged 65 or older, it is noted that this term is imprecise, and some medical conditions may require geriatric expertise at younger ages. Therefore, this guidance is not limited to a specific age range; rather, it is designed for those adult participants whose state of being may require additional considerations. The researchers must consider the potential participants involved in the study and determine if the information contained here is applicable.

Below are study design components and strategies that researchers should consider when working with older adults and participants who may require geriatric expertise at younger ages.

A. Inclusion/Exclusion Criteria

Investigators often exclude older adults either explicitly (by limiting the age range of eligible participants in the exclusion criteria) or implicitly (by excluding those with co-morbid conditions or polypharmacy use), both of which are common in older populations.[1,2] As a result, many interventions are inadequately tested in older age groups. Researchers need to carefully consider the inclusion and exclusion criteria being used in their study to ensure that older adults are given full access to research opportunities.

It is further noted that the current rules designed to protect vulnerable populations may contribute to the underrepresentation of older adults in research, even though this group may stand to benefit from participation and may have great impact on furthering scientific understanding.[1] To mitigate this disconnect, a culture shift is needed whereby protection *from* research is replaced by protection *through* research. Rather than trying to negate all risk to vulnerable populations in research, the scientific community should consider how these populations may benefit from greater participation in such research.[2]

B. Informed Consent

The researcher may be constrained by both ethical and practical challenges when obtaining informed consent. Health challenges associated with aging such as vision and hearing impairments, as well as diseases and weakness, can impact the validity and flow of the consenting process in older adults.[1] Older participants have reported a variety of problems in the current consent process that is commonly used in research studies; these problems include a lack of clarity of the consent document itself, a power imbalance causing coercion, and both physical and cognitive impairments impacting their ability to fully comprehend the consent process.

In addition to making sure the basic elements of informed consent are included in the consent process (see *IRB Policy 810: Informed Consent: General*), researchers should consider the following guidance related to informed consent when working with older adults.

1. Formatting the Consent Document
   Older adults are not any less capable of understanding consent simply because of their age. However, to allow consideration for the range of impairments an older person may have, proper formatting of the consent document is important.[1] Font size under 14 may be a challenge for older adults to read and therefore process. Findings also indicate that older adults are more likely to view a signed document as a contract; as such, they tend to be more hesitant signing such a document. Having the consent in a non-contract format may be helpful (for example, using pastel paper with a larger font).[1] The use of diagrams, photos, and graphic representations of data may be another useful tool to allow older adults to interpret the data in a visual form.

2. Physical Impairments Altering Consent and Impacting Research
   Age is associated with a 1-2% decline in functional ability per year, beginning at age 65.[3] Age-associated physiological changes may include changes in body composition– such as a reduction in muscle bulk and lean body mass—and a reduction in bone mass and strength, with an increased risk for fracture.

   a. Comorbidities
      People aged 70 or older often have one or more chronic conditions that may contribute to disability.[1,2] For example, stroke can lead to weakness, coordination problems, locomotor difficulties, and problems of communication and continence. In the same manner, hearing and visual impairments may increase the risk of social isolation and resulting depression.

   b. Strategies
      Allowing consent documents to be available in person, via video, or internet sites compatible with screen readers will grant those participants with hearing, vision, or reading impairments to have equal accessibility to the study.[4]

      When considering the facility where the research will take place, make sure buildings, rooms, and equipment meet the standards of the Americans with Disabilities Act.[4] Researchers should consider interventions such as providing technology that allow multisensory and easy input (e.g., talking watches, pedometers with large displays, electronic diaries that allow for text or voice input). Accommodations may also include providing the option for a quiet room and providing headphones for listening to auditory information or providing assistance for navigating busy or cluttered areas. The researcher should be aware that the use of accommodations may take more time and participants may fatigue easier, necessitating frequent breaks or even sessions divided over the course of several days. Some participants may want to keep the informed consent document overnight or over the course of several days to review and read at their own pace.

3. Consent Capacity and Cognitive Capacity
   The capacity to make one's own decisions is fundamental to the ethical principle of respect for autonomy and is a key component of informed consent. Determining whether

an individual has adequate capacity to make decisions is therefore an inherent and required aspect of all researcher-participant interactions.

An adult participant is generally assumed to have the capacity to make an informed decision regarding participation in research.[5,6] In accordance with standard clinical procedures, a participant may be determined to lack consent capacity if the individual is unable to understand and appreciate the nature and consequences of enrolling in research, including the benefits and risks, the meaning of personal participation in the study, and cannot reach or communicate an informed decision. The fact that a person has been determined to lack cognitive capacity to make other decisions (e.g., a conservator of the person's assets has been appointed) might not establish lack of consent capacity for a decision about research participation, nor does making the determination that a potential participant lacks consent capacity mean that the person may also lack the cognitive capacity to make other decisions.

There are many ethical and legal challenges central to including research subjects with cognitive impairments that might affect the participants' ability to consent to participate and carry out the research procedures. Researchers should consider the following four factors related to consent capacity and study participation [1]:

- Ability to communicate a choice,
- Ability to understand relative information,
- Ability to appreciate alternatives and consequences, and
- Ability to think rationally.

Depending on the study, it may be necessary to conduct further evaluations of potential participants' ability to consent to, and participate in, the research. The IRB is available to assist researchers in determining when additional evaluations are needed and the particular evaluation(s) best suited for the study. The ability to complete these assessments may be outside the qualifications of the researcher and may require completion by a medical professional.

C. Use of Legally Authorized Representatives

Impaired decision-making capacity may be a temporary condition, or it may be permanent. When working with older adults who have lost consent capacity, a legally authorized representative (LAR) for the older adult is required to be involved in the consent process. Investigators must explain how they are using an LAR. For more information on this topic, refer to *IRB Policy 813: Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives*.

1. Who is an LAR?

   In practice, there are two types of LARs. The first type is an individual who is legally appointed to make decisions for a participant who has lost their decision-making abilities. The LAR may be a relative or friend, or the LAR may be court appointed. The second type of LAR is a decision maker for the purposes of the study being conducted. This person is often the closest relative or activated Durable Power of Attorney for Health Care.

There may be potential conflicts of interest between the LAR and the potential participant. To avoid this, the researcher should watch for overly passionate decision-making from the LAR, particularly when the research involves participant compensation.

2. Obtaining Assent
   If an LAR is used, best practice requires the researcher to obtain the assent of the potential participant, if it has been determined that they have the capability of providing assent. The potential participant should be involved in the consent discussion as much as they are able. If the potential participant makes it known that they do not want to participate, this dissent must be honored even if the LAR has already provided permission for their involvement.

D. Medical Record Access*

If medical records will be used for research purposes, the researchers should have a clear plan of action regarding their use, as well as the duration for which the medical records will be accessed. The participant or their LAR must provide written HIPAA authorization before any protected health information may be accessed for research purposes, unless the IRB has issued a waiver of this requirement. HIPAA requires the researcher to access and use only the minimum necessary health information for research purposes. For more information on the use of HIPAA-protected information in research, refer to *IRB Guidance Document G-2: HIPAA Compliance, Coded Private Information, and De-Identified Data*.

E. Living Conditions of Participants*

Participants who are homebound may be socially isolated and may have additional vulnerabilities, particularly in terms of the separation of researcher and therapeutic roles. [1] Due to these potential vulnerabilities, researchers should consider whether the nature of the research study makes it necessary to consult with the potential participant's primary care provider or home health nurse. When the research involves physical demands, consultation with the physician or nurse will ensure that any precautionary measures are taken, as they are likely to have a good understanding of the participant's condition.[7] Researchers must carefully consider the anticipated risks that could be observed during the research interaction and describe the course of action that will be taken if those risks are observed during the study. Researchers should also ensure the protocol includes a plan of action for reporting unsafe conditions discovered for homebound participants.

Not only do participants need to be kept safe, but researchers should be cognizant of their own safety. When concerns arise about researcher safety and liability, the IRB will consult with the GVSU Office of General Counsel and/or Risk Management as needed.

*It is noted that this topic is not specific to older adult populations but, rather, should be considered in all protocols where applicable.

F. Research Involving Palliative Care

Palliative care is the active, total care of patients whose disease is not responsive to curative treatment.[8] The goal of palliative care is to achieve the best quality of life for patients and families.

Participants who may be in the terminal phase of their disease are often prescribed many drugs and subjected to various interventions, many of which are of unproved benefit. Terminally ill patients may be too unwell to be put through a lengthy process of information giving and consent, so for clinical investigations, the study suitability of participants should be determined at multidisciplinary meetings.[8] Participants who are too unwell, unable to understand the research, or likely to be distressed should not be approached.

However, researchers should not assume that this population is unable to provide informed consent. If participants can understand the study information and express interest in the study, they may participate in the research. LARs may be involved in helping the patient to read and understand the study information and verbal consent should be considered, as previously referenced.

G. Longitudinal Studies

Participants within longitudinal studies may develop a personal relationship with the researchers. Thus, a comfortable and pleasant environment, courteous staff, and updates on the progress and findings of the study may significantly increase the number of older adults who will continue participation in the study.[9] Participant burdens affecting a longitudinal study in an older population may include fasting requirements, weekly or frequent research appointments, lack of funds, and lack of transportation to and from research appointments.[4,9] Researchers must be knowledgeable and caring to relate well to older adults, be able to provide information and answer questions to establish trust and help solve problems such as transportation and scheduling. Due to the possible transient nature of cognitive ability in this population, the researchers should routinely re-assess the participant's capabilities for continued participation.[9]

H. Research Incentives and Compensation

If the research study will include potential incentives and compensation for older adult participants, ensure the incentive/compensation is relevant to their living status and ability of movement outside of where they reside. A potential gift may be one that reminds the patient of time spent with loved ones or something that may make their living status easier or more convenient. For more information on research incentives and compensation, refer to *IRB Policy 750: Recruitment, Selection and Payments to Research Participants*.

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