# Delirium in older adults: Ethical considerations in research participation

Presenters: Annmarie Hosie, PhD, RN, MACN  
Nola Ries, PhD, LLM, MPA  
Meera Agar, PhD, FRACP, FACHPM, FMPallCare, MBBS

<table>
<thead>
<tr>
<th>Time</th>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>02:36</td>
<td><strong>A person (not data) focused approach</strong></td>
<td></td>
</tr>
</tbody>
</table>
- Research life cycle, walk through it with “Arthur” (example older adult)  
- Plan  
- Enlist  
- Process  
- Analyze  
- Preserve  
- Results  
- Reuse |
| 03:56 | **Plan** |  
- Overarching + national + state/local ethical and legal principles  
- Justifications for inclusion of older, sicker, cognitively, and sensory impaired, even dying patients  
  - i.e., justice, autonomy, beneficence (direct and indirect, including altruism, legacy, contribution to scientific knowledge), representative study populations  
  - Consumer’s (including Arthur’s) perspectives/co-design  
- Ethical principle of justice calls for opportunities for research inclusion  
- Use research planning processes to:  
  - Enable individuals to make decisions about taking part in research  
  - Support legally authorized representatives in their role  
- Advance planning and decision-making about research  
  - “advance consent” to a particular study  
  - “advance research planning” more generally  
    - Making an advance research directive  
    - Naming a trusted-supporter/decision-maker  
  - May be facilitated through research registries, aged care facilities, hospitals, organ/tissue donation, etc.  
- ARD form and Guidance Booklet (people can be supported about future research participation decisions) |
| 19:33 | **Enlist** |  
- Recruitment  
  - Consider the target sample to determine the methods e.g.,  
    - Clinical referral? (requires engaged and knowledgeable clinicians)  
    - Population based approaches?  
    - Community outreach?  
    - Multi-pronged approach?  
  - Positive research attitudes are a factor  
  - Allow for ranging circumstantial and relational factors  
  - “Appealing” research (low risk and burden? Potential benefit? Respectful terminology?)  
- Consent methods  
  - Advanced/anticipatory (general, registry, organizational and study levels)  
  - Supported—e.g. simplified/tailored information  
  - Shared (shared decision making)  
  - Process/experienced  
  - Deferred |
<table>
<thead>
<tr>
<th>Time</th>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
</table>
| 30:15 | **Process**   | Knowledge and attitudes  
- Clinical trial investigators and trials staff, and all in the clinical context in which trial is being conducted need to understand what delirium is  
- Respect and care for the cognitively impaired person needs to be built in explicitly into site initiation conversations  
- Processes to “equalize” best standard of care in comparator arms/sites or as base within both arms  
Communication and ongoing clinical care  
- Consumer input into patient facing study materials  
- Role play/script development to optimize how study is introduced, delirium is described and future risk of delirium if prevention study  
|       |               | Delirium is a fluctuating and serious condition  
  - How do we time study measures?  
  - Ensure we are enabling the person’s voice to self-report?  
  - How do we determine capacity to withdraw - who can communicate this (a proxy, the participant themselves)?  
|       | **Analyze**   | Critical thinking about endpoints  
  - Core outcome set?  
  - Have we given the person a voice through patient reported outcomes (PROMS) and experience (PREMs)?  
  - Are we measuring things that are meaningful to our participants?  
  - Have we established there is equipoise?  
Analyses  
- Are we intending to analyze and publish all collected data (if not, is it ethical to collect it?)  
- Using contemporary frameworks to deal with post-randomization events such as attrition (Estimands framework)  
|       | **Preserve**  | Post study considerations  
  - Follow-up care (post delirium and post study)  
    - Delirium recall and psychological wellbeing  
    - Feedback of study results to participants  
  - Ensure storage of his data/personal, sensitive and health information to ensure his confidentiality and privacy  
|       | **Results**   | Optimal sharing  
- Shared with Arthur/other participants/consumers/community in relevant for a, lay language and formats  
- Published – to honor his and others’ contributions  
  - Use a reporting guideline to increase potential for future meta-analysis/synthesis  
  - Open access  
|       | **Reuse**     | Data sharing/repositories to compound Arthur’s contribution -> Meta-analysis/synthesis -> Outputs: policy/products to benefit him/others  
|       | **Summary**   | How else can we support Arthur to participate in delirium research?  |