**Delirium in older adults: Ethical considerations in research participation**

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| Time | Section |
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| 02:36 | **A person (not data) focused approach**<br>• Research life cycle, walk through it with "Arthur" (example older adult)<br>• Plan<br>• Enlist<br>• Process<br>• Analyze<br>• Preserve<br>• Results<br>• Reuse |
| 03:56 | **Plan**<br>• Overarching + national + state/local ethical and legal principles<br>• Justifications for inclusion of older, sicker, cognitively, and sensory impaired, even dying patients<br>  o i.e., justice, autonomy, beneficence (direct and indirect, including altruism, legacy, contribution to scientific knowledge), representative study populations<br>  o Consumer's (including Arthur's) perspectives/co-design<br>• Ethical principle of justice calls for opportunities for research inclusion<br>• Use research planning processes to:<br>  o Enable individuals to make decisions about taking part in research<br>  o Support legally authorized representatives in their role<br>• Advance planning and decision-making about research<br>  o "advance consent" to a particular study<br>  o "advance research planning" more generally<br>  ▪ Making an advance research directive<br>  ▪ Naming a trusted-supporter/ decision-maker<br>  o May be facilitated through research registries, aged care facilities, hospitals, organ/tissue donation, etc.<br>• ARD form and Guidance Booklet (people can be supported about future research participation decisions) |
| 19:33 | **Enlist**<br>• Recruitment<br>  o Consider the target sample to determine the methods e.g.,<br>  ▪ Clinical referral? (requires engaged and knowledgeable clinicians)<br>  ▪ Population based approaches?<br>  ▪ Community outreach?<br>  ▪ Multi-pronged approach?<br>  o Positive research attitudes are a factor<br>  o Allow for ranging circumstantial and relational factors<br>  o "Appealing" research (low risk and burden? Potential benefit? Respectful terminology?)<br>• Consent methods<br>  o Advanced/anticipatory (general, registry, organizational and study levels)<br>  o Supported—e.g. simplified/tailored information<br>  o Shared (shared decision making)<br>  o Process/experienced<br>  o Deferred |

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| | ○ Proxy<br>○ Waiver +/- opt out |
| 30:15 | **Process**<br>• Knowledge and attitudes<br>○ Clinical trial investigators and trials staff, and all in the clinical context in which trial is being conducted need to understand what delirium is<br>○ Respect and care for the cognitively impaired person needs to be built in explicitly into site initiation conversations<br>○ Processes to "equalize" best standard of care in comparator arms/sites or as base within both arms<br>• Communication and ongoing clinical care<br>○ Consumer input into patient facing study materials<br>○ Role play/script development to optimize how study is introduced, delirium is described and future risk of delirium if prevention study<br>○ Delirium is a fluctuating and serious condition<br>▪ How do we time study measures?<br>▪ Ensure we are enabling the person's voice to self-report?<br>▪ How do we determine capacity to withdraw- who can communicate this (a proxy, the participant themselves)? |
| 35:10 | **Analyze**<br>• Critical thinking about endpoints<br>○ Core outcome set?<br>○ Have we given the person a voice through patient reported outcomes (PROMS) and experience (PREMs)?<br>○ Are we measuring things that are meaningful to our participants?<br>○ Have we established there is equipoise?<br>• Analyses<br>○ Are we intending to analyze and publish all collected data (if not, is it ethical to collect it?)<br>○ Using contemporary frameworks to deal with post-randomization events such as attrition (Estimands framework) |
| 37:29 | **Preserve**<br>• Post study considerations<br>○ Follow-up care (post delirium and post study)<br>▪ Delirium recall and psychological wellbeing<br>▪ Feedback of study results to participants<br>○ Ensure storage of his data/personal, sensitive and health information to ensure his confidentiality and privacy |
| 39:46 | **Results**<br>• Optimal sharing<br>○ Shared with Arthur/other participants/consumers/community in relevant for a, lay language and formats<br>○ Published – to honor his and others' contributions<br>▪ Use a reporting guideline to increase potential for future meta-analysis/synthesis<br>▪ Open access<br>○ Engage with health policy makers |
| 41:24 | **Reuse**<br>• Data sharing/repositories to compound Arthur's contribution→ Meta-analysis/synthesis → Outputs: policy/products to benefit him/others |
| 43:39 | **Summary**<br>• How else can we support Arthur to participate in delirium research? |

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| 44:45 | **Questions and Answers** |