Complementary Case Studies Supporting the EUREC Position on Vulnerability and Responsible Inclusion in Research (16 December 2025)

Introduction

The case studies below complement the EUREC position paper on vulnerability and responsible inclusion in research, published on 16 December 2025. They provide practical illustrations for research ethics committees (RECs).

Each case study is accompanied by key points, ethical reflection questions, and examples of appropriate protections and supports to help RECs evaluate safeguards, recognise the benefits of responsible inclusion, and weigh the risks of exclusion.

Please note that the examples of ethical protections and supports set out herein are not exhaustive, and other ethical considerations may be appropriate on a case-by-case basis.

EUREC welcomes feedback on the case studies and may revise further to include additional ethical protections and supports identified by RECs. Feedback can be sent to Lazutkaite@eurec.net

1. Case example: Older adults with intellectual disabilities

A clinical trial tests a new oral medication aimed at slowing cognitive decline in adults with age-related cognitive changes or early dementia. While the medication is intended for the general population with cognitive decline, this trial evaluates its safety and preliminary efficacy in older adults with intellectual disabilities. Participants undergo regular cognitive assessments, health monitoring, and structured interviews over the course of one year.

Key Points

• Vulnerability is dynamic – older adults with intellectual disabilities may experience cognitive or communication differences, but capacity and support needs may vary by individual and context dependent.
• Exclusion can harm – failure to include older adults with intellectual disabilities risks producing evidence that is not applicable to their health needs and may reinforce existing health inequalities and contribute to evidence gaps in the assessment and treatment of cognitive decline in this population.
• Responsible inclusion adds value, recognises agency, and strengthens impact – including older adults with intellectual disabilities, with appropriate supports, improves the relevance and quality of evidence while recognising their agency as research participants and supporting the generation of more relevant evidence.
• Shared responsibility for responsible inclusion – investigators are responsible for designing and implementing inclusive research practices, while RECs assess whether adequate safeguards are in place to support ethical and meaningful participation.

Guiding Questions

• Who is potentially vulnerable in this study?
Older adults with intellectual disabilities, participants reliant on formal or informal carers, socially isolated individuals.
• What factors influence vulnerability?
Communication needs, decision-making support requirements, health status, living arrangements, carer support, socio-economic context, prior experiences of exclusion.
• How have participants been involved throughout the study?
People with intellectual disabilities may contribute to identifying relevant research questions, reviewing study procedures, and advising on consent processes or data collection methods (e.g. via patient advocacy groups).
• Are inclusion efforts proportionate to potential benefits?
o Inclusion is justified by the potential to generate knowledge that improves outcomes for older adults with intellectual disabilities; participants may experience direct or indirect benefits, though these are not guaranteed.

Protections & Supports

• Easy-to-read and pictorial study information materials as well as assent and/or consent materials.
• Participant-chosen support for medication management and communication of study-related information, where needed
• Capacity reassessment at key study stages where appropriate.
• Flexible scheduling and location options, such as home visits or repeated sessions if appropriate.
• Coordination with carers and support networks.
• Access to independent advocacy and escalation pathways for emerging concerns.

2. Case example: Children and a medical device (asthma)

A clinical trial tests a new wearable smart inhaler designed to improve medication adherence and monitor lung function in children with asthma. While the device is intended for the broader population with asthma, this trial evaluates its safety as well as usability and preliminary effectiveness in children. Participants and their parents and/or legal guardians receive interactive training on device use, and data are collected through regular clinic visits and home monitoring.

Key Points

• Vulnerability is dynamic – children have historically been viewed as requiring additional protections in research; however, individual vulnerability varies depending on age, maturity, physical and mental health status, and context.
• Exclusion can harm – failing to include children when testing a new medical device risks producing evidence that does not reflect pediatric safety, usability, or clinical needs, potentially delaying access to innovations and perpetuating therapeutic inequities.
• Responsible inclusion adds value, recognises agency, and strengthens impact – supporting children's participation improves the relevance of findings and ensures devices meet pediatric needs, while enabling responsible inclusion in research.
• Shared responsibility for responsible inclusion – investigators are responsible for designing and implementing inclusive research practices, while RECs assess whether adequate safeguards are in place to support ethical and meaningful participation.

Guiding Questions

• Who is potentially vulnerable in this study?
Children may be more susceptible to risks or burdens depending on how the study interacts with their age, maturity, health status, or support environment.
• What factors influence vulnerability?
Developmental stage, physical and mental health status, dependency on adults for consent and daily care, prior experience with medical procedures or devices, and socio-economic context.
• How have participants been involved throughout the study?
Children, parents and/or legal guardians may provide feedback on study information materials, study procedures, and study outcome measures (e.g. via patient advocacy groups).
• Are inclusion efforts proportionate to potential benefits?
Inclusion is justified by potential benefits to participants and society, though benefits are not guaranteed.

Protections & Supports

• Information, consent and assent procedures adapted to age, maturity, and legal requirements.
• Age-appropriate study information materials and interactive demonstrations.
• Parent and/or legal guardian, and child involvement throughout participation in study.• Opportunities for re-consent upon reaching the legal age of consent.
• Data protection and privacy safeguards for device-generated health data.• Clinical and/or technical support pathways if device use raises concerns about asthma control, treatment adherence, or device operability

3. Case example: Migrants and access to mental health care

A research study investigates awareness of mental health conditions, perceptions of their treatability, and barriers to accessing care. The aim is to inform the development of low-threshold diagnostic and treatment programmes for the general population. To ensure relevance, the study includes migrants, regardless of legal status. Participants are identified through healthcare records and invited to take part in individual interviews conducted by hospital staff or trained third parties.

Key Points

• Vulnerability is contextual and intersecting – migrants may experience vulnerability due to language barriers, stigma, previous experiences of trauma associated with migration or displacement, uncertain legal status, and limited familiarity with healthcare systems.
• Exclusion can harm – excluding migrants risks producing research evidence that does not reflect the experiences of populations facing structural barriers, thereby limiting the effectiveness and equity of resulting interventions.
• Responsible inclusion adds value, recognises agency, and strengthens impact – including migrants helps identify structural, social, and institutional barriers to care and supports the development of more accessible services.
• Shared responsibility for responsible inclusion – investigators are responsible for designing context-sensitive procedures, while RECs assess whether proposed safeguards adequately identify and mitigate legal, social, physical, and psychological risks associated with participation.

Guiding Questions

• Who is potentially vulnerable in this study?
Migrants with uncertain or irregular legal status, individuals with untreated mental health conditions, participants with limited language proficiency, and individuals who may fear contact with formal institutions.
• What factors influence vulnerability?
Legal status, language barriers, trauma history, cultural understandings of mental health, stigma, trust in institutions, and socio-economic conditions.
• How have participants been involved throughout the study?
Migrant communities and patient representatives may be consulted to ensure that the project responds to their needs and priorities as well as cultural, linguistic, and procedural appropriateness.
• Are inclusion efforts proportionate to potential benefits?
Inclusion is justified by the potential to generate knowledge on barriers to care and support the development of more accessible services.

Protections & Supports

• Clear communication that participation is voluntary and independent of immigration status.
• Strong confidentiality safeguards, including explicit separation from immigration or administrative authorities.
• Accredited interpreters and culturally appropriate materials.
• Trauma-sensitive interview procedures.
• Recruitment procedures that minimise perceived pressure.
• Referral pathways to mental health or social support services.

4. Case example: Antidepressant use in pregnancy

A clinical trial evaluates the safety, effectiveness, and appropriate dosing of an antidepressant medication in pregnant individuals experiencing common mental health conditions such as depression, anxiety disorders, or other disorders treated with antidepressants. The medication is already widely used in the general population and is frequently prescribed during pregnancy in clinical practice, despite limited evidence from controlled trials. Participants receive regular mental health assessments, obstetric monitoring, and follow-up throughout pregnancy and the postpartum period.

Key Points

• Vulnerability is dynamic – pregnant individuals with mental health conditions may experience intersecting vulnerabilities related to psychological distress, physiological changes, and social context, including considerations about potential effects on the fetus.
• Exclusion can harm – excluding pregnant individuals contributes to evidence gaps despite widespread use, leading to uncertainty in safety, dosing, and effectiveness for both the pregnant individual and potential fetal outcomes.
• Responsible inclusion adds value, recognises agency, and strengthens impact – inclusion supports evidence-based treatment and informed decision-making during pregnancy.
• Shared responsibility for responsible inclusion – investigators design context-sensitive studies, while RECs assess whether adequate safeguards are in place to support ethical and meaningful participation.

Guiding Questions

• Who is potentially vulnerable in this study?
Pregnant individuals with mental health conditions, participants experiencing severe symptoms, individuals with limited access to support.
• What factors influence vulnerability?
Type and severity of condition, stage of pregnancy, treatment history, stigma, social support, access to care, and concerns about potential effects of treatment or non-treatment on the fetus.
• How have participants been involved throughout the study?
Pregnant individuals and patient representatives may contribute to the design of study procedures, outcome measures, and communication of risks and uncertainties.
• Are inclusion efforts proportionate to potential benefits?
Inclusion is justified by the need to generate evidence supporting maternal and fetal health outcomes.

Protections & Supports

• Clear communication of known and potential risks, benefits, and uncertainties related to treatment during pregnancy.
• Integrated mental health and obstetric monitoring throughout participation.
• Predefined clinical pathways if mental health symptoms worsen.
• Clear consent for collection and use of maternal and neonatal outcome data and/or biological samples
• Coordination with primary care and treating clinicians.
• Decision-making supports and reasonable accommodations where mental health symptoms affect participation or understanding.

Relevant articles dealing with vulnerable research participants in the Declaration of Helsinki (2024) and CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016)

DoH:
19. Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm. When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion. In order to be fairly and responsibly included in research, they should receive specifically considered support and protections.

20. Medical research with individuals, groups, or communities in situations of particular vulnerability is only justified if it is responsive to their health needs and priorities and the individual, group, or community stands to benefit from the resulting knowledge, practices, or interventions. Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, or when excluding them would perpetuate or exacerbate their disparities.

28. ….. persons incapable of giving free and informed consent are in situations of particular vulnerability and are entitled to the corresponding safeguards. In addition to receiving the protections for the particularly vulnerable, those incapable of giving consent must only be included if the research is likely to either personally benefit them or if it entails only minimal risk and minimal burden.

CIOMS Guideline 15.
Special protections. Special protections for these groups can include allowing no more than minimal risks for procedures that offer no potential individual benefits for participants; supplementing the participant's agreement by the permission of family members, legal guardians, or other appropriate representatives;

For research interventions or procedures that have no potential individual benefits for participants, two conditions apply:
• the interventions and procedures should be studied first in persons who can give consent, and
• When the social value of the studies with such research interventions and procedures is compelling, and these studies cannot be conducted in persons who can give informed consent, a research ethics committee may permit a minor increase above minimal risk.