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Ethically and scientifically sound:

Actual reviews of applications involving vulnerable populations

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8 things
that reviewers look out for

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Vulnerable Populations

1. Pregnant women, foetuses & neonates
2. Children
3. Prisoners
4. Cognitively-impaired persons
5. Others

Vulnerable Populations

5. Others

- Ethnic minorities
- Low income persons
- Students
- HIV/AIDS individuals
- National Servicemen
- Who else?

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Ethical Concern

When research participants are

vulnerable...

We want to protect them

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Ethical Concern

Additional safeguards to protect vulnerable participants':

1. Rights
2. Safety
3. Welfare and well-being

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Scientific Concern

But if we are over-protective of vulnerable persons…

We may not conduct research that will improve the evidence base specific to caring for them

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Nuffield Council on Bioethics, Children and clinical research, May 2015

" Scientifically valid and ethically robust research, that addresses questions of importance to the health of children and young people, should be seen as intrinsically good, and as a natural and necessary part of a healthcare system. "

Nuffield Council on Bioethics, Children and clinical research, May 2015

" It should not be perceived as a threat to children… Without well-conducted research… there is a real risk that children will be harmed by procedures and medicines that are ill-adapted for their age-group or lacking an adequate evidence base. "

Nuffield Council on Bioethics, Children and clinical research, May 2015

" Such an approach is certainly not a blanket prescription of 'research at all costs' – but rather a challenge to the complacent notion that it is safe or ethical to continue promoting care to children without seeking to improve the evidence on which that care is based. "

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Actual Review

1. Pregnant women

Oral health in Chinese women who are pregnant or post-childbirth

Actual Review

2. Children – Youths aged 15 to 18

Phase 1: Online internet-based survey

Phase 2: Two interventions to reduce mental health stigma –

a) Mental health awareness talk

b) Focus group discussion

Actual Review

2. Children – Participants aged 13 to 40 (children aged 13 to under 21 included)

Web survey of Internet Gaming Disorder

No Reviews

3. Prisoners

There are no DSRB reviews that we know of

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Actual Review

4. Cognitively-Impaired Persons

Examining the relationship between plasma and salivary clozapine levels, and their association with clinical outcomes and adverse effects

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Actual Review

5. Others – Men who have Sex with Men (MSM)

Face-to-face interviews with MSM for the prevention of Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infections (STI)

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#1:

Knowledge to be obtained

1. Importance of knowledge to be obtained by the research
2. Why the need to obtain knowledge from vulnerable population?
3. Can the knowledge by obtained from non-vulnerable populations?
4. Do research questions/purposes justify the need?

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#1: Knowledge to be obtained

What are the ethical concerns?

How are they balanced with the scientific concerns?

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#1: Knowledge to be obtained

- The ethical concern of protection of vulnerable persons but not doing it at the expense of developing a scientific evidence base for their best care

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#1:

Knowledge to be obtained

Example:

- Oral health in pregnant and post-partum women study
- Why pregnant and post-partum women?
- Because these women are more prone to oral health problems, and their health status affects their babies

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#1:

Knowledge to be obtained

Example:

- Clozapine study with cognitively-impaired persons
- Why cognitively-impaired persons?
- Because the research was interested to study Clozapine-resistant patients, and many Clozapine-resistant patients are cognitively-impaired.

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#2: Protection

1. Rights
2. Safety
3. Welfare and well-being

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#2: Protection

What are the ethical concerns?

How are they balanced with the scientific concerns?

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#2: Protection

The ethical concern of protection of vulnerable persons but not doing it at the expense of developing a scientific evidence base for their best care

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#2: Protection

Example:

- Internet Gaming Disorder study
- Protecting children:
  - questions are not sensitive
  - hyperlinks to websites and contact details of services where they can seek help for emotional and addiction related problems

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#2: Protection

Example:

- Clozapine study with cognitively-impaired persons
- Protecting cognitively-impaired persons: Treating clinicians, research clinicians and research staff have direct patient contact and will do their utmost to ensure that the rights, safety and well-being are not compromised

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#3 and #4: Risks

1. What risk/s?
2. Have the risk/s been assessed?
3. Are the risks the least possible in order to achieve the research objectives?

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#3 and #4: Risks

What are the ethical concerns?

How are they balanced with the scientific concerns?

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#3 and #4: Risks

- Ethical concern - know and assess the risk to participants.
- Another ethical concern - devise ways to reduce the risk in order that vulnerable participants will feel safe to volunteer their information.
- If we don't pay enough attention to these ethical concerns, then participants will not volunteer and the scientific concern will be that of sample size.

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#3: Assessing Risks

Example:

- MSM study
- Assessing considerable forensic risks to research participants because MSM is an arrestable offence and there is a duty in law for every person aware of such an offence to report it to the police

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#4: Least Risk

Example:

- MSM study
- Reducing risk for safety of participants by anonymising all data collected, and waive documentation of consent

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#4: Least Risk

Example:

- Oral health in pregnant and post-partum women study
- Less than minimal risk to foetus
- Risk to foetus minimised through non-invasive procedures

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#5 and #6: Consent

As far as possible, let participant assent/consent.

If not possible, ensure parent/Legally Acceptable Representative (LAR) consents.

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#5 and #6: Consent

What are the ethical concerns?

How are they balanced with the scientific concerns?

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#5 and #6: Consent

- Participants consent on their own behalf
- Or else people who can represent them with their best interests in mind consent on their behalf, while they assent if possible

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#5 and #6: Consent

- When others consent on their behalf, then another ethical concern is about what the parent/LAR may then find out about the participant when their child/charge has been asked, eg to participate in a study of MSM. For children/charges who have not come out to their parents/guardians, this will be a big problem.

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#5 and #6: Consent

- Parents/LAR consenting on participants' behalf may lead to another scientific concern about how sample size is affected, for instance with opt-in vs opt-out consent.

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#5: Parental Consent

Example:

- Mental health stigma study
- Parental consent: opt-in vs opt-out
  - As opt-in consent would greatly affect the sample size, DSRB asked study team to ensure that parents will receive information about the study, and choice of opt-out will actually be received by the study team.

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#6: Participants' Consent

Example:

- Clozapine study with cognitively-impaired persons
- Many participants' inability to consent/assent and ethical alternatives, including LAR and consultation with healthcare provider

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#5 and #6: Consent

1. Cognitive abilities to give consent
2. Consent and coercion to consent
3. Assent (6-12 year olds, 13-20 year olds)
4. Legally Acceptable Representative (LAR)

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#5 and #6: Consent

3. Assent (from DSRB guidebook)

- For studies recruiting subjects aged 6-12 years old, the subjects should be provided an assent form to document their agreement regarding participation. The assent form should be written using simple words which an average 6-12 year old is able to understand.

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#5 and #6: Consent

3. Assent (from DSRB guidebook)

- For studies recruiting subjects aged 13-20 years old, the subjects' assent should be sought and documented using the full informed consent form, together with the documented informed consent of the parent or the legally acceptable representative.

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#5 and #6: Consent

5. Consultation with attending healthcare provider
6. What if the vulnerable participant is judged to be incapable of giving valid consent, and objects to participation?
7. Advocate/consent monitor

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#7 and #8: Waiver of Consent

Under some conditions, waiver of consent is allowable.

Under some conditions, waiver of documentation of consent is allowable.

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#7 and #8: Waiver of Consent

Conditions under which waiver of consent is allowed (from DSRB guidebook):

1. The study poses no more than minimal risk to research participants.
2. Waiver of informed consent will not adversely affect the rights and welfare of research participants.
3. The study cannot be practically conducted without the waiver of informed consent.
4. Whenever appropriate, research participants will be provided with additional pertinent information after participation

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#7 and #8: Waiver of Consent

What are the ethical concerns?

How are they balanced with the scientific concerns?

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#7 and #8: Waiver of Consent

- Ethical concerns are about minimising risk, not affecting the rights and welfare of research participants, and ensuring that participants are adequately informed about the study.
- The scientific/practical concern is that of being able to conduct the study and obtain the information without the waiver of consent. Usually a waiver is granted for studies in which participants are anonymous.

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#7 and #8: Waiver of Consent

- Central ethical concern for waiver of documentation of consent is usually a risk issue; that written consent will risk the safety of participants because it is the only documentation that links them with the study.

- If such safety not provided, then scientific concern will be about sample size.

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#7: Waiving Consent

Example:

- Internet Gaming Disorder study
- Waiving parental consent and child's assent while ensuring anonymity and survey questions are appropriate for young audience

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#8:

Waiving documented consent

Example:

- MSM study
- Reducing risk by waiving documentation of consent

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Take-Home Message

It is ethical to PROTECT vulnerable participants

And it is also ethical to develop the SCIENTIFIC evidence base specific to caring for them