Fact Sheet: Consent Forms and PIS

National Statement Excerpt – Chapter 2.2, 3.1, 4.3

The information contained in this Fact Sheet has been extracted from the National Statement on Ethical Conduct in Human Research (2018) available here National Statement. Please refer to the full National statement for additional, detail.

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

Principles of consent

- A person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.
- Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.
- This information must be presented in ways suitable to each participant
- The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.
- Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on:

  (a) the nature, complexity and level of risk of the research; and

  (b) the participant's personal and cultural circumstances.

Key Elements of Participant Information Sheets (PIS)

Information on the following matters should also be communicated to participants. Except where specific information below is also deemed necessary for a person's voluntary decision to participate, it should be kept distinct from the information described in the principles above. (This is generally referred to as a Participant Information Sheet.)

(a) any alternatives to participation;

(b) how the research will be monitored;

(c) provision of services to participants adversely affected by the research;

(d) contact details of a person to receive complaints;

(e) contact details of the researchers;

(f) how privacy and confidentiality will be protected;

(g) the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data;

(h) the amounts and sources of funding for the research;

(i) financial or other relevant declarations of interests of researchers, sponsors or institutions;

(j) any payments to participants;

(k) the likelihood and form of dissemination of the research results, including publication;

(l) any expected benefits to the wider community;

(m) any other relevant information, including research-specific information required under other chapters of this National Statement.

People in dependent or unequal relationships

This chapter is about pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. Examples may include relationships between:

- Carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients, or people in residential care or supported accommodation;
- Health care professionals and their patients or clients;
- Teachers and their students;
- Employers or supervisors and their employees
- Service providers (government or private) and especially vulnerable communities to whom the service is provided.

Key Inclusions for RAG/HREC application

Applications submitted to the RAG/HREC must include copies of all Consent Forms and Participant Information Sheets (PIS). Researchers should strive for a plain English approach to Consent Forms and PIS. Additional consideration of the communication needs of children and young people and , people with a cognitive impairment or disability may be required if research intends to engage these populations.

Checklists for Consent Forms and PIS have been provided below (adapted from https://research.uq.edu.au/files/16996/PIS_PCF%20Checklist%2026_03_2018.pdf)

Participant Information Sheet (PIS) Checklist

☐	Version for each participant group *(if applicable)*
☐	On letter-headed paper *(if applicable)*
☐	Full title of project
☐	Lay title of project *(if applicable)*
☐	Names, positions, & affiliations of all investigators
☐	Clear purpose of study
☐	Non-technical language - appropriate lay language and length for PIS
☐	Details of participation/ procedures
☐	Duration of participation
☐	Location for participation
☐	Risks outlined
☐	Benefits to participants
☐	What support if something goes wrong
☐	Contact details for complaints
☐	Statement that participation is entirely voluntary and that participants are free to withdraw without penalty
☐	Assurance of confidentiality
☐	Access to results
☐	Debriefing
☐	Reimbursement to participants *(if any)*
☐	Contact details for further questions
☐	Ethical Clearance paragraph

Ethical Clearance paragraph:

"This study adheres to the Guidelines of the ethical review process of Uniting Care and the National Statement on Ethical Conduct in Human Research."

Participant Consent Sheet (PCF) Checklist

☐	Version for each participant group *(if applicable)*
☐	Full title of project
☐	Lay title of project *(if applicable)*
☐	Names, positions, & affiliations of all investigators
☐	Provision of space for full name of participant
☐	Written declaration of informed consent, e.g. “I have read/ I understand…”
☐	Freedom to withdraw without penalty
☐	Assurance of confidentiality
☐	Provision of space for full name of participant
☐	Provision for signature of participant and date
☐	Provisions for signature of parent/guardian/EPOA, relationship to participant, and date *(if applicable)*
☐	Separate signature provisions for specific requirements e.g. consent for video or audio recording