Checklist for preparing Patient/Participant Information Sheets & Consent Forms (PICFs)

The NHMRC provides researchers with PICF templates. It is not compulsory to use these templates however they are useful tools and accepted by both HRECs located within Metro North. https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/standardised-participant-information-and

The National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, 2007 advises "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". The researcher/investigator is responsible for providing the participant, at his/her level of comprehension (generally no greater than English at the comprehension level of a 12-year-old person (Year 8 student)), with information about the research, purpose and background, why they have been chosen, risks and benefits.

	Yes	No	N/A
The Information Sheet & Consent Form should be given to participants allowing them sufficient time to consider the research before consent. Has this been factored into your research design? Have you advised potential participants how much time they will have to consider the study before informed consent?			
Project Title (if this is long you may like to consider recommending an additional lay title)			
Investigator(s): Name/s Qualifications Contact details			
The project title and investigator details should be repeated on the Consent Form and Revocation (Withdrawal) of Consent Form. The Information Sheet, Consent Form and Revocation of Consent Form may be developed as one whole document of as 3 separate documents with the Revocation being on the last page. Design of these documents is quite often directed by study sponsors.			
Immediately under title and contact details, it should be explained if the researcher is a postgraduate student, and is conducting this research as part of a higher degree program.			
A statement in language understandable to the participant (English at the comprehension level of a 12-year-old (Year 8 student)) inviting participation in a research study; including information about the purpose of the study; its			

background; what procedures are involved; expected duration of the study and for the participant; and what will happen to blood / tissue samples.			
A description of any possible risks to the participant that might arise during and/or after the study. National Statement 2.1 Risk and Benefit - What is risk? A risk is a potential for harm, discomfort or inconvenience (discussed below). It involves: • the likelihood that a harm (or discomfort or inconvenience) will occur; and • the severity of the harm, including its consequences.			
A description of the benefit to the participant or to others that may result from the research or a statement that there will not be any direct benefits from conducting the research.			
Description of the specific steps being taken to protect confidentiality of the data or personal records that identify the participant; explain that the research may include access to medical records; explain if tissue or genetic samples are taken and that they will only be used for the current study, unless permission is given for future research that will be ethically approved at that time.			
Reassurance for patients/participants that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without comment or penalty. It is recommended that all clinical trials provide a "Withdrawal/Revocation of Consent Form", to enable participants to notify of withdrawal if they choose to do so by this route. Receipt of a Withdrawal Form is not required from the participant to make their withdrawal valid.			
Information about how participants can contact the Principal Investigator about any matter of concern (the contact number(s) of the investigator(s) need to be given here or refer to above). The Hospital switchboard telephone number should not be the only contact number.			
Description regarding how the researcher/investigator(s) will provide feedback to the participants, or their next-of-kin, where this is requested by the participants and is practicable.			
Description of methods of birth control, e.g. a number of studies require participants to practice two methods of contraception.			
Explanation if treatment may affect fertility.			
Advice to participants so that they clearly understand that they may be randomised (by chance): that one of the consequences may be that they may not, in fact, receive the treatment that is being tested.			
“Australian” spelling is preferred in the Participant Information Sheet, e.g. anaemia not anemia.			
Use of acronyms should be described in detail the first time they are used.			
In some research studies participants will be asked to disclose information regarding illegal activity – e.g. illicit drug use. In the confidentiality clause in the Information Sheet it is recommended that participants are advised that this information is confidential			

"except as compellable by law". An example of this wording follows: The information you give to ... will remain confidential taking into account any legal requirements imposed on …. It is also recommended that this point also be included in the Consent Form.			
If tests will be conducted to exclude patients who may have HIV or Hepatitis C etc, it should be explained in the Information Sheet that these are notifiable diseases and positive results must be provided to the Health Department. In addition, a separate point should be added to the Consent Form so it clearly states that participants give informed consent for these tests to be carried out.			
Witness to the consent process In research involving adults who are competent and can consent for themselves, in Queensland a witness signature is not required on the Consent Form although the person who conducted the informed consent discussion (Researcher, Principal Investigator) should sign and date the form. Please refer to ICH GCP guidance below in regard to when there is a requirement for a witness.			
Note for guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments July 2000 states: 1.26 Impartial Witness – a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject. 4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or the subject's legally acceptable representative, and by the person who conducted the informed consent discussion. 4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or subject's legally acceptable representative, has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or subject's legally acceptable representative, and that informed consent was freely given by the subject or subject's legally acceptable representative.			

Queensland Civil & Administrative Tribunal (QCAT) A guardian is a person appointed by QCAT to help adults with impaired decision making capacity, make certain personal and health care decisions. This makes sure that the adult's needs are met and their interests are protected. Generally, guardians can be given the authority to make decisions on behalf of the adult, such as: general health care matters. Guardians are not permitted to make decisions about: special health care matters, including sterilisation or tissue donation. QCAT cannot consent to the adult's participation in special medical research or experimental health care if the adult objects or has indicated in an Advance Heath Directive an unwillingness to participate in such procedures. QCAT has the power to consent to the adult's participation only when the procedures relate to a condition that the adult suffers from or has a significant risk of being exposed to, and promote knowledge that can be used in the diagnosis and treatment of a condition that the adult suffers from.			
Generally, for patients who cannot consent for themselves, but are eligible to participate in clinical trials, it is a requirement to seek QCAT approval for the study before it commences.			
Standard Consent Form phrases: I have read (or have had read to me in my first language) - only include if required - and understand/understood the information package version … dated … and have had any questions or queries answered to my satisfaction; I have been informed of the possible risks or side effects of the tests or procedures being conducted; I understand that the project is for the purpose of research; I understand that the project may involve randomisation of participants; I have been informed that the confidentiality of the information will be maintained and safeguarded; I understand that sections of any of my medical notes relating to my taking part in the study may be looked at by responsible individuals from <Company name/sponsor> or from the appropriate regulatory authority(ies). I give permission for these individuals to have access to my records; I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected; I agree to take part in the above study.			
Revocation of Consent: It is recommended that all clinical trials provide a "Withdrawal of Consent Form". Please provide a Withdrawal of Consent Form,			

to enable participants to notify of withdrawal if they choose to do so by this route. Please note that receipt of a Withdrawal Form is not required from the participant to make their withdrawal valid. I_____no longer wish to participate in the research study named above. I understand that the medical information I have already supplied may still be reviewed but that no new information can be reviewed. OR Select option 1 or option 2 by checking the relevant box below: Option1: I do not want to continue further treatment with study medication but I am willing to remain in the study as outlined below: Check all that are applicable: ☐ I will continue to come to study visits as planned and take part in the study assessments until the study is closed. ☐ I agree to be contacted by telephone when needed and when the study is to be closed. ☐ I agree that my Study Doctor collects information regarding study related health from available sources, such as medical records Option 2: I do not want to continue further treatment or follow up and hereby withdraw my consent to the Study.			
HREC contact details to be included in all Information Sheets are as follows: "This study has been reviewed and approved by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (EC00172). Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women's Hospital, Herston, Qld, 4029 or telephone (07) 3646 5490, email: RBWH-Ethics@health.qld.gov.au" "This study has been reviewed and approved by The Prince Charles Hospital Human Research Ethics Committee (EC00168). Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the Coordinator or Chairperson, Human Research Ethics Committee, The Prince Charles Hospital, Chermside, Qld, 4032 or telephone (07) 3139 4500, email: ResearchTPCH@health.qld.gov.au"			

For further information, please use the contact details below:

The Prince Charles Hospital	**Royal Brisbane and Women's Hospital**
Research, Ethics and Governance Unit Building 14 The Prince Charles Hospital Rode Road, Chermside, Qld 4032 Email: ResearchTPCH@health.qld.gov.au Phone: (07) 3139 4500	Human Research Ethics Office Level 7, Block 7 Royal Brisbane and Women's Hospital Butterfield Street, Herston, Qld 4029 Email: RBWH-Ethics@health.qld.gov.au Phone: (07) 3646 5490

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