Human Research Ethics Office

Participant Information Statement and Consent Form Checklist

This document is a checklist designed to ensure that all the important information is included in the participant information statement and consent form. This checklist was developed using the National Statement on Ethical Conduct in Human Research (2007) – Updated March 2014, and the International Conference on Harmonisation Good Clinical Practice (ICH/GCP).

GENERAL INFORMATION TO INCLUDE ON THE INFORMATION STATEMENT	Yes	No	N/A
Project Title			
• On the participant information statement	☐	☐	☐
Investigator(s)			
• Name, qualifications and contact details	☐	☐	☐
Version Number and date			
• On the participant information statement as well as in the footer	☐	☐	☐
• On the consent form as well as in the footer	☐	☐	☐
Pagination			
• Indicate page X of Y to ensure participant receives every page of information	☐	☐	☐
Introduction			
• Background	☐	☐	☐
• State clearly that the study involves research; Why are you doing the research/what are the aims/what aspects of the trial are experimental	☐	☐	☐
• If it is a student project state what degree it is for and who the supervisor of the research is	☐	☐	☐
• Why is it important	☐	☐	☐
• How many people are taking part	☐	☐	☐
Funding Source			
• Who is providing the funding?	☐	☐	☐
• Is their financial compensation to investigator or their institution from a sponsor?	☐	☐	☐
Invitation and Instructions			
• Why are you inviting this individual to participate?	☐	☐	☐
• What does participation involve? You may want to consider a table if there are multiple visits	☐	☐	☐
• Include nature of questions if research includes questionnaire	☐	☐	☐
• Time required for visits	☐	☐	☐
• Explain randomisation if appropriate and alternative treatment groups and chance of receiving test treatment or not (mainly for clinical trials)	☐	☐	☐
• Any video or audio recording?	☐	☐	☐
• Any costs/re-imbursements?	☐	☐	☐
• Any optional aspects including data linkage, medical record access	☐	☐	☐
• Explain the duration of participation in the trial	☐	☐	☐
• Explain the subject's responsibilities (such as completing a diary, attending all scheduled appointments, reporting relevant health information)	☐	☐	☐
Benefits			
• List benefits of participation, if no benefit to individual this must be stated	☐	☐	☐
• Explain how participation may benefit others in the future	☐	☐	☐

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Risks/Discomforts and Inconveniences			
• Describe all possible known risks including physical/psychological and emotional and time required to complete participation	☐	☐	☐
• Explain the likelihood that a discomfort or inconvenience may occur and its anticipated severity (for example, there may be mild discomfort and bruising from a blood test)	☐	☐	☐
• Explain management of risks (Use of appropriately trained staff, use of anaesthetic cream)	☐	☐	☐
• State if unforseen risks may arise	☐	☐	☐
• State any treatment/counselling/compensation in the event of trial related injury and how to access help (clinical trials)	☐	☐	☐
Confidentiality			
• Storage and disposal of data, security of storage, timeframe	☐	☐	☐
• Re-identifiable or non-identifiable samples or data, state that records will be kept confidential	☐	☐	☐
• Must be in line with institution policies and local legal and privacy requirements	☐	☐	☐
• Specific wording required if use of genetic and other samples to clarify only for use for current study unless approval for future research	☐	☐	☐
• Particularly important to clarify if use of focus groups and how that effects confidentiality	☐	☐	☐
• Who has access to the data and how the research will be monitored (include HREC for monitoring purposes)	☐	☐	☐
• How you plan to publish data and that participants will not be individually identified	☐	☐	☐
• That de-identified data may be made publically available (please note some journals require this for publication, and there is a growing call for data to be made publically available)	☐	☐	☐
Reporting Results to Participants			
• Summary of overall results should be sent to participants	☐	☐	☐
• Approximate time frame for results to be sent	☐	☐	☐
Alternatives to Participation			
• Participation is completely voluntary	☐	☐	☐
• Right to withdraw at any time and what happens to data at that time	☐	☐	☐
• Decision of individuals to participate or not will have no impact on their relationship with Researchers and there will be no comment or penalty for withdrawal	☐	☐	☐
• Any alternative courses of treatment available	☐	☐	☐
Consent Process and Researcher and Institution contact details			
• Describe how you obtain consent and that a copy is provided to the participant	☐	☐	☐
• Clarify they will be informed in a timely manner if information becomes available that may affect their willingness to continue participation	☐	☐	☐
• Provide contact details for more information on the research and who to contact if they feel they have been injured by the research	☐	☐	☐
• Provide contact details for complaints or rights as a study participant	☐	☐	☐

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ADDITIONAL INFORMATION TO INCLUDE ON THE INFORMATION STATEMENT IF RELEVANT	Yes	No	N/A
The foreseeable circumstances when the subject's participation may be terminated	☐	☐	☐
Any financial or other declarations of interest of the researchers or sponsors	☐	☐	☐
Ensure PICF is consistent with the study protocol	☐	☐	☐
Language used should be non-technical and understandable to the participant (Based on age of 10-12 year old) *<u>Tip:</u> you can assess the reading level using MS Word by selecting Review>Language>Language Preferences>Proofing>Under "when correcting spelling and grammar in Word" select "show readability statistics". Run the spelling and grammar check. At the end of the check it will show you the Flesch-Kincaid Grade Level. The Grade Level corresponds to the year level your document can be understood by. You should aim for a level of 7 or 8.*	☐	☐	☐
Describe reasonable foreseeable risks to an embryo/foetus or nursing infant if appropriate and any requirement for birth control	☐	☐	☐
State if information of data or samples will be transferred within or outside of Australia as required for the conduct of the trial	☐	☐	☐
Any implications of withdrawal (such as follow up safety visit once ceased investigational product or use of device)	☐	☐	☐
Statement that researcher would like to notify primary care physician of their trial participation and requesting consent to do this (as appropriate for interventional studies)	☐	☐	☐
If approval for future research required this should be stated as an option in the information statement and an optional consent statement signed by the participant	☐	☐	☐
If an IND statement required re availability on www.clinicaltrials.gov	☐	☐	☐

INFORMATION TO INCLUDE ON THE CONSENT FORM	Yes	No	N/A
Project title/investigator name /qualification and contact details	☐	☐	☐
Statement regarding Participation is voluntary and subject may refuse or withdraw at any time	☐	☐	☐
Statement confirming the nature/purpose and possible risks and inconveniences have been explained	☐	☐	☐
Statement that participant has had sufficient time to consider participation and ask questions and that any questions have been answered to their satisfaction	☐	☐	☐
Statement that the participant will be provided with a signed and dated copy of the information and consent form	☐	☐	☐
Any Optional consent statements should be signed off separately, avoid tick boxes.	☐	☐	☐
Statement regarding project approval by governing HREC and that research will be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007) updated March 2014	☐	☐	☐
Provision for Participant and researcher to name, date and sign consent form (note each party must personally date signatures)	☐	☐	☐