Guidance for writing Participant Information and Consent Forms (PICF) in plain English

Contents

1. Background

For consent to be informed it is important that we use language that can be easily understood by all prospective participants. Plain English is the most efficient and egalitarian way of explaining research to the general public. It is faster and easier read.

Many research studies have found that the average reading and comprehension age of adults to be surprisingly low. The Oxford Guide to Plain English OUP: 3rd Edition (2009), states that the average reading age of adults in the UK and US is 13 years of age. The situation is likely to be similar in Australia. We must also consider our patients' demographics. 41% of our patients are aged 65 years and over and 50% of our patients were born outside of Australia. There are 82 different languages spoken by our patients. Additionally, there is likely to be a broad range of educational achievement levels amongst our patients. For many of our patients English will be a second language and as such their English proficiency may be limited.

2. The purpose of the PICF

The purpose of the PICF is to provide information about research and its requirements so that the prospective participant can decide if they wish to take part in the research. In general this includes **the purpose, methods, demands, risks and benefits, who to contact for questions/complaints and how to withdraw** from the research project.

The PICF must provide information that is:

- clear and concise
- in a format that participants are likely to understand
- participant centred

The PICF is NOT a legal contract and therefore legal jargon is to be avoided.

Medical terminology must be explained. However the purpose of the PICF is not to provide instructional information about participation. This should be provided in separate communications. (For further

information see: The National Statement on ethical conduct in Human Research 2007 Chapter 2.2 pg.19)

3. Considerations for the consent process

It is important to note that although important, the PICF is not considered to be the main method for providing information to potential participants (except in some low risk research), but a component of the consent process.

Consent should be obtained after a meeting of the investigator, study staff, potential participant and family member or friend (where desired by the potential participant) has been conducted. At this meeting the study is explained in full, in the context of the patient's particular situation, and the patient has the opportunity to ask and have their questions answered.

Time should be offered for the potential participant to read through the PICF and to obtain the opinion of a local doctor or other person (when so desired).

A professional interpreter must always be made available when English is not the preferred language of the potential participant, however it is not necessary (or particularly beneficial) to have the PICF translated in written format. The interpreter must be named and sign the PICF.

A witness to consent is only required when the participant cannot read the PICF for themselves for a reason other than English not being their preferred language e.g. vision issues or illiteracy.

4. Basic Guidance

Below are some basic guides and a list of "Do's and Don'ts" to help you ensure that the information you provide to prospective participants is clear, appropriate, and easy to understand:

- Consider the demographics of the target audience and pitch your writing accordingly;

  e.g. Are they elderly?

  What is their level of education likely to be?

  Is English their second language?

  What is their prior knowledge of their disease/illness likely to be? (some patient groups have substantial prior knowledge and therefore do not need further explicit explanation)

- Do have someone check the document (it is more likely that someone else will notice errors).

Do's	***Don'ts***
Use the templates provided	***Do not*** include instructional information. This is given to the participant after consent at the appropriate appointment
Personalise the text (use we and you)	***Do not*** use greater than or less than symbols (>,<) - Use words
Always refer to those who participate as "participants" not "subjects"	***Do not*** include a place for initialising/signing the document on each page
Keep sentences short (up to 20 words) and keep paragraphs short and concise	***Do not*** include a separate consent section for collection of samples and/or optional participation. All consents should be included in one consent section
Use active verbs (i.e. use verbs ending in "ing") when describing procedures	***Do not*** use legal jargon
Use every day English whenever possible and correct grammar and punctuation	***Do not*** attach sponsor privacy statements to the PICF.
Avoid medical jargon, abbreviations, acronyms	***Do not*** add extra clauses to the consent section. The statement "I agree to participant as described in this document" covers all aspects of consent
Explain all medical terms in plain English, particularly when listing side effects of drugs	***Do not*** list procedures repetitively under visit headings. Instead state and explain procedures (where necessary) once and indicate how often or how many times the procedures will be done
If including percentages, include an explanation e.g. 10 % (1 in 10)	
List side effects under the headings **Common** (1 out of 10 or less chance), **Less common** (1 out of 11 to 1 out of 1000 chance) and **Rare** (more than a 1 out of 1000 chance)	
Where possible include sub-studies in the main PICF	
Number all pages using the 'X of Y' pagination option	
Use lists where appropriate. A list that is part of a continuous sentence has a semicolon (;) after each point and each point begins with a lower case letter)	
Note Australian tablespoons equal 20 mL as opposed to American tablespoons which equal 15 mL	
Consider also obtaining consent for use of collected information and/or tissue in future research	
If including future research explain who will have access for future research, what testing is likely to be performed for what type of research, in what area of research	
If using translated PICFs, provide an English version, a translated version and a certificate of authenticity by a translating service to the HREC	

4 Genetic Analysis and Genetic Testing Considerations

See Melbourne Health Guidelines - Use of Human Tissue Samples in Research Appendix B. Guidance for Wording for Participant Information and Consent Forms (PICF)

Genetic Analysis:

Additional information to be included in the case of genetic analysis:

- The nature of the testing e.g. pharmacogenetic/genomic, pharmacokinetic, biomarkers
- If the testing is optional or mandatory.
- Include a statement that explains that this analysis does not include genetic testing.

E.g. “The type of testing being done in this study is not testing that would result in information about a participant’s future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the project.”

Genetic Testing:

Additional information to be included in the case of genetic testing:

Genetic Testing is testing that is intended to produce or could potentially yield information about an identifiable participant’s future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members.

It must be explained in the PICF that this is the intent or possibility of the genetic testing. The additional information should be provided as to the following:

- The nature of the testing and the research aim.
- If the testing is optional or mandatory.
- An explanation of what genes and DNA are.
- Include the names of any specifically targeted genes.
- The potential for the research to detect/generate information of social significance, e.g. non-paternity or non-maternity and that this information will not be disclosed.
- That genetic material or information may have uses unrelated to research and that this information will not be released for such uses, without consent, unless required by law.
- Information about any proposal to store genetic material and data for future as yet unspecified research.
- That if they do not consent to “future use” their samples and data will be disposed of once sample storage and record keeping requirements have been met.
- That they are free to withdraw from the research and request that their genetic material and data be disposed of (or if this is not possible, due to samples being made non-identifiable).
- The availability of counselling regarding the possible consequences of consenting to this use of genetic material.
- If relatives are also to be approached, the researcher will need the consent of the research participant to do this, and should provide information concerning the method of approach to relatives in the PICF.
- Whether participants will be advised of test results and whether the participant can choose not to be informed of the results. Additionally, include information regarding the possibility of information being provided to family members even if the participant does not wish to receive results (In the case where the testing may have health meaning for family members).
- Whether the results will be added to the participant’s hospital medical records or stored separately.

- Information should also be provided about the procedures to be followed in response to a request for access (e.g. requests by a donor, relative, other researchers, insurer, employer) to stored genetic material, or related information generated by the research.
- If a genetic register is proposed, state that genetic registers will be established and conducted in accordance with the Guidelines for Genetic Registers and Associated Genetic Material (NHMRC, 1999).

5 Links and Resources explaining medical terminology in plain English

Melbourne Health Guidelines - Use of Human Tissue Samples in Research

Appendix B. Guidance for Wording for Participant Information and Consent Forms (PICF) involving the use of human tissue samples in research.

Melbourne Health Guidelines – Data Management in Research

Websites for further assistance:

- **http://www.plainenglish.co.uk/files/howto.pdf**
  This site is the reference for the above text. You can download more information about plain English from this site.
- **https://pifonline.org.uk/resources/how-to-guides/using-plain-language-in-health-information/**
  This site provides information on writing using plain English.
- **http://www.healthinplainenglish.com/**
  This website has health articles and summaries of current medical research written in jargon-free, easy to understand English.
- **https://www.cancer.org/cancer/risk-prevention/genetics.html**
  This site provides plain English explanations for all things related to genetics and cancer.
- **https://www.cancer.org/cancer/understanding-cancer/what-is-cancer.html** This site provides plain English explanations for cancer.
- **https://www.cancer.org/cancer/understanding-cancer/glossary.html**
  This site provides allows you to search for plain English explanations of cancer types and cancer terminology.
- **https://www.nhlbi.nih.gov/health**
  This site provides plain English explanations about all things related to the heart, lungs and blood.
- **https://www.nih.gov/health-information**
  US National Institutes of Health, health information website.

6 Frequently used terms in PICFs and plain English alternatives *

Remember that your text should be pitched at the level of a 13 year old's (Year 7) understanding. Next to each of these words is the UK reading age for the word.

Frequently used terms are provided in three lists based on the following categories:

1. General words
2. Medical/Research Terminology
3. Possible Risks terminology

6.1 General words

General words to avoid where possible (UK reading age)	*Plain English Alternative*
A	
additional (13)	extra
administer (13)	give
adverse (13)	bad, unwanted
advise (9)	tell
allocated (18)	put in to
approximately (11)	about
associated	linked to
attend (9)	come to
B	
beneficial (15)	helpful, useful
biannual (13)	twice a year
biased (17)	not true and correct
biennial (19)	every 2 years
biweekly (13)	twice a week
C	
cease (13)	stop
coincides (15)	at the same time
commence (15)	start
complete (9)	fill in
consequently (13)	so
convalesce (21)	get better
corroborate (21)	confirm, check
D	
decline (17)	worsening of
defective (15)	faulty
deficiency (15)	lack of
deleterious (21)	harmful
demonstrated (13)	shown
deteriorates (17)	gets worse
E	
eligible (15)	able to
F	

fluctuates (17)	changes
G	
gauge (15)	assess
I	
initially (17)	to begin with, at first
in the event of	if
O	
onset (15)	beginning, start
opt (18)	choose, pick
P	
periodically (15)	regularly
persons	person
prior to	before
Q	
query (17)	questions
R	
regarding (15)	about
reimburse (17)	pay back
relevant (21)	related
S	
scope (17)	range
subsequently (17)	following, after
surname (21)	last name
T	
technique	method, procedure
terminate (17)	end
U	
undergo (15)	have
W	
waive (21)	give up a right
whilst (17)	while
whereby (17)	by which

* Adapted from Plain English Lexicon June 2011, Plain Language Commission
http://www.plainenglish.co.uk

1.2 Medical/Research Terminology

Medical/Research Terminology (UK reading age)	*Plain English Alternative*
A	
abdominal (11)	stomach area
adverse event	unwanted (bad) effect
albumin	protein
anaesthetic (15)	drug to numb your sense of pain/ put you to sleep
angina (21)	heart pain
antibodies	a protein made by the body to attack and disable something
antibiotic (15)	medicine for infection
anticoagulant (17)	drug that decreases forming of blood clots
antidote (15)	drug that stops the effect of a poison
antihistamine (13)	drug that treats allergy symptoms
artery (15)	blood vessel
arteriosclerosis (13)	thickening and stiffening of the blood vessels
B	
benign (17)	not harmful
biopsy (17)	collecting a small piece of body tissue
bone density	bone thickness and strength
C	
carcinoma (18)	cancer, tumour
cardiovascular (15)	heart and blood vessel system
catheter (18)	tube
cognitive (18)	thinking
cohort (18)	group
D	
data (13)	information
debility (21)	weakness
demographics (21)	personal details
E	
efficacy (21)	effectiveness, can treat
extremities (15)	arms and legs
F	

fissure (18)	deep crack
fistula	abnormal connection or passageway
G	
gastrointestinal	digestive system, stomach and bowel
generic (18)	common
H	
haemorrhage (17)	bleeding
hyper/o tension (18)	high/low blood pressure
hyper/o glycaemia (18)	high/low sugar levels in the blood
hypothermia (18)	low temperature
I	
incontinence(17)	unable to control bladder or bowel movements
ingest (18)	eat/drink
intravenous (17)	into a vein
M	
malignant (17)	harmful, cancerous
migraine (17)	severe headache
myocardial (17)	of the heart muscle
myopia (18)	short/near sighted
N	
nasal (15)	in the nose
natal (21)	birth
O	
obese (18)	overweight, fat
objectives (17)	aims
obstruction (15)	blockage
oncologist (21)	cancer doctor
ophthalmologist (21)	eye doctor
outpatient (17)	visiting patient, not staying overnight
P	
paediatrician (15)	child's doctor
palliative (21)	supportive care
pathogenic (17)	causes disease, sickness
placebo	tablet or solution that looks like the study treatment but does not contain any active ingredients
pre-existing (17)	came before

prevalent (17)	common
pruritis (18)	itching
pulmonary (17)	of the lungs
R	
renal (18)	of the kidneys
retrospectively (18)	back to the past
revocation (18)	withdrawal
S	
sciatica (21)	back pain that also goes down the leg
sclerosis (18)	thickening and stiffening
screening (15)	assessing
sedentary (21)	sitting
siblings (17)	brothers or sisters
stoma (21)	small opening
stool (17)	bowel action
T	
therapeutic (17)	healing, treatment for
thrombosis (21)	clot blocking a blood vessel
tolerance (17)	how well drugs are accepted by the body
torsion (21)	twisting
toxin (21)	poison
toxicity	the level of damage a drug can cause
transient (18)	of a short time, comes and goes
U	
unbiased (15)	fair, balanced, true and correct
V	
validate (17)	prove true and correct
vascular (21)	of the veins
vertigo (21)	loss of balance, dizziness

* Adapted from Plain English Lexicon June 2011, Plain Language Commission
http://www.plainenglish.co.uk

6.3 Possible Risks terminology

Possible Risks terminology	*Plain English Alternative*
A	
abdominal pain	pain in the stomach area
alopecia	hair loss
anaemia	low red blood cell count
anaphylaxis	serious allergic reaction that needs urgent treatment
anorexia	no appetite or hunger, not wanting to eat
aphasia	unable to speak
arthralgia	joint pain
arrhythmia	fast, slow or irregular heart rate
ascites	a build-up of fluid in the belly
ataxia	poor balance or coordination
atrial fibrillation	fast and irregular heart beat
B	
bronchitis	infection of the airways
C	
cardiac arrest	heart stops beating
carditis	inflammation of the heart or its lining
cardiomyopathy	enlarged weak heart muscle
cellulitis	inflammation (swelling) of the skin
cardiac failure	poor heart function
constipation	constipation
D	
deep vein thrombosis	clot in a vein in the legs
dehydration	low fluid levels
dermatitis	rash
diarrhoea	diarrhoea
diplopia	seeing doubles, double vision
dyspepsia	indigestion, upset stomach
dysphagia	difficulty or trouble swallowing
dysphasia	difficulty speaking
dyspnoea	shortness of breath
E	
eczema	dry, red itchy skin

F	
fainting	fainting, pass out
fever	high temperature
fatigue	tiredness, weakness
H	
haemorrhage	bleeding
halitosis	bad breath
hepatomegaly	enlarged of the liver
hypo/hyperglycaemia (18)	low/high sugar levels
hypo/hypercalcaemia	low/high calcium levels
hypo/hyperkalaemia	low/high potassium levels
hypo/hypernatremia	low/high sodium levels
hypo/hypertension (17)	low/high blood pressure
hypo/hyperthyroidism	under/overactive thyroid
I	
inflammation	redness, swelling
insomnia	trouble sleeping, poor sleep
J	
jaundice	yellow skin and eyes due to poor liver function
L	
leucopaenia	decrease in infection fighting blood cells
lymphocytopaenia	decrease in infection fighting blood cells
lymphocytosis	increase in infection fighting blood cells
M	
macular oedema	serious swelling in the eye
malaise	feeling unwell
migraine	severe headache with nausea/vomiting
muscle spasm	cramps in arms or legs
myocardial infarction	heart attack
N	
nausea	nausea
necrosis	death of tissue
neuropathy	condition causing pain or numbness in hands or feet
neutropenia	decrease in infection fighting blood cells
O	
oedema	swelling

osteonecrosis	death of bone tissue
P	
pancytopaenia	decrease in all types of blood cells
parasthesia	tingling, prickling or numbness
peripheral oedema	swelling of arms and legs
phlebitis	inflamed blood vessel
pleural effusion	fluid in the lining of the lungs
pneumonia	lung infection
proteinuria	protein in the urine
pulmonary embolus	a blockage in an artery in the lung
pruritus	itchiness
R	
rash	rash
rhabdomyolysis	breakdown of muscle
S	
seizures	fits
sepsis, septicaemia	serious infection in the blood
septic shock	life threatening infection in the blood
stomatitis	inflamed gums
superventricular tachycardia	fast heart beat
T	
tachy/bradycardia	fast/slow heartbeat
thrombocytopenia	low number of blood clotting cell in the blood
thrombocytosis	high number of blood clotting cells in the blood
tremor	shaking
U	
urinary retention	difficulty emptying the bladder
V	
ventricular fibrillation	serious abnormal heart beat rhythm
ventricular tachycardia	fast heart beat
vertigo	loss of balance, dizziness
V	
vomiting	vomiting

7 VERSION AND APPROVAL HISTORY

Date	No	Author, approval and summary of changes
June 2013	1	Angela Gray Manager HREC Melbourne Health, Angela Watt Director Research Governance and Ethics
January 2021	2	Document underwent consumer review via RMH Consumer Engagement process
27 June 2021	3	Sarah Rickard Manager Research Governance and Audit, Angela Watt Director Research Governance and Ethics Formatting updates including addition of table of contents and moving lists toward the end of the document.