19 July 2016

Mr Simon Windsor
National PICF Project Manager
129 Glen Osmond Road
EASTWOOD SA 5063

Dear Simon

Thank you for inviting Cancer Council Australia and our clinical partner, the Clinical Oncology Society of Australia, to comment on the National Patient Information and Consent Form (PCIF) Project documents. In principle, both organisations support the initiative and found the documents and guidelines clear and helpful, especially for people who have not previously written a template consent form. We would be happy to endorse, particularly if our recommended amendments are incorporated.

The following comments are provided for consideration and have been set out to address Part A and Part B of the Patient Information and Consent Form and the related sections.

PART A – General Information

Consumer review of drafted patient information material can be helpful and many cancer cooperative groups have access to trained consumer advocates. We recommend including a point suggesting that consumer review (if available) of the PCIF should be organised prior to submission to a Human Research Ethics Committee. This could sit under "please ensure that your final document is proof-read".

What happens to information about me?

The reference to information that "identifies you" should be explained. Patients who are not familiar with clinical research may not understand that a study code is used to link to their personal identifying details at the hospital.

PART B – Trial Details

General comments:

- Many clinical trial sites prefer to avoid a lengthy PICF and aim for eight -12 pages
- Specific PICF guidelines for Catholic Health Australia could be added to the user guide for inclusion by relevant sites
- The term "researcher" is used at the beginning; this changes to "study doctor" later in the document, for consistency and clarity use "trial researcher" throughout
- Avoid using acronym "GP", use General Practitioner

PICF Header

The detail included in the PCIF header is too complex and repeats information in the body of the document. The key information required in a header is the name of the study, the site name and the Principal Investigators name.

PICF Footer

The detail included in the PCIF footer is too complex. The content can be restricted to the name and current version of the master PICF, the local site information and the current version date.

Study Title

Space should be provided for the full title of the study. Using only the short title could become confusing, particularly if the same or similar title is used for other studies.

Section 4 – What are the main steps in the study?

"We first need to confirm that you are eligible to take part". This would be better expressed as "we first need to do some of the screening tests listed below to make sure that the study is right for you".

Section 5 – What other options do I have?

This section must explain standard of care in relation to the person's condition. Information allows a person to make an informed decision about the care that they choose to receive. This section must acknowledge that participating in the clinical trial is not the only option to receiving quality care for their condition and that a person can consider receiving treatment through their healthcare practitioner through the health system, and not as part of the clinical trial.

Sections 14 – What happens if I am injured as a result of my participation in this trial, and Section 19 – What if I have a question or need to make a complaint or seek compensation for injury?

We recommend the two sections listed above must be integrated or follow on from each other to improve awareness of how a participant can raise a question or needs to make a complaint of seek compensation for injury during their participation in the study.

Section 20 – The consent form

The advice that "we will arrange for someone to read the form to you in a language you understand" must be located at the beginning of the document.

Tables

Drawing from the experience of clinical trials research health professionals in our networks, tables are not helpful, can confuse patients and is not recommended for inclusion in the PICF. A statement outlining any visits required in addition to standard of care should be sufficient. It is unlikely that the patient will refer to a table during participation in the study and the visit schedule may be subject to change. Participants are provided an appointment

schedule and receive support from the research nurse who will explain study visits/tests, which could vary per individual depending on response to treatment, adverse events etc.

Terminology page

The terms are not consistent and at times could be confusing.

Medical/Research terminology:

- The document recommends avoiding the term 'artery' but the term is then used to describe 'Pulmonary embolus' in plain English
- The document recommends avoiding the term 'vascular' however, the plain English alternative is incorrect as 'vascular' does not refer only to the veins

Possible Risks terminology:

- The document recommends avoiding the term 'inflammation' but the term is then used to describe phlebitis, stomatitis, carditis and cellulitis
- The recommended plain English alternative to 'stomatitis' is 'inflamed gums' however, inflamed gums describes gingivitis and not stomatitis which is related to the whole mouth
- The document recommends avoiding the term 'oedema' and provides 'swelling' as the plain English alternative. Swelling is also a suggested plain English alternative to the term 'inflammation', therefore the document says that inflammation and oedema are the same thing
- The same plain English alternative ('decrease in infection fighting blood cells') is currently listed for both 'leucopaenia' and 'lymphocytopaenia'. A clear distinction is required.

We wish you all the best in implementing the National Participant Information and Consent Form Framework for clinical trials.

Yours sincerely,

Prof Sanchia Aranda
Chief Executive Officer
Cancer Council Australia

Prof Mei Krishnasamy
President
Clinical Oncology Society of Australia