Research and Ethics Informed Consent and Writing Patient Informed Consent Forms Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research at, or under the auspices of, Monash Health.

PURPOSE

This procedure outlines the process in obtaining written approval and informed consent from patients prior to commencing of the trial.

PRECAUTIONS/CONTRAINDICATIONS

All Researchers at Monash Health must strive to conduct research in the manner indicated in the "Research and Ethics" policy document

PROCEDURE

The investigator(s) must:

- Comply with local Human Research Ethics Committee (HREC) requirements, the NHMRC National Statement on Ethical Conduct in Human Research (2007 updated 2018) and other applicable regulatory requirement(s), and adhere to Good Clinical Practice and to the ethical principles that have their origin in the Declaration of Helsinki.
- Obtain the HREC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to subjects prior to the beginning of the trial.
- Ensure that the written informed consent form and any other written information to be provided to subjects is revised whenever important new information becomes available that may be relevant to the subject's consent.
- Obtain the HREC's approval/favourable opinion in advance of use for any revised written informed consent form, and written information.
- Ensure the person or persons taking the informed consent have an adequate understanding of the trial and of the informed consent process.
- Inform the subject or the subject's legally acceptable representative in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.
- Not, nor permit trial staff to coerce or unduly influence a subject to participate or to continue to participate in a trial.
- Permit any of the oral and written information concerning the trial, including the written informed consent form, to contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

- (Or a person designated by the investigator), fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the Human Research Ethics Committee.
- Ensure that language used in the oral and written information about the trial, including the written informed consent form is as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.
- Ensure that before informed consent is obtained, they, or a person designated by the investigator, provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.
- Ensure prior to a subject's participation in the trial, that the written informed consent form is signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.
- Ensure if a subject is unable to read or if a legally acceptable representative is unable to read, that an impartial witness be present during the entire informed consent discussion, and that discussion be held in an appropriate language.
- Ensure that 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 the 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.
- Ensure prior to participation in the trial, the subject or the subject's legally acceptable representative receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects.
- Ensure during a subject's participation in the trial, the subject or their legally acceptable representative receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.
- Ensure that when a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject is informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.
- Ensure that (except as described immediately below), a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), is conducted in subjects who personally give consent and who sign and date the written informed consent form.

Note: Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

a. The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally.

b. The foreseeable risks to the subjects are low.

c. The negative impact on the subject's well-being is minimized and low.

d. The trial is not prohibited by law.

e. The approval/favourable opinion of the HREC is expressly sought on the inclusion of such subjects, and the written approval/ favourable opinion covers this aspect.

The investigator(s) must ensure:

- That such trials, unless an exception is justified, are conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.
- That in emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, is requested. When prior consent of the subject is not possible, and the subject's legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favourable opinion by the HREC, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements.
- That the subject or the subject's legally acceptable representative are informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested.

Please refer to the ***National Statement on Ethical Conduct in Human Research, 2007 updated 2018*** for details on obtaining consent in special cases.

4.2 Writing patient informed consent forms

The investigator(s) must:

- Ensure the written informed consent form and any other written information provided to subjects include explanations of the following:

a. That the trial involves research.

b. The purpose of the trial.

c. The trial treatment(s) and the probability for random assignment to each treatment.

d. The trial procedures to be followed, including all invasive procedures.

e. The subject's responsibilities.

f. Those aspects of the trial that are experimental.

g. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, foetus, or nursing infant.

h. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

i. The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

j. The compensation and/or treatment available to the subject in the event of trial related injury.

k. The anticipated prorated payment, if any, to the subject for participating in the trial.

l. The anticipated expenses, if any, to the subject for participating in the trial.

m. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

n. That the monitor(s), the auditor(s), the HREC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

o. Those records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

p. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

q. The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

r. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

s. The expected duration of the subject's participation in the trial.

t. The approximate number of subjects involved in the trial.

4.3 Training Records

The investigator(s) must:

- Ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
- Ensure that documentation of this training be kept current and available for review on request.

REFERENCES

1. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 4.
2. National Statement on Ethical Conduct in Human Research, (2007 updated 2018).

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KEYWORDS

PICF

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