

Meeting Minutes

At the end of each set of questions for each study, chose the appropriate statement to record for each of the following items:

A. The Committee's assessment of the risk/benefit (National Statement section 1.6):

1) The Committee was satisfied that the risks were justified by the potential benefits.

OR

2) The Committee did not consider that the potential benefits justify the risks involved in the research. Questions regarding the study design have therefore been sent to the Principal Investigator.

(Second sentence not required if the study is rejected.)

B. The Committee's consideration of vulnerable groups (per National Statement Section 4):

1) The Committee was satisfied that vulnerable groups have been appropriately considered, taking into account the values, principles and themes described in the National Statement.

OR

2) The Committee was not satisfied that vulnerable groups have been appropriately considered taking into account the values, principles and themes described in the National Statement.

OR

3) No vulnerable groups were included in the participant population.

National Statement Section 4 Chapters:

4.1 - Women who are pregnant and the human fetus

4.2 - Children and young people

4.3 - People in dependent or unequal relationships

4.4 - People highly dependent on medical care who may be unable to give consent

4.5 - People with a cognitive impairment, an intellectual disability, or mental illness

4.6 - People who may be involved in illegal activities

4.7 - Aboriginal and Torres Strait Islander Peoples

4.8 - People in other countries

C. The Committee's conclusion about the study (National Statement section 5.2.21):

1) The project was approved subject to satisfactory response and recommended changes to the documentation.

COMPLETE

OR

2) The project was not approved in its current format. The Committee will await the investigator's response before deciding further action.

i) Authority delegated to PR/SR/Chair to review response and decide further action.

OR

ii) Response to be reviewed by all Committee Members to discuss and decide further action.

ONGOING (Remains on Agenda as item 4)

OR

3) The project was rejected.

COMPLETE PENDING LETTER TO INVESTIGATOR