



Ethics applications for Traditional Chinese Medicine (TCM) and Western Herbal Medicine (WHM) research: a survey of Australian researchers and human research ethics committees

When completing the questionnaire can you please check boxes and insert text where prompted. Where multiple options are presented and several of these options apply, please check all boxes that apply.

Firstly we'd like to ask you some background questions relating to the number and details of Traditional Chinese Medicine (TCM) &/or Western Herbal Medicine (WHM) ethics applications reviewed.

1. Have you ever reviewed a Traditional Chinese Medicine (TCM) &/or Western Herbal Medicine (WHM) human research ethics application?

Yes (Please go to Q.2)

No (No further questions, thank you. Please return your survey.)

2. How many TCM &/or WHM applications have you reviewed in the past 3 years?

1-2

3-5

6-10

>10

3. Which modality or combination of modalities of TCM or WHM did the ethics application(s) address?

TCM:

Acupuncture

Acupressure

Chinese Herbal Medicine - ingested/internally applied

Chinese Herbal Medicine - topically/externally applied

Massage

Therapeutic exercise e.g. tai chi, qigong

Other e.g. moxibustion, cupping

WHM - ingested/internally applied

WHM - topically/externally applied

4. What type of study design did the application(s) use?

Experimental:

- Randomised controlled trial
- Non-randomised controlled trial
- Uncontrolled clinical trial

Observational:

- Cohort
- Cross-sectional
- Case-control studies

The following questions explore the familiarity of the committee and the evaluation methods used to assess TCM and/or WHM ethics applications.

5. Currently, are there members of your committee with expertise and/or knowledge in TCM &/or WHM?

- No
- Yes If yes, how many people? _____

6. How do you evaluate the scientific validity of TCM/WHM ethics applications?

- Consult current literature e.g. journals
- Consult within institution e.g. hospital, university
- Consult other ethics committees
- Make decision based on current knowledge and expertise of committee or scientific sub committee
- Other (please give detail below)

TCM and WHM can be described as complex interventions. Complex interventions are defined as those built up from a number of components, which may act both independently and interdependently. Methodological and ethical complexities may arise from the nature of these interventions.

7. Listed below are examples of methodological and ethical complexities common to TCM and WHM. Have researchers provided sufficient information within their ethics application for assessment by the committee on any of the components listed in Q.7 a.-i.? Please check the box if this applies to any TCM/WHM ethics application you have assessed over the last 3 years.

- | | Yes | No |
|---|--------------------------|--------------------------|
| a. Blinding or lack thereof | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Complex intervention or multi-modality holistic treatment approach | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Treatments individualised according to traditional diagnosis | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Knowledge of traditional diagnostic methods (e.g. tongue and pulse diagnosis in TCM) | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Mode of action not well defined from a scientific perspective | <input type="checkbox"/> | <input type="checkbox"/> |
| f. Safety issues when combining herbal ingredients | <input type="checkbox"/> | <input type="checkbox"/> |
| g. Limited Phase I trials, reliance on anecdotal evidence for safety and dosage levels | <input type="checkbox"/> | <input type="checkbox"/> |
| h. Insufficient information on herbal product characterisation, standardisation and stability for quantifying chemical constituents, therapeutically active compounds and product shelf life. | <input type="checkbox"/> | <input type="checkbox"/> |
| i. Other (please give details below) | <input type="checkbox"/> | <input type="checkbox"/> |

8. Have you ever encountered any of the following ethical issues when reviewing TCM/WHM ethics applications?

	Yes	No
a. Conflicts of interest for TCM/WHM researchers e.g. due to their strong belief in value of TCM/WHM conveyed in their ethics protocol	<input type="checkbox"/>	<input type="checkbox"/>
b. Conflicts of interest for TCM/WHM researchers e.g. arising from funded research which has not been handled in a transparent or ethical way	<input type="checkbox"/>	<input type="checkbox"/>
c. TCM/WHM surveys which create unnecessary anxiety for the patient, or raised positive expectations, which may have lead to disappointment when they are not or cannot be met	<input type="checkbox"/>	<input type="checkbox"/>
d. Insufficient information regarding the interactions and cumulative effects of combining herbal ingredients or the potential risks and side effects	<input type="checkbox"/>	<input type="checkbox"/>
e. Insufficient information regarding the Australian regulations relevant to that modality (eg. TGA)	<input type="checkbox"/>	<input type="checkbox"/>
f. Assessing the clinical application claims of the formula	<input type="checkbox"/>	<input type="checkbox"/>
g. Product quality concerns regarding herbal interventions	<input type="checkbox"/>	<input type="checkbox"/>
h. Other (please give details below)	<input type="checkbox"/>	<input type="checkbox"/>

9. What strategies are commonly employed by ethics committees to address problems raised when reviewing TCM/WHM applications?

- Request further information/clarification
- Request alteration to study design
- Dismiss due to lack of scientific rigour
- Other (please give detail below)

10. Would you or any other person in the committee be interested in receiving guidelines and/or training assembled as a result of this survey?

- Guidelines
- Training
- Neither, thank you

The following demographic questions will allow us to describe the characteristics of responders to the survey.

11. Please indicate how many years you have spent serving on this ethics committee?

- Less than 1 year 1 year
- 2 years 3 years or more

12. In which state are you currently serving on/acting on behalf of the ethics committee?

- | | | | |
|------------------------------|--------------------------|--------------------|--------------------------|
| New South Wales | <input type="checkbox"/> | South Australia | <input type="checkbox"/> |
| Victoria | <input type="checkbox"/> | Western Australia | <input type="checkbox"/> |
| Queensland | <input type="checkbox"/> | Northern Territory | <input type="checkbox"/> |
| Australian Capital Territory | <input type="checkbox"/> | Tasmania | <input type="checkbox"/> |

13. Please indicate the membership composition of the human ethics committee

- | | | | |
|---|--------------------------|--|--------------------------|
| Nurse | <input type="checkbox"/> | Social worker | <input type="checkbox"/> |
| Lawyer | <input type="checkbox"/> | Clinical psychologist | <input type="checkbox"/> |
| Minister of religion | <input type="checkbox"/> | Researcher with a background in complementary medicine | <input type="checkbox"/> |
| Researcher with a background in health, medical, social, psychological, or epidemiological research | <input type="checkbox"/> | Other (please give details below) | <input type="checkbox"/> |
- _____

14. Do you have any further comments or suggestions you would like to make?

Appendix 2 Questionnaire for researchers.



Ethics applications for Traditional Chinese Medicine (TCM) and Western Herbal Medicine (WHM) research: a survey of Australian researchers and human research ethics committees

There are four topic areas of the questionnaire to complete. When completing the questionnaire can you please check boxes and insert text where prompted. Where multiple options are presented and several of these options apply, please check all boxes that apply.

Firstly we'd like to ask you some background questions relating to the number and detail of ethics applications submitted

1. Have you ever submitted an ethics application as a Principal Investigator (PI) (or PI at a collaborating site) that related to the use of Traditional Chinese Medicine (TCM) &/or Western Herbal Medicine (WHM)?

Yes (Please go to Q.2)

No (No further questions, thank you. Please return your survey.)

2. How many TCM &/or WHM ethics applications have you submitted in the past 3 years?

3. Which WHM or TCM modality(ies) did the application(s) address?

TCM:

- Acupuncture
- Acupressure
- Chinese Herbal Medicine - ingested/internally applied
- Chinese Herbal Medicine - topically/externally applied
- Massage
- Therapeutic exercise e.g. tai chi, qigong
- Other e.g. moxibustion, cupping
- WHM - ingested/internally applied
- WHM - topically/externally applied

4. What type of study design did the application(s) involve? (Please check all that apply)

Experimental:

- Randomised controlled trial
- Non-randomised controlled trial
- Uncontrolled clinical trial

Observational:

- Cohort
- Cross-sectional
- Case-control studies

The following questions ask about your experience with your TCM/WHM research ethics applications

5. Do you feel your knowledge or confidence with preparing ethics applications, or responding to questions from the ethics committee could be improved?

- No
- Yes

6. Have you received generic feedback from the ethics committee seeking clarification or changes to the following on any TCM/WHM ethics application?

- | | | | | |
|--|----|--------------------------|-----|--------------------------|
| Clarifying the language used on information sheets | No | <input type="checkbox"/> | Yes | <input type="checkbox"/> |
| Clarifying the language used on informed consent processes | No | <input type="checkbox"/> | Yes | <input type="checkbox"/> |
| Assessing the study population | No | <input type="checkbox"/> | Yes | <input type="checkbox"/> |
| The procedures for gaining consent | No | <input type="checkbox"/> | Yes | <input type="checkbox"/> |
| Maintaining the scientific validity of the research | No | <input type="checkbox"/> | Yes | <input type="checkbox"/> |
| Other _____ | | | | |

The following question applies to researchers of Chinese herbal or Western herbal medicine only. Researchers in acupuncture, please go to Q.8.

7. Have you been requested by the ethics committee(s) to provide additional information relating to composition or ingredients of the herbal medicine such as the following:

Characterisation (of active ingredients) to quantify chemical constituent values

- No Yes (If yes, please provide details)
-

Standardisation of the therapeutically active compounds

- No Yes (If yes, please provide details)
-

Stability and shelf life of intervention

- No Yes (If yes, please provide details)
-

Dosage levels

No Yes (If yes, please provide details)

Interaction and cumulative effects of combined herbal ingredients when using formulas

No Yes (If yes, please provide details)

Safety for herb –drug interactions

No Yes (If yes, please provide details)

Side effects of the herb(s)

No Yes (If yes, please provide details)

For researchers undertaking research on Chinese herbal medicine or Western herbal medicine please go to Q.9.

8. Acupuncture researchers, have you been requested to provide additional information to the ethics committee relating to the following:

Assessment of successful blinding in trials of acupuncture

No Yes (If yes, please provide details)

Action of specific acupuncture points

No Yes (If yes, please provide details)

Safety of acupuncture and potential risks

No Yes (If yes, please provide details)

Clarification of the term differential diagnosis

No Yes (If yes, please provide details)

Clarification of sham acupuncture

No Yes (If yes, please provide details)

9. Have you been requested to amend any TCM/WHM study protocol by an ethics committee?

No Yes (If yes, please provide details)

10. Has ethics approval been given to all of your TCM/WHM research?

No (If no, please provide details) Yes

The following demographic questions will allow us to describe the characteristics of responders to this survey.

11. Please indicate your gender

Female Male

12. Please indicate your age

18-24 years 25-34 years 35-44 years
45-54 years 55-64 years 65 years and over

13. In which state are you currently involved in TCM/WHM research?

New South Wales	<input type="checkbox"/>	South Australia	<input type="checkbox"/>
Victoria	<input type="checkbox"/>	Western Australia	<input type="checkbox"/>
Queensland	<input type="checkbox"/>	Northern Territory	<input type="checkbox"/>
Australian Capital Territory	<input type="checkbox"/>	Tasmania	<input type="checkbox"/>

14. What is the highest qualification that you currently hold?

Diploma	<input type="checkbox"/>	Advanced Diploma	<input type="checkbox"/>
Graduate Diploma	<input type="checkbox"/>	Bachelor's degree	<input type="checkbox"/>
Bachelor's degree with honours	<input type="checkbox"/>	Masters	<input type="checkbox"/>
PhD	<input type="checkbox"/>	Other (please give details below)	<input type="checkbox"/>

15. Would you be interested in receiving guidelines and/or training assembled as a result of this survey? (Please check all that apply)

Guidelines
Training
Neither, thank you

16 Do you have any further comments you would like to make?
