Cayman Islands Ethics Committee

Application to conduct human research on the Cayman Islands

Please do not exceed the allotted space and electronic print should be at least 12 point, Arial. Please return to Mr. Shawn Biscette (shawn.biscette@hsa.ky). The ethics committee meets monthly on the second Wednesday of the month and will endeavour to review all applications at its next meeting provided they are received at least a week before the meeting.

The following documents should be submitted electronically along with your application:

a. A letter on headed paper from your research supervisor (scanned and emailed although the paper copy should be available) supporting the aims and methodology of your project. If your research is not being supervised by a University or some other body, please provide details of your research credentials.

b. Details of the background to the work proposed, along with your aims and methods e.g. as submitted to your research supervisor

1. Name and Submission Date

2. Full title of the research

3. Chief Investigator

4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

5. Summary of the study

6. Summary of main issues

7. Select the appropriate methodology description for this research

8. What is the principal research question/objective?

9. What are the secondary research questions/objectives if applicable?

10. What is the scientific justification for the research?

11. Please summarise your design and methodology

12. In which aspects of the research process have you actively involved, or will you involve patients, service users, and/or their carers, or members of the public?

13. Please list the principal inclusion and exclusion criteria

14. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol

15. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol

16. How long do you expect each participant to be in the study in total?

17. What are the potential risks and burdens for research participants and how will you minimise them?

18. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

19. What is the potential for benefit to research participants?

20. What are the potential risks for the researchers themselves?

21. How will potential participants, records or samples be identified?

22. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

23. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

24. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

25. How and by whom will potential participants first be approached?

26. Will you obtain informed consent from or on behalf of research participants?

27. Will you record informed consent (or advice from consultees) in writing?

28. How long will you allow potential participants to decide whether or not to take part?

29. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?

30. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants) (tick as appropriate)?

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside of the Cayman Islands
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
  - ☐ Manual files including X−rays
  - ☐ HSA or other organisational computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

31. How will you ensure the confidentiality of personal data?

32. Who will have access to participants' personal data during the study?

33. How long will personal data be stored or accessed after the study has ended?

34. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

35. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

36. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

37. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

38. Will the research be registered on a public database?

39. How do you intend to report and disseminate the results of the study?

40. Will you inform participants of the results?

41. How has the scientific quality of the research been assessed?

42. What is the sample size for the research?

43. How was the sample size decided upon?

44. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives

45. Other key investigators/collaborators

46. Sponsor's contact point for correspondence

47. Has this or a similar application been previously rejected by a Research Ethics Committee in another country?

48. How long do you expect the study to last?

47. Is this a single centre study?

48. Where will the research take place?

49. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?

50. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators/employers arising from harm to participants in the conduct of the research?