THE DEPARTMENT OF HEALTH REGULATORY SERVICES

HEALTH PRACTICE COMMISSION RESEARCH REVIEW BOARD ('HPCRRB')
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RESEARCH REVIEW APPLICATION FORM

1. Date of Submission: _____
2. Name of Applicant: _____
3. Full Title of Research/ Project: _____
4. Research Contact/ Administrator: _____
5. Do you have a Medical Tourism Certificate? (If yes, please provide proof.) □Yes □No
6. Description of Project – Please attach to form (Refer to Protocol Submission Requirement Policy)
7. Purpose of Research & Scientific Justification of Research:

_____

_____

_____

_____

_____

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_____

8. Detailed Plan of Research Methodology:

_____

_____

_____

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_____

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_____

9. Summary of main issues:

_____

_____

_____

_____

_____

10. Who is the Principal Investigator?

_____

_____

11. Name(s) and respective roles of other persons in team conducting research.

_____

_____

_____

_____

12. Proof of valid certification of Principal Investigator in the ethics of human subject research.

13. Where will research be conducted? _____

14. Who is the Sponsor of the Research Project?

_____

_____

15. Has a previous application ever been made to any other Research Board for approval to conduct this project? _____

(a) If yes, was it approved?

_____

(b) If no, why?

_____

16. How will participants be recruited?

a) Cold calling _____

b) Advertisement _____

c) Secondary recruitment _____

d) Other, please specify _____

17. Please provide copies of telephone scripts, information sheets, advertisement or any other document used to recruit participants.

18. Where will Participants be recruited from:

_____

_____

_____

(a) Will any participant be recruited from the PI's clinical pool of patients?

_____

(b) If yes, who will determine eligibility and obtain informed consent of participant(s)

_____

(c) Will family member(s) of the PI or any other number of the Study Team be allowed to participate? _____

(d) If yes, how will they be recruited?

_____

_____

_____

19. Please List principle inclusion and exclusion criteria:

_____

_____

_____

_____

20. Describe the process used in obtaining informed consent of participants.

_____

_____

21. Will there be any vulnerable participants(s)? _____

(a) Please justify the inclusion of vulnerable participant(s).

_____

_____

_____

_____

(b) What measure(s) will be taken to adequately protect them?

_____

_____

_____

_____

22. Will persons mentally capable of consenting but physically unable to sign the consent document be recruited? _____

(a) If yes, how will the legality of their consent be ensured?

_____

_____

_____

_____

_____

23. Will physically handicapped, economically or educationally disadvantaged persons be allowed to participate? _____

(a) If yes, how will the legality of their consent be verified/ ensured?

_____

_____

24. Will illiterate or seeing-impaired persons be allowed to participate? _____

(a) If yes, what precautions will be taken to ensure the legitimacy of the process, in particular, obtaining informed consent?

_____

_____

25. Does the consent form fully inform the participant about the nature and purpose of the research? (refer to Informed Consent Policy)

_____

26. Will non-English speaking persons be recruited? _____

(a) If yes, please provide details of the recruitment process, including the plan for obtaining Informed Consent.

(b) Please submit a translated version of the Information given to non-English speaking recruits and the informed consent form used.

(c) What plan will be implemented during the course of the project to accommodate any non-English speaking participant?

_____

_____

_____

_____

27. Does it fully describe the role of the participant in the research? In particular, does it fully describe how much pain and suffering he/she is likely to experience?

_____

28. Does the Consent Form identify any anticipated risks involved?

_____

29. Will a copy of the Consent Form be kept in the research file(s)?

_____

30. Will a copy be given to participant(s)

_____

31. Will the individual be informed of their right to refuse consent without negative consequences to treatment, payment health plan enrolment or benefit eligibility?

_____

32. How do you expect the participant to be in this study:

_____

_____

_____

_____

_____

33. When does the individual's Consent expire?

_____

34. Will the individual be informed of:

a) Their right to revoke authorisation at any time? _____

b) How to exercise that right? _____

c) Whether there are any applicable exceptions to that right? _____

35. Will participants be remunerated for their time and effort in participating in the Project?

_____

(a) Will they be reimbursed for any expenses incurred? _____

(b) Will they be paid any incentive for time and discomfort? _____

(c) Will they be compensated for treatment of adverse outcomes? _____

(d) Will they be given any tangible gifts?

_____

(e) If so, are these financial details clearly explained in the Consent Form?

_____

(f) Please elaborate giving a detailed description and justification of payment amounts, timing and method of payment.

_____

_____

_____

36. Will the project involve obtaining access to and/or use of participants(s) medical records (Protected Health Information-PHI)?

_____

(a) Will you use a separate consent form for this purpose?

_____

(b) Do you require a waiver of requirement for authorisation (consent) of participant(s) to access/use their medical records?

(c) If yes, please give reason(s).

_____

_____

_____

37. Will the Project require access to the medical records of deceased person(s)?

_____

38. Please indicate what PHI will be used in the Project

_____

_____

(a) How will this information be used?

_____

_____

_____

(b) How will this information be protected and confidentially maintained?

_____

_____

_____

(c) Who will have access to this information?

_____

_____

(d) For how long will they keep this information?

_____

(e) Who will use and disclose PHI?

_____

_____

(f) What is the purpose of the use or disclosure of the PHI requested?

_____

_____

(g) Please provide copies of all Informed Consent Forms which will be used.

39. Will the project directly involve children?

_____

(a) If so, describe fully, how the child's involvement in the study will be explained to them:

_____

_____

_____

(b) Will the assent of the child's parents(s) or legal guardian(s) be obtained?

_____

(c) Has the parent(s) and child been informed that assent expires when the child becomes and adult at which time an approved adult form will need to be signed if he/she wishes to continue participating in the Project?

_____

(d) Have both parents and/or legal guardians consented for the child to participate in the Project?

_____

(e) If no, are there extenuating circumstances which preclude this happening?

_____

(f) Will there be a need to request a Waiver of Consent of any participant?

_____

(g) If yes, why?

_____

_____

_____

_____

_____

(h) Is there potential parent conflict of interest?

_____

(i) If yes, who else will represent the child when obtaining parental permission?

_____

40. Will the project include chart reviews and the use of PHI of children?

_____

41. Will emancipated minor(s) participate in the research?

_____

42. Will the research project include

a) Pregnant women? _____

b) Human foetuses? _____

c) Neonates? _____

d) Pregnant subjects who are minors? _____

43. Has parental Consent been obtained for pregnant minors? _____

44. Has any previous study been conducted on

a) Pregnant animals? _____

b) Non-pregnant women? _____

c) Animal neonates? _____

45. If yes, what were the results? _____

46. Please justify the reason(s) for including:

a) Pregnant women

b) Neonates

_____

_____

_____

_____

_____

47. What are associated risks of participants in the Project, and what is done to minimize them?

_____

_____

_____

48. Besides ensuring that participant(s) fully understand the nature of the Project, are there any additional safeguards to protect the rights and welfare of the participants, particularly children?_____

_____

_____

49. Does research involve organ donation? _____

50. Have you conducted past research projects? □Yes □No

(a) If yes, what project(s)?

_____

_____

_____

(b) Were there any past or present complaints regarding any of the above research projects?

_____

_____

_____

51. Has approval been granted to conduct this Research Project by any Authority outside of the Cayman Islands? _____

(a) If yes, please submit a copy of the approval letter, name and contact details of the Authority.

52. Will placebos be used in the Project? _____

(a) Has this been explained to the participant(s)?

_____

(b) If yes, please include a copy of the explanation.

53. Will any participant be required to undergo a washout period?

_____

54. Will it be necessary to access Limited Data Sets of participants(s)?

_____

55. Has a Data Use Agreement been signed with the covered entity? (Holder of Information)

_____

56. If yes, please provide a copy of the Agreement.

57. Please be reminded that if the research finds are intended for presentation in the USA, you will be bound by the requirements of the USA's Privacy Rule even if the research is conducted outside of the USA.

58. Will any of your employees, house staff or students be allowed to participate in the research?

_____

(a) If yes, what action(s) have been taken to prevent coercion or undue influence to participate?

_____

_____

_____

59. Will the Principal Investigator be a participant in the project?

_____

(a) If yes, who decided the eligibility of the Principal Investigator?

_____

60. Will prisoners be recruited to participate in the research project? _____

(a)If yes, please complete the HPC form: "Additional Required Information for a Study that Includes Prisoners".

61. How often will you apprise the HPC about the progress of the research project?

_____

After fully understanding the following, please sign, have witnessed and date this form:

To the best of my knowledge, the above statements are correct. I understand that a copy of this form and attachments that are needed to process this application will be shared with Administrative staff of the Health Practice Commission and the current membership of the Health Practice Commission Research Review Board. I also give authorisation to the HPC to obtain records from practitioners, medical departments (private or public), insurer, employer, or any other relevant party on my behalf. I represent that I have the proper authority to execute this release.

Signature: **Date (DD/MM/YY)**	**Alternate contact information if different from above:**
Print Name:	
Signature of Witness: **Date (DD/MM/YY)**	**Print Witness Name:**