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IRB APPLICATION FORM AND QUESTIONNAIRE

Form HRP-IRB-010

NAME OF ORGANIZATION/INSTITUTION: _____ **REFERRENCE NO:** _____

TITLE OF RESEARCH:	
Anticipated start date	Date
Anticipated end date	Date
Principal Investigator: (Must be a member of the consultant staff of Chong Hua Hospital)	
Specific Role in this project:	
Sub – Investigator: (Must be a member of the consultant staff of Chong Hua Hospital)	
Specific Role in this project:	
Has this protocol been disapproved by another IRB/IEC or hospital? YES _____ NO _____ **If YES from which IRB/IEC or HOSPITAL?**	

INVESTIGATOR'S ASSURANCE
THE SIGNATURES BELOW SIGNIFY THAT:
● **The information and documents provided is/are accurate, current and valid**
● **The principal investigator has the ultimate responsibility for the protection of rights, welfare and safety of the subjects**
● **The principal investigator has the ultimate responsibility for the ethical conduct of the research**
● **Each individual listed as investigator has received the required training on Good Clinical Practice**
● **Each investigator and member of the team has the necessary experience on how to conduct a research on human subjects and shall abide by the regulations of Chong Hua Hospital in its conduct**
● **The principal investigator has the ultimate responsibility for the prompt management of any adverse reactions or suspected adverse reactions attendant to the conduct of the study.**
● **No research or part of it will commence before the IRB has given its approval**
● **The research will be conducted according to the protocol or its amendments duly approved by the Chong Hua Hospital IRB.**

Principal Investigator:	[Printed Name and Signature]	**Date**
Sub – Investigator:	[Printed Name and Signature]	**Date**
Received by:	[Printed Name and Signature]	**Date Received** **Time Received**

SECTION I: INVOLVEMENT OF HUMAN SUBJECTS

1. Does the study involve human subjects? ___ **Yes** ___ **No**

*If the answer is **No**, you may not submit the study for IRB review*

SECTION II: PROJECT FUNDING

1. Is the project funded? ___ **Yes** ___ **No**

If the project is funded, kindly specify the funding source.

_____

_____

SECTION III: CONFLICT OF INTEREST (only required for funded research)

1. Is there any real, potential or apparent conflict of interest on the part of Investigator or any of the study team? ___ **Yes** ___ **No**

*If **Yes,** please declare and explain.*

N.B. NON DISCLOSURE OF ANY CONFLICT OF INTEREST MAY AFFECT IRB APPROVAL.

_____

_____

SECTION IV: TYPE OF RESEARCH STUDY

STUDY TYPE: (Mark "✓ " whichever apply to the study)

☐ Survey	☐ Social	☐ Medical	☐ Community Based	☐ Individual Based
☐ Screening	☐ Observational	☐ Epidemiology	☐ Intervention Study	
☐ Clinical Trial:	☐ Phase I	☐ Phase II	☐ Phase III	☐ Phase IV
☐ Genetic Study	☐ Retrospective	☐ Prospective	☐ Others_____	
☐ Single Center	☐ Multicenter	☐ Others_____		

SECTION V: Study Population

1. Does the study involve healthy volunteers? ___ **Yes** ___ **No**
2. Does the study involve patients with disease? ___ **Yes** ___ **No**
3. Does the study involve a vulnerable population? ___ **Yes** ___ **No**

   *If **Yes,** please identify.*

   _____

4. Will the study exclude a particular group of individuals ___ **Yes** ___ **No**

   *If **Yes,** please identify.*

   _____

SECTION VI: Characteristics of Study Population (Mark "✓ " whichever apply to the study)

Age Range ⇨	☐ 0 -17 yrs	☐ 18 - 44 yrs	☐ 45 - 65 yrs	☐ ≥ 66 yrs
Pediatric ⇨	☐ None	☐ < 1 yr	☐ 1-3 yrs	☐ 4 -14 yrs
Impaired ⇨	☐ None	☐ Physically	☐ Cognitively	☐ Mentally

SECTION VII: Drugs/Devices, Genetic Testing, Radiation and Biological Samples

Does the study involve the use of any of the following?

1. An FDA approved drug or medical device ___ **Yes** ___ **No**
2. Unapproved indication for an FDA approved drug ___ **Yes** ___ **No**
3. An investigational medical device ___ **Yes** ___ **No**
4. A non-medical device ___ **Yes** ___ **No**
5. A proprietary product ___ **Yes** ___ **No**
6. A biological agent ___ **Yes** ___ **No**
7. A genetic testing ___ **Yes** ___ **No**
8. Radiation exposure ___ **Yes** ___ **No**