Human body research ethics review application form

Part One Application Project Summary

1. Information related to research projects					
item eye base Book letter breath	project name	Chinese			
		English			
	Item Number				
	field of study				
	Project sponsor				
	Project undertaking unit				
	Project cooperation unit				
	Countries and regions involved				
	Project start and end time				
item eye burden responsibility people	Project manager	Chinese		English	
		job title		Bachelor of Science	
	employer				
	Telephone			fax	
	E-mail			post code	
	address				

	Name	Bachelor of Science	hold office	Division of labor
item eye host want ginseng and By				

2. Research categories: ÿ Basic research ÿ Epidemiological research ÿ Drug research ÿ Medical device testing

ÿNew diagnostic and treatment methodsÿOthers _____

3. Experimental drug category (if it is a drug trial, please select according to the SFDA classification):

Traditional Chinese Medicine and Natural Medicine Category 1-9: ÿ1 ÿ2 ÿ3 ÿ4 ÿ5 ÿ6

ÿ7 ÿ8 ÿ9

Chemical drugs 1-6 categories: **ÿ1 ÿ2 ÿ3 ÿ4 ÿ5 ÿ6**

Biological products Category 1-15: **ÿ1 ÿ2 ÿ3 ÿ4 ÿ5 ÿ6**

ÿ7 ÿ8 ÿ9 ÿ10 ÿ11 ÿ12

ÿ13 ÿ14 ÿ15

Whether to import drugs ÿ Yes ÿ No **Whether the drug is on the market ÿ Yes ÿ No**

4. Research stage: ÿ Bioequivalence test **ÿ Phase I trial**

ÿ Phase II trial **ÿ Phase III trial**

ÿ Phase IV trial **ÿ Others** _____

5. Research design (multiple choices available):

ÿ Single center trial

ÿ Multi-center trial

ÿ. Is this committee the central ethics committee?

ÿYes **ÿNo (please specify the center ethics committee** _____ **ÿ**

ÿ.Has the research draft been approved by other ethics committees?

ÿYes (please specify _____ **ÿ** **ÿNo**

ÿ.Has the draft been rejected by other ethics committees?

ÿYes (please specify _____ **ÿ** **ÿNo**

ÿ.Whether this research involves overseas regions or countries

ÿYes (please specify _____ **ÿ** **ÿNo**

ÿ Parallel control

ÿ Cross-reference

ÿ Single blind

ÿ Double blind

ÿ Random sampling

ÿ Others _____

Part 2 Research Project Contents

6. Scientific basis and background (please briefly describe it in plain and easy-to-understand language, within 500 words)

7. Project research purpose (please briefly describe it in plain language)

8. Has the research project undergone independent scientific review? ÿYes (please specify) _____ ÿNo

9. Application of research results

9.1 After the trial is completed, what will the research results be used for?

9.2 Are there any restrictions on publication of results?

ÿYes (please specify) _____

ÿNo

10. Determination of research objects

10.1 How potential research subjects are identified and recruited **ÿHealthy ÿSick ÿOthers**

10.2 Whether the purpose of the research is explained to the research subjects **ÿYesÿNo**

10.3 Are there criteria for selecting research subjects? **ÿYesÿNo**

10.4 How to perform statistical analysis on sample data? (Please briefly describe the statistical method, the sample size is large Small and statistical commissioning units) _____

11. Are there any study termination criteria? Yes (please specify) _____

_____ÿNone

12. Biological samples

Is it necessary to collect biological samples from subjects? ÿYes (if "Yes", please fill in the following items) ÿNo

12.1 Sample type and sampling size: _____

12.2 Sample storage time: _____

12.3 Is sampling performed by qualified professionals from the local health care system? ÿYes ÿNo

12.4 Who will ultimately conduct the testing and analysis of the samples? _____

12.5 Are samples stored for future research?

ÿ Yes (Method of obtaining informed consent: ÿ Obtained for the first time ÿ Ethics Committee decision) ÿ No

12.6 Will samples be sent overseas? ÿYes (please specify where) _____ **ÿNo**

13. Informed consent

13.1 In what form will consent be obtained from research subjects? ÿWritten ÿOral, (please specify your choice "oral" reasons) _____

13.2 Who will explain the purpose of the experiment to the research subjects? _____

13.3 Whether oral interpretation is provided when necessary ÿYesÿNo

13.4 If the research subjects (such as children) are unable to express their wishes, please indicate who expresses informed consent?

_____

14. Confidentiality:

14.1 Who has access to raw data or study records during and after a trial?

_____

14.2 After the experiment is completed, how to deal with the raw data?

_____

14.3 In order to protect the personal privacy and rights of research subjects, does the researcher ensure that no impartiality is observed in the paper report?

Give a personal name? ÿYesÿNo

15. Risk assessment

15.1 Will this research result in clinical intervention for the research subjects Yes No

15.2 Will this research impose additional burden on the research subjects?

ÿYes (measures taken_____) ÿNo

15.3 Does this research involve personal privacy? ÿYesÿNo

15.4 Does this research involve the following vulnerable groups?

fetus in uterus	ÿYesÿNo
Non-viable fetus/aborted fetus	ÿYesÿNo
Infant (0~1 years old)	ÿYesÿNo
Children (1~13 years old)	ÿYesÿNo
Teenagers (13~18 years old)	ÿYesÿNo
Pregnant/lactating women	ÿYesÿNo
Elderly (over 60 years old)	ÿYesÿNo
Special people are mentally retarded	ÿYesÿNo

Part 3 Others

16. Benefits:

16.1 Research may bring benefits to society ÿYesÿNo

16.2 The research will not bring direct benefits to the research subjects ÿYesÿNo

16.3 Are certain compensatory remunerations (should not be regarded as benefits) paid to research subjects? ÿYesÿNo

17. Potential hazards:

17.1 Is there any potential harm to the subjects in this study? ÿYes, (please explain what precautions are taken measure) _____ ÿNo

17.2 Are research subjects provided with the researcher's telephone number for emergency contact or necessary inquiries?

ÿYesÿNo

18. Will it be reviewed by an independent data and safety monitoring board? ÿYesÿNo

19. The researcher guarantees:

19.1 Comply with the provisions of the Declaration of Helsinki (2008 revised edition) adopted by the World Medical Association (WMA).

Based on the principles described above, in cooperation with the World Health Organization (WHO) International Council for Medical Sciences (CIOMS)

International Code of Ethics for Biomedical Research Involving Humans (2002), UNESCO

(UNESCO) "Universal Declaration on the Human Genome and Human Rights" (1997) and the Ministry of Health of my country promulgated

"Measures for Ethical Review of Biomedical Research Involving Humans (Trial)" (2007.11), Ministry of Science and Technology, Ministry of Health

The ethical requirements stipulated in the "Interim Measures for the Management of Human Genetic Resources" (1998.6) issued by the Ministry of Health.

19.2 We will respect the ethical recommendations made by the Ethics Committee on this project research, and during the research process

If any risks to research subjects or unexpected problems are discovered, please contact the Ethics Committee at any time.

communicate.

19.3 We will keep the personal privacy of research subjects and ensure confidentiality. All original data and related information will be kept confidential.

Relevant documents and materials shall be kept as confidential files for at least three years after the completion of the research.

19.4 We keep accurate records during the research process for inspection and summary.

Applicant unit: _____ date: _____

principal signature): _____ Position: _____