APPLICATION TO USE HUMAN RESEARCH SUBJECTS

UNIVERSITI PENDIDIKAN SULTAN IDRIS (UPSI)

AHLI JK ETIKA PENYELIDIKAN MANUSIA

PENGERUSI
PROF DR RAHMATTULLAH BIN WAHAB KHAN

SETIAUSAHA
DR NURUL AIN HIDAYAH BINTI ABAS

PANEL PAKAR

PANEL BUKAN SAINTIFIK
•PEGAWAI UNDANG-UNDANG
•PEGAWAI HAL EHWAL ISLAM

PANEL SAINTIFIK

- PROF. EMERITUS DATO' DR. AMINAH BINTI AYOB
- PROF MADYA NUR IKHWAN BIN MOHAMAD
- DR PAU KEE
- DR NURUL HASYIMAH BINTI MAT RANI
- PROF MADYA DR AHMAD JAZIMIN BIN JUSOH
- PROF. MADYA DR NORAINI BINTI AHMAD
- PROF. MADYA DR. JAMAL @ NORDIN BIN YUNUS
- DR. MAZLINA BINTI CHE MUSTAFA
- PROF MADYA DR GOH SWEE CHOO
- DR GRACE ANNAMMAL A/P GNANA PIRAGASAM
- DR THARIQ KHAN AZIZUDDIN KHAN
- DR. MASITA ARIP (IMR)

FORMS

- **APPLICATION TO USE HUMAN RESEARCH SUBJECTS (UPSI/PPPI/UPP/BE01)**
- **APPLICATION FOR HUMAN RESEARCH ETHICS WORKSHOP FORM (UPSI/PPPI/UPP/BE07)**
- **NOTICE OF SUBSTANTIAL AMENDMENT FORM (UPSI/PPPI/UPP/BE04)**
- **ADVERSE EVENT REPORTING FORM (UPSI/PPPI/UPP/BE05)**

APPLICATION FORM

Section 1: Application Detail

- Title of research
- Research code (if applicable)
- Funding institution (if applicable)
- Research design (eg: survey or experimental)

Section 1. Application Detail		
Title of Research	:	
Research Code (if applicable)	:	
Funding Institution (if applicable)	:	
Research design (e.g.: survey or experimental)	:	

Section 2: Responsible Research Principal Investigator (PI)

- Name
- Telephone
- Email
- Office address
- Faculty (if applicable)
- Department

Section 2. Responsible Research Principal Investigator (PI)					
Name	:				
Telephone	:		E-mail	:	
Office Address	:				
Faculty (if applicable)	:		Department	:	

Section 3: Investigator(s)

- Name
- Position
- Faculty
- Role

Section 3. Investigator(s)
If more investigators exist than lines provided, please attach a separate list.

Name	Position	Faculty	Role	Signature

Section 4: Type of Research

- University research
- External research
- Doctoral research / post doctoral research
- Master's research
- Bachelor's research (eg: Final year project)
- Others

Section 4. Type of Research

This research is being conducted as part of (please tick all that apply):

☐ University Research	☐ Master's Research
☐ External Research	☐ Bachelor's Research (e.g.: Final Year Project)
☐ Doctoral Research/ Postdoctoral Research	☐ Other (specify)_____

Section 5: Research Period

- State the start date and end date
- Duration of research

Section 5. Research Period
Start date (DD/MM/YY) _____/_____/_____ End date (DD/MM/YY) _____/_____/_____ Duration : _____

Section 6: Location(s) of the Research

- Please indicate city and state
- Locations:
  - *UPSI campus*
  - *School / Academic institution(s)*
  - *Government or non-government organization(s)*
  - *Community setting*
  - *Other*

Section 6. Location(s) of the Research

This research will be conducted at the following location(s): (Please indicate city & state)

Locations:

☐ UPSI Campus: _____

☐ School/ Academic Institution(s) (Specify): _____

☐ Government/ Non-Government Organization(s) (Specify): _____

☐ Community setting (Specify): _____

☐ Other (Specify): _____

Section 7: Human Subject Review

- Has this research been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects?
  - If yes, please attach the relevant document
- Has you or any of the co-researcher (s) completed any Human Research Ethics Workshop (HREW)?
  - If yes, please attach the relevant document and date
  - If not, please download the HREW form from RMIC website and attach to this application

Section 7. Human Subject Review

Has this research been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects?

☐ Yes (please attach the relevant document)

☐ No

Has you or any of the co-researcher (s) completed any Human Research Ethics Workshop (HREW)?

☐ Yes (please attach the relevant document)
Date (DD/MM/YY) _____/_____/_____

☐ No (please download the HREW form from RMIC website and attach to this application.)

Section 8: Subjects

- Indicate the anticipated maximum number of subjects to be enrolled in this protocol as justified by the hypothesis and research procedures
- State the vulnerable subjects if this research will involve potentially vulnerable subject population(s) such as children under 18, pregnant women, indigenous people, disabled athletes and etc.

Section 8. Subjects

Indicate the anticipated maximum number of subjects to be enrolled in this protocol as justified by the hypothesis and research procedures: _____

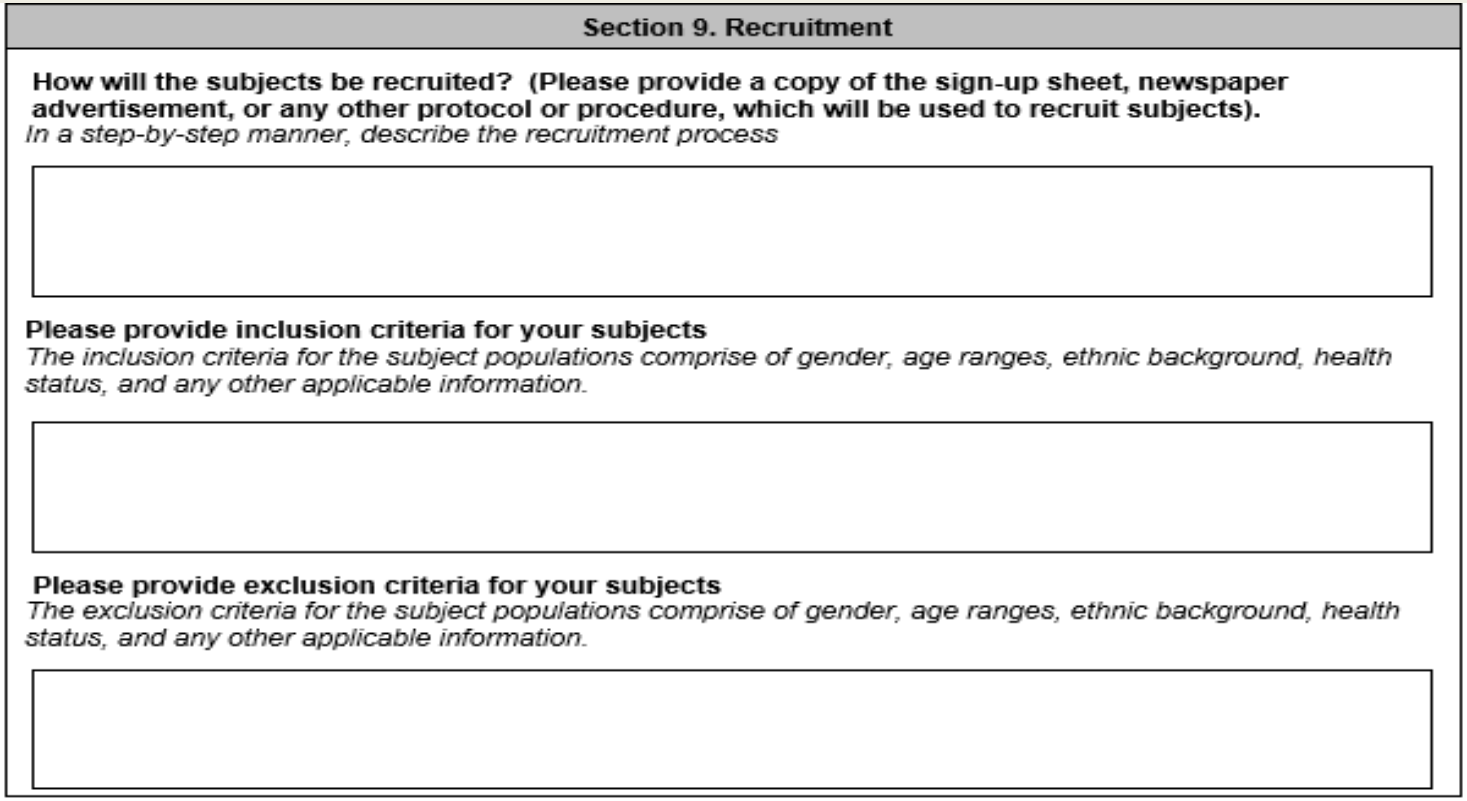
Vulnerable Subjects:
If this research will involve potentially vulnerable subject population(s), please tick all that apply.

- ☐ Children (under age 18)
- ☐ Pregnant Women
- ☐ Indigenous People
- ☐ Disabled athletes
- ☐ People diagnosed with Sickness
- ☐ Patients in Emergency Care
- ☐ Patients with Mental Health Problems
- ☐ People on Welfare/Social Assistance
- ☐ Homeless People
- ☐ Elderly People (age: 65 and above)
- ☐ Economically/ Educationally Disadvantaged Persons (e.g. to investigate the lower income of SES)
- ☐ Developmentally Disabled Persons (e.g. for Special Education purposes)
- ☐ Poor and Unemployed
- ☐ Victims/ Survivors
- ☐ Interventions (s) that include medical or psychological treatment
- ☐ Single parent

Others (specify): _____

Section 9: Recruitment

- How will the subjects be recruited?
  - *Provide a copy of the sign-up sheet, newspaper advertisement, or any other protocol or procedure, which will be used to recruit subjects*
    - In a step-by-step manner, describe the recruitment process
- Inclusion and exclusion criteria(s) for the subject populations
  - *Comprise of gender, age ranges, ethnic background, health status, and any other applicable information*



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In a step-by-step manner, describe the recruitment process

Please provide inclusion criteria for your subjects
The inclusion criteria for the subject populations comprise of gender, age ranges, ethnic background, health status, and any other applicable information.

Please provide exclusion criteria for your subjects
The exclusion criteria for the subject populations comprise of gender, age ranges, ethnic background, health status, and any other applicable information.

Section 10: Devices (if applicable)

- Name of the device(s)
- State the reasons for using it
- Is there any specific protocol that needs to be followed?
  - *Provide the relevant document*

Section 10. Devices (if applicable)
Name of the Device(s): _____
Please state the reasons: _____
Is there any specific protocol that needs to be followed: (Please provide the relevant document)

Section 11: Biological / Chemical Materials (if applicable)

- State the biological / chemical materials will be used with the subjects
- Describe how are these materials being used in the research
- State if the research need to collect biological material and describe the biological materials
- What is the intended use of the biological material that will be collected?
- Who will have access to biological material?
  - *Used by members of the research team or shared with outside researcher*
- Will the biological material be destroyed after completion of the study?

Section 11: Biological / Chemical Materials (if applicable) (cont.)

Section 11. Biological/ Chemical Materials (if applicable)

Will any biological/ chemical materials will be used with the subjects?

☐ Yes (please state: _____)

☐ No (please proceed to Section 12)

How are these materials being used in the research? Please describe

Is the research need to collect biological material?

☐ Yes (please state who: _____)

☐ No (please proceed to Section 12)

Describe the biological materials that will be collected.

What is the intended use of the biological material that will be collected?

Who will have access to biological material? (Tick all that apply)

☐ Biological material will be used by members of the research team

☐ Biological material will be shared with outside researchers

☐ Others (Specify): _____

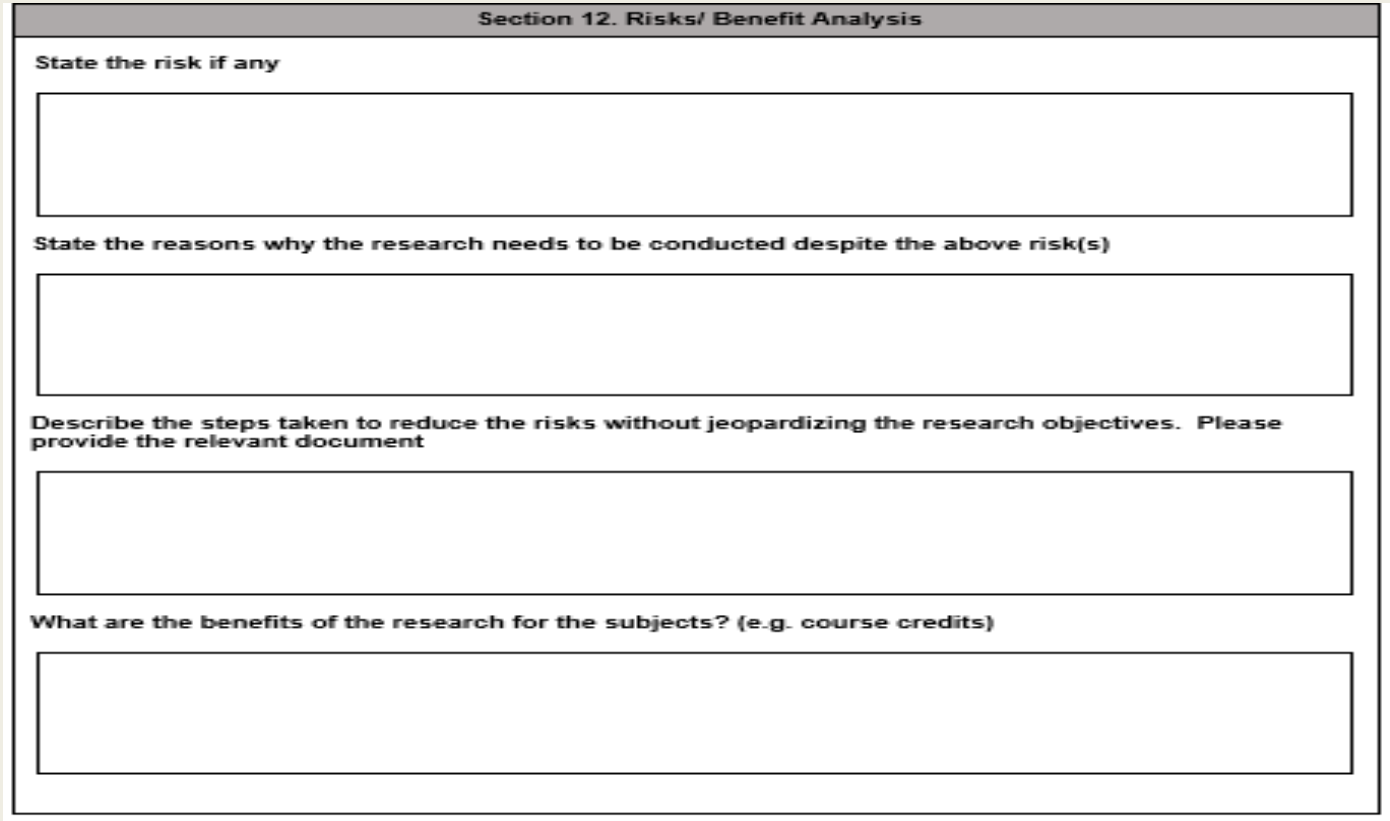
Will the biological material be destroyed after completion of the study?

☐ Yes

☐ No

Section 12: Risks / Benefit Analysis

- State the risk if any
- State the reasons why the research needs to be conducted despite the above risk(s)
- Describe the steps taken to reduce the risks without jeopardizing the research objectives
  - *Provide the relevant document*
- Benefits of the research for the subjects? (e.g. course credits)



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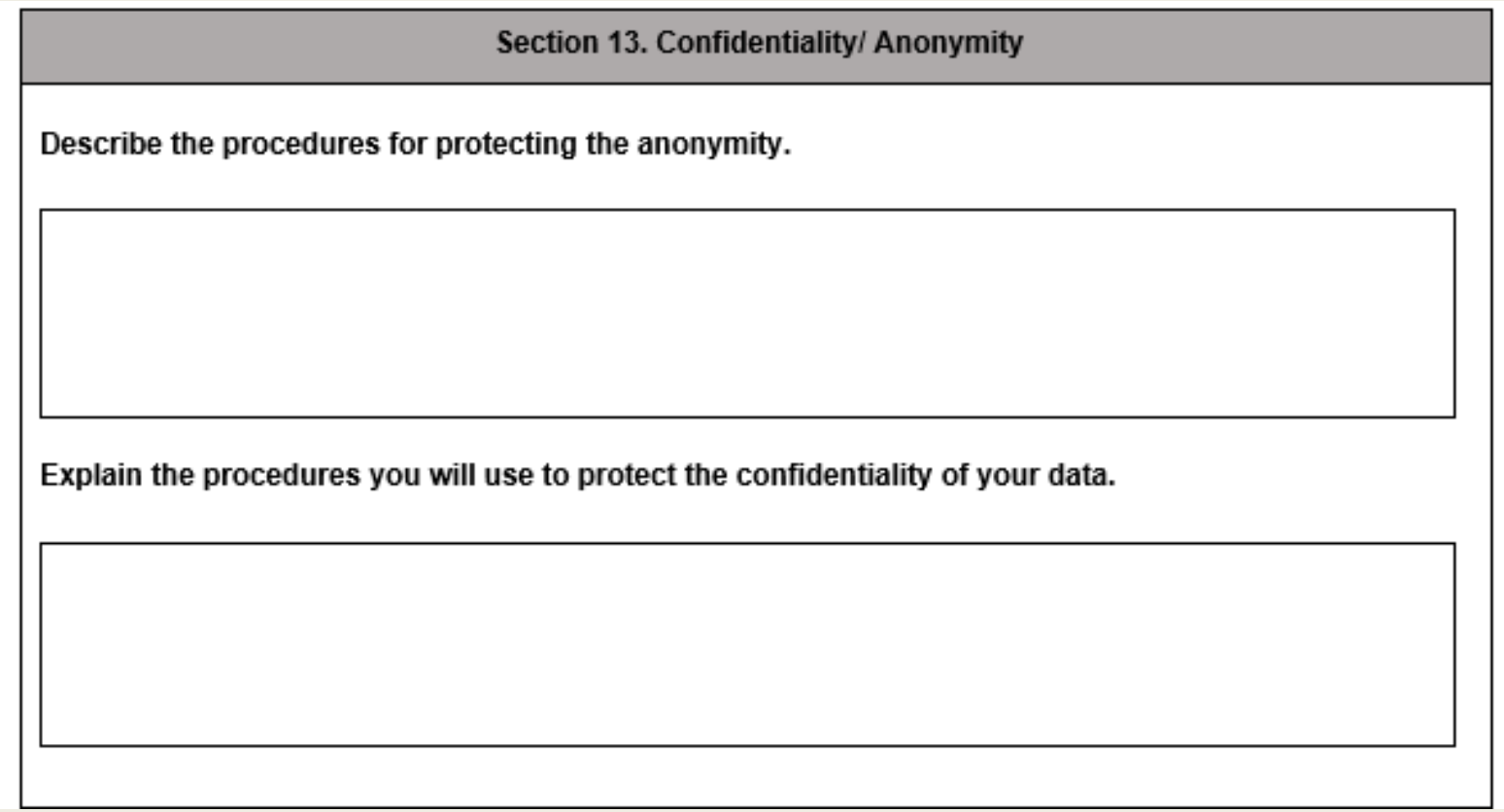
State the reasons why the research needs to be conducted despite the above risk(s)

Describe the steps taken to reduce the risks without jeopardizing the research objectives. Please provide the relevant document

What are the benefits of the research for the subjects? (e.g. course credits)

Section 13: Confidentiality / Anonymity

- Describe the procedures for protecting the anonymity
- Explain the procedures you will use to protect the confidentiality of your data



Section 13. Confidentiality/ Anonymity

Describe the procedures for protecting the anonymity.

Explain the procedures you will use to protect the confidentiality of your data.

Section 14: Consent

- Describe the process to obtain informed consent from subjects
- Describe the approach in ensuring that the subjects are voluntary

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Describe the approach in ensuring that the subjects are voluntary.

Section 15: Declaration

- Declaration of research principal investigator

Section 15: Declaration

I hereby declare that the information given is accurate and complete in all respects. Upon request, I agree to provide with any information or documents required in relation to the application and ensure to inform any changes of information if applicable soon as possible.

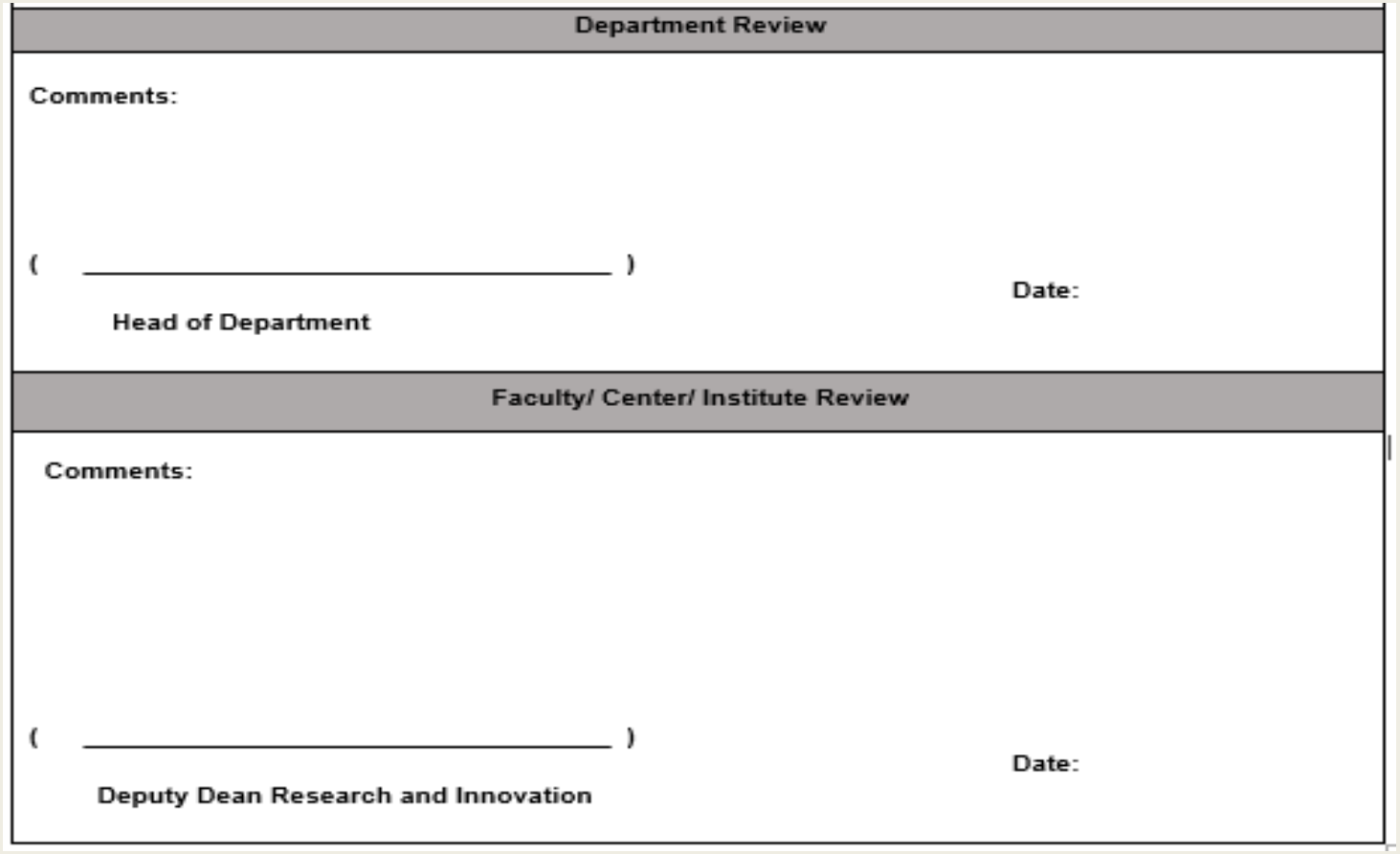
(_____)

Research Principal Investigator

Date:

Review Stages

1. Department review
2. Faculty / Center / Institute Review
3. Human Ethics Review Committee Endorsement
4. Human Ethics Committee Approval



Department Review

Comments:

(_____)

Head of Department

Date:

Faculty/ Center/ Institute Review

Comments:

(_____)

Deputy Dean Research and Innovation

Date:

Review Stages

Human Ethics Review Committee Endorsement

Comments:

Endorsed (without presentation) ☐
Endorsed, and present ☐
Amend and resubmit ☐

(_____) Date:
Chairman of Human Ethics Review Committee

Human Ethics Committee Approval

Comments:

Approved ☐
Approved, with amendment ☐
Not approved ☐

(_____) Date:
Chairman of Human Ethics Committee