School-Level Ethics Review of Student Research Involving Human Subjects

Under NTU's <u>Policy on Research Involving Human Subjects</u>, student research involving human subjects is also subjected to ethics review and approval to protect the welfare of research participants. However, NTU-IRB recognises that some student research can be better reviewed at the School-level **Ethics Review Committee (ERC)**, and this document aims to provide guidance to Schools to facilitate student research.

A. Types of student research allowed for School-level review

The School shall review student research which constitutes/is:	All student research involving human subjects must be:
Undergraduate Final Year Project (FYP)	 i. Construed as "research"; ii. Research must not fall under the scope of HBRA; iii. Research with risk levels that qualify for Exempt or
URECA projects	Expedited (SBER) review categories; please refer to <u>Annex</u> <u>A</u> for examples of Expedited (SBER).
Research project that is part of an undergraduate or graduate program by coursework (e.g: postgraduate critical inquiry)	* Project of low risk involving children as participants (e.g. classroom observations/ surveys) can be reviewed at School-level.
Nanyang Research Programme (NRP) Projects	iv. The research is not part of a faculty member's research project already subject to review by NTU-IRB.

Note that School-level ERCs may escalate projects up to NTU-IRB for ethics review and approval whenever necessary.

B. Types of student research **NOT** allowed for School-level review

- 1. Research under the scope of HBRA.
- 2. Research with risk levels that should normally be reviewed at <u>Full Board</u> category (e.g. research involving deception and sensitive topics, human endurance studies or vulnerable populations) or Expedited (HBR) category.
- 3. Any student research/project which is funded by any funding agency. (If funders e.g. charities or commercial companies, have no specific ethics requirements, then it can be reviewed by SERC.)
- 4. Any research project part of a graduate degree by research e.g. PhD, M.Sc., M.A., etc.
- 5. Student research which forms part of the supervisor's own IRB-approved research, or an additional procedure tagged on to an existing NTU-IRB approved project. The PI and the student should submit a Protocol Amendment to the previously approved NTU-IRB protocol. Such student research should not be separately reviewed at the School-level.

The above types of research should be sent to NTU-IRB for review and approval. Note that NTU-IRB does not grant retrospective review and approvals for research already conducted.

C. Training requirements for student researchers

- 1. Schools need to ensure that NTU students have completed the (CITI) certificate (either Student course or the Complete CITI course) to understand basic ethics principles.
 - Note that NTU's Epigeum Research Integrity Course (ERIC) certificate is <u>not a</u> <u>substitute</u> for CITI certificate.
- NTU takes a serious view on maintaining the confidentiality of personal data obtained from research. Supervisors are to ensure that students understand NTU's Data Governance Policy. Please also refer to NTU-IRB's guideline page on the <u>proper handling and protection of</u> research data.
 - School ERCs may consider getting students to complete the <u>PDPA course on NTULearn</u> to learn the basics of handling personal data.

D. Reviewing and approving processes at Schools

- 1. Schools may form a School-level Ethics Review Committee (ERC) with members appointed by the School management. There is no restriction on the number of members in each School ERC, but there should be minimally one NTU-IRB member on the ERC.
- 2. Members of School ERC should minimally have a valid CITI certificate.
- 3. Each student application shall be reviewed and endorsed by 1 reviewer from the School ERC. **Note**: Supervisors or Internal Co-Investigators should not review their own students' projects.
- 4. To facilitate ERC's review and approval, reviewers may refer to **Annex B** for a checklist of items to guide their reviews.
- 5. All reviews and approvals at the School-level ERC should be properly recorded and archived for tracking and audit purposes.

E. Post-approval processes

1. Amendments:

Schools shall have their own process to allow for amendments to approved protocols.
 (For reference, NTU-IRB's Amendment form is available here.)

2. Incident report:

- In the event of any <u>incident</u> during the conduct of student research, School ERC may resolve incidents within the School, or follow-up with the relevant NTU office. School ERC may also consult NTU RIEO for further advice.
- Examples of incidents include protocol deviations, unanticipated problems, and adverse events (including loss or leakage of personal data).

3. Reporting of ethical concerns:

• Schools may contact NTU-IRB or NTU RIEO if there are any ethics concerns.

Annex A: Examples of studies in Expedited (SBER/HBR) Category

Expedited (SBER) – to be reviewed at School-level	Expedited (HBR) – to be reviewed by NTU-IRB		
Collection of data from voice, video, digital, or image recordings made for research.	Procedures commonly done in clinical settings, such as taking hair, saliva, excreta or small amounts of blood (by venipuncture).		
Methodologies involving survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies that does not qualify for Exempt review. Includes, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour.	Non-invasive means (does not include studies that require general anaesthesia or sedation for research purposes) routinely employed in clinical practice, including MRI (3 Tesla or under), ECG, ultrasound. Research involving materials (data, documents, records, or human biological materials) that have been collected or will be collected solely for research purposes. Mobile applications that only track information and do not directly inform care of the research subject.		
If any of the research procedures in the examples above involves factors that would qualify for Full-			

If any of the research procedures in the examples above involves <u>factors</u> that would qualify for Full-board Review at NTU-IRB level, the research project must be reviewed by NTU-IRB.

Annex B: Reference review checklist to guide School ERC

General		Yes/No
1.	Does the project fall within scope of review at School level?	
2.	Does the student researcher have the required CITI training?	
Consent-related matters		
3.	Does the consent form have all relevant components, including the clauses on personal data? (School ERC may adopt NTU-IRB's <u>templates</u> .)	
4.	Is the applicant requesting for any waivers of consent? Reviewers need to ensure this is properly justified.	
	(Please refer to NTU-IRB <u>waiver</u> guidelines.)	
	Waiver from obtaining informed consent	
	 Waiver from obtaining written (documented) consent 	
	 Waiver from obtaining parental permission. 	
5.	Is the applicant requesting for <u>remote consent</u> taking? Is the consent properly documented?	
Recruitment materials		
6.	Method of recruitment is appropriate and accurately described, and does not	
	disproportionately mislead, incentivise or coerce potential participants.	
	(School ERC may adopt NTU-IRB's <u>recruitment</u> guidelines.)	
Handling and protection of personal data		
7.	Ensure that students are aware of the responsibility of protecting confidential data. This could	
	be stated in the ethics application form for students to fill out.	
	(Refer to NTU-IRB's guidelines on data handling and storage requirements.)	
8.	Note that NRIC numbers should not be collected from participants.	