**Ethics review of Faculty Research that Qualify for an**

**IRB exemption by the Departmental Ethics Review Committee**

1. **Introduction:**
	1. All faculty research[[1]](#footnote-1) involving humans as research participants must be subject to ethics review by either the NUS Institutional Review Board (NUS-IRB) or the Department.

* 1. From 1 June 2019, faculty research that qualify for an Exemption[[2]](#footnote-2) may be reviewed and approved by a Departmental Ethics Review Committee (DERC).
	2. However, all human biomedical research as defined by section 3 of the Human Biomedical Research Act (HBRA) 2015 must be referred to the NUS-IRB for review.
		1. The meaning of “*human biomedical research*” is defined by section 3, HBRA, which provides:

“***Meanings of “human biomedical research” and “supervision and control****”*

*3.—(1) In this Act, “human biomedical research” means the research specified in subsection (2) or (3) but subject to subsection (4).*

*(2) Any research that is intended to study —*

*(a) the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body;*

*(b) the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or*

*(c) the performance or endurance of human individuals,*

*where the research involves —*

1. *subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual;*

*(ii) the use of any individually-identifiable human biological material; or*

*(iii) the use of any individually-identifiable health information.*

*(3) Any research that involves —*

*(a) human gametes or human embryos;*

*(b) cytoplasmic hybrid embryos;*

*(c) the introduction of any human-animal combination embryo into an animal or a human;*

*(d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of development (including a prenatal animal foetus or animal embryo); or*

*(e) any entity created as a result of any process referred to in paragraph (c) or (d).*

*(4) Subsections (2) and (3) do not apply to such research, studies or activities that are specified in the Second Schedule.*

*(5) For the purposes of this Act, human biomedical research is treated as conducted under the supervision and control of a research institution if the research institution is identified as the research institution for that research and that research has been reviewed by an institutional review board appointed by that research institution*.”

* 1. As a general rule, the NUS-IRB does not conduct retrospective reviews for ethics approval of projects as these tend to be problematic.
	2. The NUS-IRB will issue a statement of concurrence for DERC-approved studies, upon request by the PI for the purpose of publication and/ or release of grant funding.
1. **Responsibilities:**
	1. The DERC may review all faculty research involving human subjects when:
		1. they are construed as “research”;
		2. the research is excluded from the HBRA;
		3. the faculty’s research is of minimal risk[[3]](#footnote-3) and qualifies for an Exemption;
		4. the research does not involve vulnerable populations[[4]](#footnote-4) and/or deception[[5]](#footnote-5) (see IRB-GUIDE-020 on use of deception in research), or sensitive topics;
		5. the research involves the use of lucky draws in lieu of reimbursement for participation in the study, where the conduct of the lucky draws or research fulfill the criteria as stated in the NUS-IRB’s guidelines for lucky draws; and
		6. the research does not involve any testing of a medical device or health product as defined in the Health Products Act.
	2. All research not covered in section 2.1 above will have to be reviewed by the NUS-IRB. The DERC may also refer research studies to the NUS-IRB if they are uncomfortable with undertaking the review. Faculty can also submit their research that qualify for Exemption to the NUS-IRB directly for ethics review.
2. **Composition of the Departmental Ethics Review Committee (DERC):**
	1. If a Department should desire to set up a DERC, it is recommended that the Committee consist of 5 members - 3 domain-specific academic staff members and 2 “others” (who may be laypersons, alumni or graduate students). The membership should encompass expertise in various methodologies used in the department’s research.
	2. Where the volume of applications is not likely to be large, a few Departments may come together to form a DERC.
	3. The Chair and members (and any necessary replacements) shall be appointed by the Head of Department.  Faculty members shall serve for staggered 2-year terms while students serve 1-year terms. Letters of appointment should be issued to members, whose terms are renewable.
	4. The Committee is encouraged to consult relevant experts within the faculty and NUS-IRB, if necessary. It is also recommended that appropriate minutes of DERC meetings are documented.
3. **Notification to the NUS-IRB:**
	1. The Department should submit an initial notification to the Research Compliance & Integrity Office (RCIO) and the NUS-IRB prior to the commencement of the DERC’s first meeting. The RCIO should also be given a list of the DERC Chair and members. Prompt notification should be given if there are any changes to this list.
	2. The DERC is expected to submit reports to NUS-IRB once every 6 months on the faculty research that they have reviewed and approved. Such reports should include the reasons for approving the research and evaluation of risks to the human subjects. A template of the report can be downloaded from the NUS-IRB’s website at <http://nus.edu.sg/research/irb/guidelines/sber-guidelines>.
	3. The same 6-monthly report on the DERC-approved research should also be forwarded to Ms Chan Ching Ting, ODPRT, at email dprcct@nus.edu.sg, so that all DERC-approved studies approved have insurance coverage.

**DERC Operations and FAQ**

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| **DERC MEMBERSHIP** | **FAQ on Oversight, Supervision, Control, etc.** |
| The appointment, role and responsibility | 1. Head of department (HOD) or Vice Dean Research (VDR) to issue letter of appointment to DERC Chair and members.
2. DERC to provide NUS-IRB with members’ names when DERC is established and whenever any changes are made.
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| Supervision and control | 1. Regular report to NUS-IRB in the appropriate format every 6 months Sep and March to coincide with the reporting for research insurance.
2. DERC to provide all documents to NUS-IRB upon request for re-review or when the DERC approved research needs an endorsement from NUS-IRB for journal publications.
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| Training  | 1. CITI online training for all DERC chairs and members.
2. If required by faculty or DERC, all staff and students are welcome to attend the CITI online training. The CITI training modules have been updated by IRB.
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| Insurance for DERC chairs and members | 1. All properly appointed DERC chairs and members are covered by NUS insurance.
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| **DERC APPROVED RESEARCH** |  |
| Reports on all DERC approved protocols  | 1. NUS-IRB will remind DERC Chairs once if reports to NUS-IRB are not submitted in a timely manner.
2. All non-compliance will be report to NUS RCIO for appropriate action.
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| Administration and follow up on starting and end of research  | 1. All research applications must be stored for a period of 10 years at least in electronic manner.
2. DERC should be able to provide e-copy of all approved document upon request of NUS-IRB or RCIO.
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| Compliance, SAE and Contraventions | 1. All issues of non-compliance to be handled by RCIO (rcio@nus.edu.sg), by completing the appropriate forms.
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| Insurance for all the research | 1. All reported DERC research every 6 months, i.e., Sep and March will be forwarded to NUS insurer for research insurance documentation.
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1. Any systematic investigation with the intention of developing or contributing to generalizable knowledge. [↑](#footnote-ref-1)
2. See SBER Guidelines on IRB Exemption Form at <http://nus.edu.sg/research/irb/guidelines/sber-guidelines> to determine if a study could be exempted. [↑](#footnote-ref-2)
3. Risk is considered minimal where the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [↑](#footnote-ref-3)
4. Refers to subjects who may be unduly coerced or influenced to participate (e.g. children, prisoners, pregnant women, cognitively impaired persons, or educationally disadvantaged persons who require special consideration to protect their welfare.) [↑](#footnote-ref-4)
5. Deception occurs when (i) a researcher deliberately gives subjects false information about some aspect of the research; or (ii) knowingly withholds information about the real purpose or nature of the research (i.e. incomplete disclosure or concealment). [↑](#footnote-ref-5)