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DSRB-012012: Conditionally Registered Doctors as Principal Investigators

With effect from 7th September 2011, the NHG Domain Specific Review Board will be allowing doctors of Level 2 and 3 Conditional Registration status with the Singapore Medical Council (SMC) to be Principal Investigator according to the risk level of the study.

Previously, only doctors with Full Registration with the SMC are allowed to be appointed as Principal Investigator for research studies, as Conditionally Registered doctor are required to work under supervision at all times and hence, according to the SMC, should not be appointed in positions that require them to assume supervisory roles.

We have noted, in recent years, the increasing number of foreign-trained doctors who would be given conditional registration for at least 2 years by the SMC. We believe that many of these research-motivated and experienced foreign-trained doctors bring a wealth of knowledge and research experience that could manifest in the ability to lead research studies as Principal Investigators.

In view of this, the NHG DSRB, in discussion with the SMC, the Health Sciences Authority and the NHG Research Ethics Committee, will be allowing doctors of Level 2 and 3 supervision to be PI according to the risk level of the study (refer to the following table).

For less than minimal risk studies	For more than minimal risk studies
<ol style="list-style-type: none">1. The doctor must be at <u>Level 2</u> supervision – i.e. After 0.5 years at Level 1 and received at least "above average" performance grading for the past 6 months (L1).2. That his/her supervisor declare in writing that:<ol style="list-style-type: none">a. She/he aware and support the involvement of the Conditionally Registered doctor as PIb. She/he will provide guidance and include research activity in regular progress report to SMCc. Based on the doctor's current progress, technical and ethical competency, the Conditionally Registered doctor is deemed competent to assume the role of PI and affirm that the Conditionally Registered doctor has adequate medical expertise to provide medical care and make medical decision for safety and welfare of the subjects3. PI declares that his involvement in research as PI has been provided to SMC (and no objection has been received from SMC)4. Department Representative and Institutional Representative approve the Conditionally Registered doctor to be PI.	<ol style="list-style-type: none">1. The doctor must be at <u>Level 3</u> supervision – i.e. After 0.5 years at Level 1 and received at least "above average" performance grading for L1, and after 1.0 year at L2 and has been ascertained to be ready to work independently, but have yet to fulfill the specified period of supervised practice required for computation towards Full registration.2. That his/her supervisor declare in writing that:<ol style="list-style-type: none">a. She/he aware and support the involvement of the Conditionally Registered doctor as PIb. She/he will provide guidance and include research activity in regular progress report to SMCc. Based on the doctor's current progress, technical and ethical competency, the Conditionally Registered doctor is deemed competent to assume the role of PI and affirm that the Conditionally Registered doctor has adequate medical expertise to provide medical care and make medical decision for safety and welfare of the subjects3. PI declares that his involvement in research as PI has been provided to SMC.4. Department Representative and Institutional Representative approve the Conditionally Registered doctor to be PI.

Definition of Minimal Risk – Minimal risk is defined as “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”