Special Considerations

**Visiting Consultants** – If the PI holds a Visiting Consultant position within NHG or partner institutions, there should be at least one full time staff who is a part of the study team for that study. Visiting Consultants may not be the PIs of studies unless the NHG or partner institutions have given their approval for the Visiting Consultant to conduct studies in their respective institutions.

**Note:** You are encouraged to check with your institutions if Visiting Consultants are allowed to conduct research in your institution.

Multi-centre studies between NHG/ NHG-Partner Institutions and SingHealth/ SingHealth-Partner Institutions – From 1st October 2014 onwards, cross-cluster research applications can be submitted to either SingHealth CIRB or NHG DSRB, depending on the Overall Principal Investigator’s (PI) cluster.

Example:
- If it is a grant-awarded study, the Overall PI, would be the person who is awarded the grant, and the application should be submitted to his/ her cluster’s IRB.
- If it is an industry or commercially sponsored study, the Overall PI would have to be selected and application to be submitted to his/her cluster’s IRB.
- If it is an investigator-initiated study (no grant/ funding required), the Overall PI would be the person who initiated the study, and the application should be submitted to his/ her cluster’s IRB.

**Multi-centre between two or more clusters** – If the research project involves two or more institutions from different clusters and the PI for the project is from an institution outside of NHG/ SingHealth cluster; it is necessary to have a PI from NHG/ NHG partner institutions and/or SingHealth/ SingHealth-Partner Institutions.

**Multi-centre within NHG and Partner Institutions** – If the research study is going to be conducted in more than one site within NHG and/or partner institutions, the PI for one of the sites should be the PI for the study for the purposes of communication with the DSRB. The rest of the PIs may be listed as Site-PIs. The site PIs do not relinquish their responsibility for the study at their institution.

**Conditionally Registered Medical Practitioners for Greater than minimum risk research**
1. The research proposals that do not qualify for exempt / expedited review and are reviewed by the full board are considered to be greater than minimal risk.

To be a PI for a greater than minimal risk study that does not require Clinical Trial Certificate (CTC), the individual should at least be:
   a. Clinician – Fully Registered Associate Consultant and above, or a Level 3 Conditionally Registered Associate Consultant and above.
   b. Nursing - Senior Staff Nurse (SSN) - Must have an Associate Consultant and above on the research team.
   c. Allied Health staff – Senior therapist / pharmacist – must have an Associate Consultant and above on the research team.

For clinical trials and other clinical research that requires Clinical Trial Certificate (CTC), the PI should be a Locally Registered doctor or dentist who is a Fully Registered Associate Consultant and above, or a Level 3 Conditional Registered Associate Consultant and above.

2. Level 2 Conditionally Registered medical practitioner - After 0.5 years at Level 1 and received at least “above average” performance grading for the past 6 months (L1), but not for studies that are greater than minimal risk.

3. Level 3 Conditionally Registered medical practitioner - 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 has yet to fulfill the specified period of supervised practice required for computation towards Full registration.

4. The following set of conditions must be fulfilled before a Level 2 or Level 3 Conditional Registered medical practitioner is accepted as a PI for a study:
i. The supervisor of the Level 2 or Level 3 practitioner must declare in writing that:
   a. She/he is aware of, and supports, the involvement of the Conditionally Registered doctor as PI
   b. She/he will provide guidance and include research activities in regular progress reports to SMC
   c. Based on the doctor’s current progress and 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
      decisions for safety and welfare of the subjects

ii. The Conditionally Registered doctor declares that his involvement in research as PI has been
    provided to SMC and no objection has been received from SMC.

iii. The Department Representative and Institutional Representative / Institutional Officer written
    documentation of the approval of the Conditionally Registered doctor to be the PI of the study is
    required. (The PI should also attach a copy of SMC’s confirmation on the level of conditional
    registration.)