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 within the institution who is a part of the study team for that study. The Visiting Consultant may not be PIs of studies unless the NHG or partner institutions have given their approval for the Visiting Consultant to conduct studies in their respective institutions.

II. Conditionally Registered Medical Practitioners

- A level 2 conditionally registered medical practitioner is one who has fulfilled 0.5 years of practice at level 1 and has received at least an "above average" performance grading for the past 6 months.
- A level 3 conditionally registered medical practitioner is one who has fulfilled 0.5 years of
 practice at level 1 and has received at least an "above average" performance grading for
 level 1, as well as fulfilled 1.0 year of practice at level 2 and has been ascertained to be
 ready to work independently, but has yet to fulfil the specified period of supervised practice
 required for computation towards full registration.

The following set of conditions must be fulfilled before a level 2 or level 3 conditionally registered medical practitioner may be accepted as PI of a study:

- a. The supervisor of the level 2 or level 3 practitioner must declare in writing that:
 - i. He / She is aware of, and supports, the involvement of the conditionally registered doctor as Pl.
 - ii. He / She will provide guidance and include research activities in regular progress reports to the SMC.
 - iii. 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 that the conditionally registered doctor has adequate medical expertise to make medical decisions for the safety and welfare of subjects.
- b. The conditionally registered doctor declares that his/ her involvement in research as PI has been provided to SMC and no objection has been received from SMC.
- c. The DR and IR / IO approve of the conditionally registered doctor to be the PI of the study.

III. Conditionally/ Temporarily Registered Dentists

For a conditionally/ temporarily registered dentist to be accepted as a PI for a study; the following conditions must be fulfilled:

- a) The supervisor of the dentist must declare in writing that:
- i. He/ she is aware of, and supports, the involvement of the conditionally/ temporarily registered dentist as PI;

- ii. He/ she will provide guidance and include research activities in regular progress reports to Singapore Dental Council (SDC); and
- iii. Based on the conditionally/ temporarily registered dentist's current progress and technical and ethical competency, the conditionally/ temporarily registered dentist has adequate dental expertise to provide clinical care and make clinical decisions for the safety and welfare of the subjects.
- b) The conditionally/ temporarily registered dentist declares that his/ her involvement in research and PI has been provided to SDC and no objection has been received from SDC.
- c) The DR and IR/ IO approve of the conditionally temporarily registered dentist to be the PI of the study.

IV. Multi-Cluster Studies

For cross-cluster research studies such as between NHG/ NHG-partner institutions and SingHealth / SingHealth-partner institutions, the IRB application can be submitted to either SingHealth CIRB or NHG DSRB, depending on the overall PI's cluster. Some examples are highlighted below:

- If the study 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 the study is an industry- or commercially-sponsored study, an overall PI would have to be selected and the application submitted to his / her cluster's IRB.
- If the study is an investigator-initiated (with no grant or funding required), the overall PI
 would be the person who initiated the study. The application should be submitted to his /
 her cluster's IRB.
- If the research project involves different clusters, and the overall PI for the research project is not from NHG or partner institutions; it would be necessary to have a Site PI from NHG or partner institution.

V. Multi-Centre Studies Within NHG Institutions 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 submitting 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 does not relinquish their responsibility for the study at their respective institutions.