

Guideline for Researchers, Primary Investigators and Research Nurses for studies which involve Intensive Care and High Dependency patients.

For all studies and clinical trials, which involve Intensive Care and High Dependency unit patients, it is essential that the studies have been discussed with the appropriate staff prior to the commencement of the study.

This is to ensure the safety and good clinical care of the patients enrolled in the study and also for the protection of the ICU and HDU staff caring for these patients.

It is an institutional requirement for researchers to seek the approval and signature of the Clinical Director of the area where the research is likely to have an impact. This is part of the WDH B Research Policy, Appendix 1: Research Proposal Checklist for Final Authorisation.

A Guideline for this process is as follows:

- An initial meeting with ICU Consultant, Dr Frank van Haren, who holds the research portfolio, and the ICU Research Nurse, Mary La Pine, to outline the study and discuss the requirements for the ICU and HDU staff.
- A copy of the study protocol, patient information sheet and consent form and any other relevant information must be provided.
- The researcher must also receive final approval and signature of the Clinical Director of ICU, Dr Nick Barnes, before the study is commenced.
- The role of ICU and HDU staff in the study must be agreed upon prior to the study commencing.
- The Researcher or the Research Nurse co-ordinating the study (if applicable) must liaise with the ICU Research Nurse to ensure the staff receive comprehensive education and support for the role they are required to take e.g. blood tests, drugs etc.
- All researchers must provide their names and contact details to enable staff to be able to contact them at anytime, as necessary.
- Compensation for increased staff workload will be discussed and agreed upon on an individual basis.

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