NON-COMPLIANCE REPORT:
CONDUCTING RESEARCH WITHOUT PRIOR DSRB APPROVAL

Non-Compliance Report

Late last year, an Investigator had conducted a retrospective case notes review and published the results in a journal without obtaining prior approval from Domain Specific Review Board (DSRB).

Two significant shortfalls in the protection of research participants were identified:

1. **Failure to obtain DSRB Approval** for research.
2. **Failure to obtain Informed Consent,** or a valid approval of waiver of Informed Consent from DSRB.

Do All Studies Require DSRB Approval?

In general, activities that involved systematic investigation and are designed to develop generalisable knowledge are considered research and will require review and approval by DSRB.

In some instances, DSRB may grant an "exemption" status to a study. An Exempt status does not mean that the study is exempted from DSRB review, but that the study is exempted from the full requirements of DSRB policies and procedures.

For example, a study reviewed by Exempt Review, does not need to undergo annual continuing review, which is a requirement for studies reviewed by Expedited or Full Board Review.

What Types of Research Studies Qualify for Exemption?

Research studies that involve anonymous surveys & questionnaires, collection or study of existing data or tissue specimens, where data / tissue are either publicly available or subjects cannot be identified, or Public Benefit Programs may qualify for review by Exempt Review category. A full list of examples of research activities that may qualify for exemption is available in the DSRB Investigator Manual.

Principal Investigators must submit study protocols to DSRB, and allow DSRB to make the determination.

I am doing a simple survey! Do I need DSRB approval?

Yes, as long as your research project involving human subjects, it will require ethics approval from the DSRB.

If your survey is conducted in a manner in which the participants will be anonymous (no patient identifiers or links that connect to patient identifiers are maintained), the research proposal will be reviewed by the exempt procedure. Otherwise, it will be reviewed by "expedited review" or "full board review", depending on the risks involved.

Do All Studies Require Informed Consent to be Obtained?

The DSRB requires that informed consent should be obtained from all human subjects prior to their participation in any research, unless the process has been waived by the DSRB.

Principal Investigators should also note that prospective studies generally require informed consent to be obtained from participants.

More information about when a Waiver of Consent may be granted is explained on Page 5.

Where Can I Get More Information?

Investigator Manual

Chapter 04 Submissions to DSRB (Non-Compliance)

Chapter 05 Review Process (Exempt Review, Non-Exempt Review, Criteria for Approval)

Chapter 08 Guidance Documents (Informed Consent)