

Guideline

Subject: Design of Research Studies and Abnormal Pathology Test Results
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When considering research protocols involving human subjects in Australia, ethics committees require that protocols adequately address situations where a research participant may require medical care as a result of their participation in a research project as per the National Health and Medical Research Council “National Statement on Ethical Conduct in Human Research” (2007)*. This situation may arise when pathology tests are included in research protocols.

The College is aware that many research studies include baseline “screening” laboratory testing and/or further follow-up laboratory investigations during the study and that researchers frequently may not be qualified to interpret these results, particularly when unexpected abnormal findings seemingly unrelated to the research arise. This guideline is designed to help researchers in designing protocols intended to include pathology tests and the College recommends that Human Research Ethics Committees do not approve protocols that do not adequately address medical issues for participants relating to laboratory testing as per the NHMRC National Statement.

Issues to Consider

- Any laboratory testing on human blood or tissue for the purposes of research should be performed in an RCPA/NATA accredited laboratory under the same quality standards as clinical laboratory testing.
- Any research protocol including pathology testing must include a clearly documented procedure for responding to abnormal results.
- There should be a designated medical practitioner responsible for reviewing any abnormal results and determining if the results are clinically significant and warrant further action. The medical practitioner should be in active clinical practice and may be the participant’s normal general practitioner.
- The arrangements must include both the fully informed consent of the participant and clear understanding/agreement on the part of the designated medical practitioner.
- The medical practitioner’s contact details should be included on the pathology request form to allow direct communication of urgent results to the medical practitioner by the pathologist if required. If the medical practitioner cannot be contacted, alternative mechanisms for communicating urgent results should be made available.
- The arrangements must include clear actions arising from abnormal test results that are in the best interest of the participant. Such actions may include repeating the test, the requesting of further tests, a full review of the participant by their treating doctor, exclusion of the participant from the study and referral for ongoing medical care.
- Abnormal test results should be referred to the part of the study responsible for adverse events and recorded in a database for comparison with other participants with a view to identifying if these relate to adverse outcomes of the research protocol. Any concern regarding adverse events should trigger further investigation and consideration of suspending or terminating the research study.
- Researchers should seek expert advice from discipline-specific pathologists when considering inclusion of laboratory testing in research protocols, particularly with inclusion of tests that are outside their scope of practice or with unknown or unproven implications.

* Reference: NHMRC recommend checking website for latest version

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>