

Protocol for research projects utilizing tissue resected or biopsied from patients

Premise

Alfred Health aims to provide the highest quality of care to all their patients all of the time. Accurate Anatomical Pathological assessment of tissue that is resected at the time of surgery is critical both for diagnosis and accurate staging. Treatment paradigms hinge upon these assessments.

Alfred Health also recognises the importance of research to improve our understanding of disease and drive new therapies. This means at times researchers will seek samples of tissues to examine to further explore the disease of interest or test new drugs *in vitro*.

When patients generously donate their tissue for research purposes, their clinical need must always outweigh the need of the research project. Tissue must therefore be taken in such a way that the anatomical pathological assessment of the tissue is not compromised. There should always be participant consent for the collection of human biospecimens specifically for research.¹

Purpose of this protocol

To create a framework for researchers who (a) require tissue from operative, endoscopic or biopsy specimens that will also be primarily handled and assessed by Anatomical Pathology as a part of patient care, and/or (b) propose to take additional tissue samples for research purposes at the time of surgery

Setting

Where tissue is required for research from a patient with a condition of interest. This may include tissue from organs at the time of surgery and biopsies which may be operative (open), needle (open or percutaneous) or endoscopic.

Process

- The researchers should identify as part of their research protocol if the tissue being taken would normally be sent to Anatomical Pathology or if this is tissue that is being sampled for research purposes only
- In all cases, the Anatomical Pathology Service Request Form (<https://www.alfredhealth.org.au/research/ethics-research-governance/use-of-hospital-resources-for-research>) should be completed as part of the Ethics application. The application will be reviewed by the Director of Anatomical Pathology (or delegate) and any concerns will be addressed before the submission is considered by the Ethics Committee
- When developing the Protocol and ethics application, the researcher should contact the Director of Anatomical Pathology for advice on how to best collect the specimen required for research
 - If the researcher is taking tissue from a cancer within an organ then the entire resected organ should be taken to Anatomical Pathology where an appropriate sample will be taken for the researcher by the Anatomical Pathology staff. If the surgery is completed after hours the specimen should be sent to pathology as per normal protocols. Tissue

¹ NHMRC National Statement on Ethical Conduct in Human Research, 2007 (updated March 2014): Chapter 3.4, Item 3.4.2 "The consent of donor(s) should be obtained and recorded when collecting biospecimens specifically for research in order to meet the requirements of *Chapter 2.2: General requirements for consent*.

required for research could then be taken by Anatomical Pathology staff the next day. If fresh tissue is required, the research team will be responsible for the cost of calling in the on-call scientist or pathologist if there is no clinical requirement for them to attend.

- If the researcher is taking tissue from an organ that has been resected for reasons other than cancer that would normally be sent to Anatomical Pathology due to the risk of incidental carcinoma or other disease processes (eg Sleeve Gastrectomy, cholecystectomy), the researcher should also receive the tissue they require from the department of Anatomical Pathology.
- Biopsy specimens (for example taken at the time of endoscopy) may be taken separately for research and pathological purposes, however, the research specimen should be also reviewed by an anatomical pathologist. If this is not possible (eg snap frozen tissue for PCR and other molecular biological testing) then the protocol must be discussed with the Director of Anatomical Pathology.
- Samples taken specifically for research purposes which would not normally be taken (eg fat or skin samples). The protocol should be discussed with the Director of Anatomical Pathology to assess the requirement for formal anatomical review to minimise the risk of missing incidental disease.
- Samples taken from tissue that would normally be discarded (eg bone, liposuction fat). The protocol should be discussed with the Director of Anatomical Pathology.

Related documents

[Anatomical Pathology Service Request Form](#)

[National Statement on Ethical Conduct in Human Research \(2007\)](#) (incorporating all updates)

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