AUCKLAND
DISTRICT HEALTH BOARD
Te Toka Tumai

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22 June 2020

Amy S Van Wey Lovatt

Email address: fyi-request-12501-86e41167@requests.fyi.org.nz

Dear Amy

Re **Official Information Request – Policy on requests third party providers of pathology specimens – additional request**

Thank you for your email of 29 May 2020. You have an additional request in reference to our response sent to you on 1 April 2020.

You mention that Auckland DHB does not have a policy regarding requests by third party providers for second opinions of pathology specimens.

Your additional request as of 29 May 2020:

Request 1:

To be clear, does this mean that Auckland DHB does not follow the RCPA policy regarding such requests? Even if there is not a written policy, ADHB must have a standard practice.

Auckland DHB does not have a specific policy in relation to requests from third party providers for a second opinion from its service.

Request 2:

I respectfully request a description of ADHB's standard practice regarding requests by third party providers for second opinions of pathology specimens.

The RCPA guidelines relevant to your new enquiry are attached for your review. I would point out that Auckland DHB is a statutory body that does not necessarily have to comply with an independent educational provider's policy. However, it would be expected that fellows of the RCPA comply with relevant College policies and professional guidelines as appropriate. In particular, in New Zealand all health professionals are expected to comply with the Health Information Privacy Code 1994.

Request 3:

In the event that ADHB's standard practice is inconsistent with the RCPA policy, I respectfully request an explanation for why ADHB deviates from the professional standard set out by the RCPA policy.

Labplus does have a policy relating to release of specimens to Police, ACC, Patients and Third Parties. A copy of this is attached.

You are entitled to seek a review of the response by the Ombudsman under section 28(3) of the Official Information Act. Information about how to make a complaint is available at www.ombudsman.parliament.nz or freephone 0800 802 602.

Please note that this response, or an edited version of this response, may be published on the Auckland DHB website.

Yours faithfully

pp Rik Percival

Ailsa Claire, OBE
Chief Executive

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RCPA
The Royal College of Pathologists of Australasia

Policy

Subject:	**Provision of second opinions with particular reference to morphological examination**
Approval Date:	March 1999, Revised 11 October 1999, Revised March 2001, Revised March 2007, November 2013, October 2016, November 2017
Review Date:	November 2021
Review By:	Anatomical Pathology AC, Cytopathology AC
Number:	2/1999

Key Issues

1. Introduction

The growing complexity of modern medical practice, particularly sub-specialisation, has increased the frequency and widened the circumstances under which second and subsequent opinions may be requested on a variety of pathological specimens, but particularly those which involve evaluation of cell or tissue morphology. Most of what follows is directed predominantly towards histopathology and cytopathology but the principles may apply in any area of pathology testing where material is examined morphologically, eg. blood and bone marrow films. The College has separate Guidelines for Provisions of Second Opinions in Forensic Pathology

Coinciding with this increased demand for referral for second and subsequent opinion is increased privacy requirements for personal health information. Accordingly, when material is provided for a second opinion, care must be exercised to ensure there is no breach of statutory and common-law privacy principles (see RCPA Guideline: Managing Privacy Information in Laboratories

Of particular note, pathologists should at all times put the interests of patients first when other opinions are requested and should not unreasonably refuse to provide material to allow a second opinion as this may cause harm to patients. This includes pathology providers who are in direct commercial competition with each other. All pathologists involved in the second opinion process should behave in a professional and ethical manner towards peers, clinical colleagues and patients, acknowledging that second opinions frequently involve additional clinical information and diagnostic refinement rather than discordance of opinion and should not trigger unintended consequences such as referral inducements, commercial advantage, punitive actions etc.

2. Definitions

To assist with understanding this document, a few definitions are provided for terms that are used frequently in subsequent sections:

"(pathological) material"	This is any specimen or part of a specimen of human tissue or cells in a form suitable for examination by any pathology test. It includes but is not limited to: unfixed, fixed or embedded tissue,

	stained or unstained tissue sections and smears or films of blood or normal or abnormal body fluids.
"pathologist of record"	The pathologist responsible for the initial report on the material in question. In some situations, this pathologist may be the person who initially performed the examination and wrote the original report. In others, however, it may be a designated pathologist on whose behalf the test was done by a non-pathologist member of staff or Department or Pathology Service Director under whose authority the report was issued. The latter are likely to become involved when a second opinion is requested on material stored for a period of time, long after the original reporting pathologist has left the practice.
"effective control of pathological material"	This is exercised by the medical practitioner who at the time the request is made for a second opinion, exercises administrative control over the stored material. Usually this will be a Department or Service Head (including a Managing Partner). The term is used to avoid involvement in the complex issue of "ownership" of pathological material.
"pathologist of referral"	The pathologist responsible for provision of the second opinion in question. Implicit in this concept is that the pathologist of referral would personally provide that opinion unless the request is clearly made to a pathologist in his or her capacity as a Department or Service Head.

3. Policy Statements

This section contains a series of separate, but related statements that deal with some specific common "scenarios" in which second and subsequent opinions may be requested and with some specific issues that are common to more than one of these scenarios.

3.1 Second Opinions requested by the "pathologist of record"

3.1.1. This statement deals only with the situation where:

a) the second opinion is requested formally; and

b) the pathologist of referral is a member of a pathology practice different from that of the pathologist of record.

Showing a slide to a colleague "out of interest" is not regarded as seeking a second opinion in the context of this statement. Arrangements for second opinions within a practice also are not covered by this statement but should be addressed by an appropriate internal practice policy.

3.1.2. Requests for second opinions should either be made in writing or confirmed in writing after a verbal request (this includes communication by facsimile or e-mail).

3.1.3. The request should include all relevant clinical and other information known to the pathologist of record in a professional capacity. It may however be useful to "package" this information in such a way that the pathologist of referral has the option of considering the material "blind" in the first instance and considering the clinical information afterwards.

3.1.4. The nature and origin of the material submitted for second opinion should be clearly evident. In particular, slides should be identified either as "recuts" or the "originals" which have been examined by the pathologist of record.

3.1.5. The pathologist of referral should attempt to fulfil the request only if he or she has the expertise and resources to do so.

3.1.6. In the circumstances covered by this statement, a pathologist is not under any obligation to act as a pathologist of referral unless required to do so under some form of contract. Any refusal of a referral should however be timely and courteous but no justification is necessary.

3.1.7. The second opinion should be issued in writing. It may be in the format of either a letter or of a standard report from the pathologist of the referring practice.

As a rule it should include:

- the clinical information provided, or at least a summary of relevant issues;
- a description of the material submitted on which the report is based;
- any description of relevant microscopic appearances;
- the conclusion including diagnosis and/or differential diagnosis and any comments; and
- the results of any additional testing performed in the course of the review (eg additional IHC stains or molecular studies).

3.1.8. On receipt of the second opinion by the pathologist of record, this should be provided to the original requesting practitioner intact with full attribution to the pathologist of referral. If an extract is made, this should be quoted *verbatim* and attributed to the pathologist of referral.

3.1.9. Any component of the report by the pathologist of record should ensure that his/her findings or comments are clearly and unambiguously distinguished from those of the pathologist of referral.

(NOTE: In context of this scenario, patient consent is implied provided that the referral by the pathologist of record is in good faith and in the course of normal professional practice).

3.2 Second opinions requested by a third party who is a medical practitioner currently involved in the medical care of the patient from whom the pathological material was originally obtained.

3.2.1. This statement deals only with the situation where the request is from an institution or medical practice different from the one to which the material was originally submitted. Arrangements between departments or units within the same institution are for them to determine internally however it is recommend that second opinions be appropriately recorded in the patient record.

3.2.2. In these circumstances, the request to provide material for a second opinion should be made to the pathologist of record provided that person is still a member of the practice which is in effective control of the material. If not, the request should be directed to some other medical practitioner who is in the control of the material, usually a department or service head.

3.2.3. Unless mutually agreed otherwise, any such requests should be in writing or confirmed in writing. Before acceding to the request, the person responsible for the material should be satisfied, of its *bona-fides*. In the absence of a written consent form, some information should be supplied to substantiate that this request is for the purpose of patient care.

3.2.4. The request should clearly identify the pathologist to whom the material is to be sent and who will be responsible for the second opinion.

3.2.5. Provided the issues in 3.2.3. and 3.2.4. are adequately addressed, provision of material for this purpose should not be unreasonably withheld.

3.2.6. Unless agreed otherwise, the material requested under these circumstances should be accompanied by:

a) A copy of the original report issued by or on behalf of the pathologist of record;

b) A covering letter to indicate whether the material submitted is that on which this original report was based or if it consists of recut sections. It is also advisable to indicate whether or not some or all of the material is to be returned. It would however be unacceptable for the pathologist of referral to retain material contrary to the expressed wishes of the person providing it, once all examination was completed. It is accepted practice that all material is returned unless the original laboratory specifically indicates it is not necessary, or the pathologist of referral makes specific request to keep a representative slide and this is agreed to.

3.2.7. The second opinion should be issued in writing. It may be in the format of either a letter or of a standard report from the pathologist of referral's practice.

As a rule it should include:

- the clinical information provided or at least a summary of relevant issues;
- a description of the material submitted on which the report is based;
- any description of relevant microscopic appearances;
- the conclusion including diagnosis and/or differential diagnosis and any comments; and
- the results of any additional testing performed in the course of the review (eg additional IHC stains or molecular studies).

3.2.8. This report should be provided to:

- the medical practitioner requesting the review;
- any other person who is entitled to receive such reports in the institution in question, eg. Medical Record Administrator;
- as a courtesy, the pathologist of record or other person who had provided the material; and,

- in some instances, to the patient.

3.2.9. Any such report received by the pathologist referred to in the preceding paragraph shall not be used other than for clinical management of the patient without the agreement of the pathologist of referral.

3.2.10. If there is a genuine difference of opinion between the pathologist of referral and the original opinion of the pathologist of record, a reasonable attempt should be made to notify the pathologist of record. If the pathologist concerned is no longer at the practice providing the material, the pathologist currently in charge should be notified. That person will in turn then have to determine whether it is a matter which requires them to contact the pathologist of record.

3.2.11. If there is a revision to the original diagnosis based on a genuine difference of opinion between the pathologist of referral and the original pathologist of record and/or if additional testing is performed in the course of the review (eg additional IHC stains or molecular studies), the original pathologist of record should ensure they are appended to the original report.

3.2.12. It is unacceptable conduct for a pathologist of referral to artificially exaggerate a difference of opinion from that of the pathologist of record by use without explanation of alternative, but equivalent terminology, or to otherwise make any statements which could be perceived as enhancing personal prestige or "cultivating" referrals.

3.2.13. If the pathologist of referral in turn intends to seek a further opinion on the material, eg. from an overseas expert, this should be notified as soon as practicable to the person providing the material for the referral.

Please note that there may other permutations to this scenario of a second and subsequent opinion.

For example:

Clinician A sends a specimen to Pathologist B.

The patient then goes for a second clinical opinion to Clinician C who asks that another pathologist, Pathologist D, review a new specimen. The specimen may be the same type of sample or different tissue (for example a fine needle aspirate or biopsy).

There has been an initial diagnosis of malignancy with a subsequent diagnosis of benign lesion.

As clinicians have no ownership of patients and the patient has agreed to see Clinician C, who as is often the case refers the material to a pathologist at Clinician C's institution, Pathologist D has an obligation to provide a report to the requesting Clinician.

If it is apparent that the diagnosis is different, the same approach outlines in this section should be adopted in relation to obtaining the specimen for review from Pathologist B.

In addition, it is professional courtesy for Pathologist D and Clinician C to notify Pathologist B and Clinician A of a variation in the diagnosis.

3.3 Review of material requested for purposes of education or quality assurance

3.3.1. When the material is provided for this purpose, the issue of the patient consent requires consideration.

3.3.1.1. If the patient is

currently an inpatient or outpatient at the institution where the educational or quality activity is taking place; and the purpose is a review of past lesions to compare with current pathology; and at least some persons present at the educational or quality activity are involved with the case, it could be accepted that the presentation, while of an educational or quality assurance nature, has a component of discussion of current patient care, so consent might be considered to be implied.

3.3.1.2 If the patient is not a patient currently receiving active medical management where the educational or quaiity activity is taking place, but; is a person with pathology, educational or quality activity interest,
consent may not be needed provided that the material and any accompanying documentation is irreversibly de-identified.

3.3.1.3. If neither of the above apply, patient consent may be required. If in doubt, advice should be sought from the relevant institutional Ethics Committee.

3.3.2. Material used for this educational purpose should be properly attributed during the presentation to the pathologist of record and the practice from which it has originated.

3.3.3. For many educational purposes, it may be sufficient to do no more than present the findings and conclusions of the pathologist of record without modification. If, however, in addition to presenting the original findings, there is a review of the material with production of a second opinion, the process set out in 3.2 above should apply.

3.3.4. Unless agreed otherwise, once the educational activity has ended, the entire material should be returned to the pathologist of record as soon as possible.

3.4 Review of material requested for purposes of research

3.4.1. Again the issue of patient consent requires consideration. This should be provided in writing unless the request is accompanied by documentation in relation to the project from the relevant Institutional Human Research Ethics Committee(s) indicating that this is not required. This may require the material to be de-identified. Provided this issue is resolved and the project is *bona-fide* research, co-operation should not be unreasonably withheld.

3.4.2. The material should be used only for the purpose specified in the original request. A further request must be made if additional studies are to be made together with evidence of approval of the change to the project by the Institutional Human Research Ethics Committee.

3.4.3. In the event that a researcher wishes to provide a second opinion, the process of 3.2 must be followed with an approach to the pathologist of record being made before this is done.

3.4.4. Unless agreed otherwise, any residual material should be returned when the research is complete.

3.4.5. Unless the pathologist of record and/or the laboratory concerned is a participant in the research, an offer should be made by the researchers to cover any costs incurred in providing the material.

3.5 Review of material requested for medico-legal, commercial, insurance or employment purposes

3.5.1. Unless covered by a *subpoena*, or some other legally enforceable instrument of power (see 3.6), the written consent of the patient must be supplied before complying with the request. Once supplied however, it is suggested that any refusal to comply with the request should occur only following legal advice.

3.5.2. With requests of this type, the pathologist of record usually has no entitlement to a copy of the report of the pathologist of referral however the pathologist of referral should clarify the legal status of the report and their own medico-legal status with respect to the case with their medical indemnifier.

3.5.3. When the material is no longer required for the purpose for which it was requested, it should be returned as soon as possible.

3.5.4. All reasonable costs associated with compliance should, as a rule, be met by, or on behalf of, the person making the request.

3.6 Review of material required under a subpoena, warrant or some other legally enforceable instrument

3.6.1. The demand must be in writing and the pathologist of record or other named person or any other person with authority to respond must satisfy themselves that is in order.

3.6.2. Such valid requirements must be complied within the manner and time limits specified. If however, the person who is required to respond has concerns about the validity or appropriateness of the demand, advice should be sought from the legal advisor to the pathology practice. This is particularly relevant if the demand is to produce a range of material and documents apparently more extensive than would seem to be necessary for the intended purpose (sometimes referred to as a "fishing expedition"). Application to the court concerned may result in some limits being placed on the scope of this demand.

3.6.3. The material should be returned to the practice providing the information as soon as possible as once it is no longer required.

3.6.4. In a civil case, reasonable expenses to cover costs of compliance should be paid by the person or organisation making this demand. In some jurisdictions, and for some services, there may be a set scale of fees and charges. In criminal cases, material and documents may have to be produced without any costs being paid, eg. in response to a search warrant.

3.7 Request by a patient for reports and material

3.7.1. The purpose of the request must be established clearly. An interview with the patient may be necessary in order to ensure the patient understands the possible implications for future testing if material is no longer available.

3.7.2. If this request has arisen because the patient is travelling overseas or interstate and has a continuing medical condition, it would be reasonable to provide the patient with a copy of each relevant report in an envelope to be given to any attending medical practitioner.

3.7.3. It would be inadvisable to provide the patient with any actual material, particularly if this is of an irreplaceable nature, but contact details should be provided so that it could be forwarded to any pathologist of referral who may in future become involved in this patient's case.

3.7.4. In the event of a patient's insistence that all material be provided, the problem should be resolved in accordance with the policy of the practice. Legal advice may be necessary.

3.8 "Irreplaceable Material"

There are some types of pathological material where the quantity containing the medically significant changes is small, eg. a slide of a single level of one block of tissue, a tissue block which has been almost cut through or a single abnormal cytology smear.

When such material is requested for review in any of these situations set out above, it is recommended that:

3.8.1. All reasonable options for the pathologist of referral to review the irreplaceable specimen in the laboratory that currently controls the specimen should be examined.

3.8.2. If there are no such options, the material must be transported to the requesting laboratory by a secure method, eg. courier, taxi or registered mail.

3.8.3. If the material relates to a clinical or medico-legal issue of critical importance, a detailed photographic or electronic record may be advisable before it is dispatched.

3.8.4. It would be advisable to notify the laboratory or pathologist of referral of its dispatch including date, time and identity of the carrier and any relevant invoice or waybill number. Receipt should be notified to the laboratory that has dispatched the material.

3.8.5. When examination has been completed at the referring laboratory, the material should be returned by the same, or equivalent, secure method.

3.8.6. The requesting laboratory or persons for whom they are acting should bear the full costs of transport to and from the referring laboratory unless agreed otherwise.

3.9 Australian Medical Benefits Schedule Items for Morphological Second Opinion

3.9.1 There are two items in the Australian MBS schedule (72858 & 72859) to fund the provision of morphological second opinions.

3.9.2 The items are available to be used in two different scenarios:

(i) a pathologist of record requests a second opinion on a difficult case from an expert referral pathologist, or

(ii) a non-pathologist clinician requests a second opinion in a case where some doubt exists regarding the diagnosis in order to facilitate appropriate care of the patient

3.9.3 The two items (72858: non-complex <30 mins opinion and 72859: complex >30 mins opinion) are restricted to services covered by histology items, non-gynaecological cytology items and bone marrow items, where the second opinion is provided by a referral pathologist located in a different laboratory (APL) to the pathologist of record. The item descriptors also require that a full written report is provided.

3.9.4 Additional investigations (such as further IHC tests) may be requested and funded in addition to the second opinion item, and the specimen referred fee (73940) may recoup some of the administrative and handling costs (at least for the referring laboratory).

3.9.5 The items are not intended to provide funding for intra-departmental/intra-institutional case review, quality assurance activities or mandatory/routine review of all cases referred to treatment centres. Simple presentation of non-controversial referred cases at Multi Disciplinary Team meetings are expected to be funded only under Multi Disciplinary Team meeting items 871 & 872.

3.9.6 In order to limit inappropriate utilisation of the items, in both scenarios, current MBS descriptors require that the pathologist of record and the requesting clinician must agree that a second opinion is reasonably necessary for diagnostic purposes for further clinical management of the patient.

3.9.7 In scenario (i), this means that the pathologist of record needs to obtain sign-off from the requesting clinician.

3.9.8 In scenario (ii), this means that the pathologist of record has to agree with the requesting clinician to refer the case for second opinion in the interests of optimal patient care. This does not necessarily imply that the original pathologist of record's report is inconclusive or wrong, but recognises that the requester may have access to other information which leads them to seek confirmation/clarification of the diagnostic findings before proceeding with definitive treatment.

In this scenario:

- The request for material to be sent for second opinion clearly comes from the treating clinician, who should attest that the second opinion is required for optimal patient management
- The request should clearly indicate the referral pathologist to whom the material should be sent for second opinion
- The request should include an acknowledgement by the pathologist of record that by releasing the case they agree with provision of a second opinion being reasonably necessary in the interests of appropriate patient management. This acknowledged position should not be unreasonably withheld.
- The request should include appropriate patient demographic details and Medicare assignment information.

3.9.9 If there is more than one pathologist of record (eg multiple specimens from different laboratories) permission should be obtained from each.

3.9.10 Professional collegiality is required to make these items workable, both on the part of the pathologist of record, and by the referral pathologist, who may be in possession of additional/follow-up information not available to the pathologist of record.

Attachment A provides an example of a form that could be used requiring a second opinion for scenario (ii) above.

3.10 Charges by the pathologist of referral for providing second opinions when the MBS Item is not available

When a pathologist is requested to provide a second opinion on pathological material from a pathology practice different from the one by which they are either employed or otherwise engaged, a charge may be made by or on behalf of the referral pathologist should the MBS item not be available to them for the service.

In rendering any such charge, the following should apply:

3.10.1. The likelihood of such a charge being made should be advised before any work is undertaken in providing the second opinion and, in general, practices should publish their scale of charges. If charges are to be directed to the patient, they should be advised of charges and consent to payment be obtained prior to the work being undertaken.

3.10.2. The charge should have regard for the substantial professional component involved in provision of many second opinions.

3.10.3. Responsibility for ensuring payment of any charge shall lie with the person or organisation initiating the request for the second opinion and, where appropriate, assurances in respect of payment may be sought before any review is done. In the event that it is intended that the charge for such review is to be paid by the patient concerned, and not by or on behalf of the clinician, an employing institution or other third party, the clinician, should obtain the patient's informed consent and advise the pathologist of referral accordingly in writing.

3.10.4. Any revenue accruing from provision of second opinions shall be treated in the same way as revenue for any other professional services provided by the referral pathologist.

3.10.5. Pathologists and pathology practices should have an unrestricted right to waive any such charge. The College would expect the proprietor of a pathology practice to heed the advice of the pathologist providing the second opinion that the charge be waived.

3.11 Charges by or on behalf of the pathology practice to recover costs involved in providing second opinions which it has not requested when the MBS Item is not available

3.11.1. Where the material is provided other than in accordance with a statutory duty or a contract for which no charge can be made, it would be reasonable for the pathology practice concerned to recover any significant costs.

3.11.2. Any such charge should be notified promptly to the requestor before the material is provided.

3.11.3. The charge should be sufficient only to recoup costs necessarily incurred in responding to the request or in accordance with any applicable published scale of fees.

4. Conclusion

While the statements in this document may cover many of the situations encountered in current practice it is unlikely that they will deal with every eventuality.

As a general guiding principle, however, any action should be judged on whether it has as its principle objective of safeguarding the interests of the patient concerned. In addition, any actions with a potential to be controversial should be documented by adequate contemporaneous notes.

In addition, in the event of difficulties, advice should be sought as appropriate from professional colleagues in the practice concerned, Office Bearers of this College, any relevant Institutional Ethics Committee and if necessary, legal advisers of the practice.

Attachment A is found on the following page:

REQUEST FOR A SECOND OPINION ON HISTOPATHOLOGY OR CYTOPATHOLOGY

PATIENT DETAILS or PATIENT LABEL

NAME: .....

DOB: DD/MM/YYYY UR NO: .....

ADDRESS: .....

.....

MEDICARE NO: .....

CLINICAL INFORMATION/REASON FOR REQUEST

.....

.....

.....

.....

.....

SELF DETERMINED ☐

REFERRING CLINICIAN

NAME: .....

PROVIDER NO: .....

I confirm that I am involved in the care of this patient and request a second opinion for confirmation of diagnosis and treatment planning.

SIGNATURE: .....

DATE: DD/MM/YYYY

REFERRAL LABORATORY DETAILS

REFERRAL LABORATORY:

.....

ADDRESS: .....

.....

If an opinion is required from a specific pathologist, please nominate:

.....

[if unavailable the case will be referred to another appropriate pathologist in the practice]

ORIGINAL LABORATORY DETAILS

ORIGINAL PATHOLOGY LABORATORY:

.....

REF/ACCESSION NO: .....

DATE OF COLLECTION: DD/MM/YYYY

A Medicare Rebate is available for a second opinion on histopathology and cytopathology samples where both the original pathologist and specialist involved in the care of the patient are in agreement that a second opinion is reasonably required for confirmation of diagnosis and management planning.
By releasing this case material for review, the initial pathologist agrees the above criteria are met.

PATIENT ASSIGNMENT OF MEDICARE REBATE

MEDICARE AGREEMENT (Section 20A of the Health Insurance Act 1973)
I offer to assign my right to benefits to the approved pathology practitioner who will render the requested pathology service(s) and any eligible pathologist determinable service(s) established as necessary by the practitioner.

SIGNATURE: .....

DATE: DD/MM/YYYY

PRACTITIONER USE ONLY:
Reason patient cannot sign:

.....

State the patient's status at the time of this request

.....

PLEASE SEND A COPY OF THIS FORM TO THE REFERRAL LABORATORY WITH A COPY OF THE PATHOLOGY REPORT, PLUS:

☐ Stained Slides

☐ A representative block (which will be returned) in case additional IHC is required (or 10 unstained sections on positively charged slides)

A COPY OF THE 2ND OPINION WILL BE PROVIDED TO BOTH THE REQUESTING CLINICIAN AND ORIGINAL PATHOLOGIST. CASE MATERIALS WILL BE PROMPTLY RETURNED TO THE ORIGINAL LABORATORY.

DETAILS OF MATERIAL PROVIDED:

.....

.....

APSMGMTQUALPR043 Specimens - Release to Police, ACC, Patients & Third Parties

Copy of version 1.0 (approved and current)

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Approval and Periodic Review Signatures

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Periodic review	Yearly Review	13/06/2019	1.0	Moqsheda Khan	Periodic Review
Approval	Lab Director	08/06/2018	1.0	Moqsheda Khan	
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1.0	Approved and Current	Initial version	18/05/2018	07/06/2018	Indefinite

SPECIMENS - RELEASE TO POLICE, ACC, PATIENTS & THIRD PARTIES

1 Purpose of the Document

1.1 This document outlines the process and documentation required for release of specimens (tissue, blocks, slide etc.) to Police, Accident Compensation Corporation (ACC) patients and third parties.

- No specimens are to be released without prior approval from APS authorised staff (refer to section 8 for list).
- Release of specimens/tissues can only be approved and handed over by authorised staff specified in this document (refer to section 8 for list).
- Requests for specimens to be used for quality control purposes refer to APS Policy on Ethics for Residual Tissue APSMGMTQUALPR010.

1.2 This procedure excludes:

- Requests for patient information or laboratory results refer to APS Policy Results Release APSMGMTADMPR001.
- Return to patient tissue/body parts collected at the time of surgery refer to APS Policy Return to Patient APSMGMTQUALPR025.

2 Requests Received for Specimen Release (all staff)

2.1 Obtain patient and requestor details. Confirm dates and specimen types required.

2.1.1 **Tissue or Body part** – refer to Technical Head or Quality Lead. No further action required. Local policy applies.

2.1.2 **Clinical Trials (tissue, tumour blocks or slides)** – refer to Section Head Office or Quality Lead. No further action required. Local policy applies.

2.1.3 All other requests not on the list above proceed as follows.

2.2 Record details on the 'Specimens Release/Hold Form (APSMGMTQUALFO064) – Step 1 on the form.

2.3 Explain the specimens and/or tissue cannot be released immediately and we will set aside pending approval. Explain APS does not offer a weekend, STAT holiday or after hour's handover service, except in exceptional circumstances.

2.4 Caller must provide a written request to APS quoting under whose authority they are requesting specimens. They will need to include contact details.

- If you are asked to release specimens urgently, afterhours or if you are unsure of the process, contact one of the authorised staff listed in Section 8. Contact details are available in the Emergency Contacts; Cascade & Communication document (APSMGMTQUALIN004)

2.5 Proceed to specimen retrieval.

3 Retrieving Specimens (all staff)

3.1 Print out a list from Delphic of all specimens retrieved on the patient for the dates and specimen types requested and attach to the Specimens Release/Hold Form.

3.2 Highlight all specimens that we currently have in storage that match the requested dates.

3.3 Retrieve all specimens and record the reason for specimen removal in the 'Referred Out' Database on Delphic AP.

3.4 Record details of all the retrieved specimens on the Specimens Release/Hold Form.

3.5 Notify an authorised staff member as listed in section 8 of this procedure that specimens for release approval have been retrieved and require follow-up.

3.6 Record this communication on the Specimens Release/Hold Form – Step 3 on the form

- No specimens are to be released without prior approval from an APS authorised staff member (refer to section 8). This includes afterhours.

4 Release Criteria and Approval Process for Release of Specimens to Police / Third Party, NOT ACC Requests (authorised staff only)

4.1 Refer to section 6 for the release, approval and sending of ACC requests.

4.2 Only authorised APS staff detailed in section 8 of this document can approve release of specimens to police, patients or third parties in the following circumstances:

- On receipt of letter requesting release under the Coroners Act;
- Official police warrant;
- Signed consent/request in writing by the patient themselves

4.2.2 In all other circumstances authorised APS staff will seek advice from ADHB Medico-legal representative.

1) Review written request for release.
2) Contact ADHB medico-legal team if release criteria not met.
3) Sign approved (or not approved as applicable) on the Specimens Release/Hold form (APSMGMTQUALFO064) – Step 4 on the form
4) Contact requestor and advise whether approval for release has been given.
5) Arrange a time for hand over if approval has been given.
6) Document all relevant communications on the Specimen Release/Hold form (APSMGMTQUALFO064) – Step 3 on the form
7) If specimens not collected within 1 month of the request, contact APS Quality Lead who will follow-up with the requestor.

5 Handover Process (authorised staff only)

5.1 Check ID of specimens prior to handover with another staff member to confirm specimen identifiers and specimen numbers on all specimens match the request.

- Only one of these needs to be an authorised staff member.

5.2 Both staff members must sign the Specimens Release/Hold Form (APSMGMTQUALFO064) – Step 5 on the form

5.3 Package all specimens to safeguard against leaks and breakage, ensure lid is leak proof, place in absorbent pouch or sheets and inside a biohazard bag.

- Confirm identity of the person collecting the specimens by sighting photographic ID - Police ID, NZ Drivers Licence or Passport. For acceptance of other forms of identification, discuss with APS Quality Lead.
- Handover of package to occur at Technical Head Office / APS Library not in the Labtests Reception Area.

5.4 Ask the person collecting the specimen to complete the recipient details and sign the recipient section of the Specimens Release/Hold Form (APSMGMTQUALFO064) – Step 6 on the form.

5.5 Make 2 copies of the Specimens Release/Hold form and other documentation. Hand one copy to the person collecting the specimens.

5.6 Forward the original copy and extra copies of the Specimens Release/Hold form and other documentation to APS Quality Lead.

6 Release Criteria and Approval Process for Release of Specimens to ACC

6.1 APS Quality Lead only can approve release of specimens to ACC in the following circumstances (See section 8 for staff authorised to approve release of specimens to ACC in the absence of the Quality Lead)

- On receipt of letter requesting release from ACC via ADHB Consumer Liaison, Clinical Records or Release of Information Team.
- Request must include a signed consent/request in writing by the patient or delegated authority.

6.1.2 In all other circumstances authorised APS staff will seek advice from Medico-legal representative.

1) Review written request for release.
2) Contact ADHB Medico-legal team if release criteria not met.
3) Sign approved (or not approved as applicable) on the Specimens Release/Hold Form (APSMGMTQUALFO064) – Step 4 on the form
4) Contact the ACC Case Administrator and advise whether approval for release has been given **(this person is not to be confused with the ADHB-ACC Business Manager based at Greenlane, specimens and documentation is NOT to be sent to the ADHB-ACC Business Manager as they only deal with the billing requests).**
5) Request the correct physical address for the specimen and documentation to be sent to – Do NOT send to the address on the written request.
    a. Inform the ACC Case Administrator that the specimen and documentation will be sent via Track & Trace Courier with a signature required on receipt.
    b. Also request details of who will be responsible for sending the specimen back to APS and the expected time frame for this to occur.
6) Document all relevant communication on the Specimen Release/Hold form (APSMGMTQUALFO064) – step 3 on the form
7) Package the specimen adequately ensuring the specimen is protected and meets transport requirements.
8) Include a copy of the Specimen Release/Hold form and the written request in the package to be sent and clearly address the package with the address details provided.

9) Complete the Sendaway Dispatch Form (APSMGMTQUALFO065), place completed form and correctly addressed parcel in the National Sendaway Box in the Cytology building.

10) Contact the ACC Case Administrator once the specimen has been sent, and request that they phone APS once the specimen has been receipted by ACC.

11) Retain a copy of the Specimens Release/Hold form (APSMGMTQUALFO064) with all communications in APS Quality so, that the return of specimen can be followed up within the expected time frame.

7 Recording the Release (APS Quality or Admin Team)

7.1 Scan or attach on Delphic AP the written request, the Specimen Release/Hold form and any other relevant documentation from the requestor into the patient's clinical records.

7.2 If the request does not go ahead (e.g. no specimens remain or specimens not released for any reason) – record details on the Specimen Release /Hold form and scan into patient's clinical records.

8 Staff Authorised to Approve Release & Hand Over Specimens:

Authorised Staff Member	Tissue / Body Part	Clinical Trial Specimens	Police	ACC	Third Party or Patient
APS Quality	✓		✓	✓	✓
Cytology Secretary				✓ - not authorised to approve release, dispatch to ACC only	
Histology Technical Head	✓			✓ - in absence of Quality Lead	
Cytology Technical Head	✓			✓ - in absence of Quality Lead	
Histology Admin Section Lead		✓ - not authorised to approve, dispatch only	✓		✓
Records Administrator		✓ - not authorised to approve, dispatch only			
Cut-Up Section Lead	✓				
Cut-Up Senior Staff	✓				
Clinical Lead / Pathologist	✓	✓	✓	✓ - in absence of Quality Lead	✓

9 Release of Specimens to Patients (authorised staff only)

9.1 Patients have a right to request the return of their specimens. The request must be in writing and approved by an authorised staff as per list in section 8. Follow the process outlined in Section 5 above and complete form Release of Slides & Blocks (APSHISTADMFO013)

9.2 Scan or attach a copy of the Release of Slides & Blocks form into the patient's clinical records.

10 Reference / Associated Documents

Results Release	APSMGMTADMPR001
Specimens Release / Hold Form	APSMGMTQUALFO064
Sendaway Dispatch Form	APSMGMTQUALFO065
Release of Blocks & Slides Form	APSHISTADMFO013
Ethics for Residual Tissue	APSMGMTQUALPR010
Return to Patient Policy	APSMGMTQUALPR025
APS Emergency Contacts; Cascade & Communication	APSMGMTQUALIN004
ADHB Board Policy	Clinical Record Management September 2013
ADHB Board Policy	Body parts/Tissue Storage, Cremation and Return
ADHB Release of Information	Release of Information Form CR2645 http://adhbintranet/hims/clinical_records/cr2645x.pdf