TUMOURS OF THE HEART, PERICARDIUM AND GREAT VESSELS

STRUCTURED REPORTING PROTOCOL

(1st Edition 2016)

Based on the:

International Collaboration on Cancer Reporting (ICCR)

Neoplasms of the Heart, Pericardium and Great Vessels Dataset

www.ICCR-Cancer.org

Core Document versions:

- ICCR Neoplasms of the heart, pericardium and great vessels Histopathology Reporting Guide 1st edition v1.0
- WHO (World Health Organization) (2015) Classification of Tumours of the Lung, Pleura, Thymus and Heart. Fourth edition 2015 Travis WD, Brambilla E, Burke AP, Marx A and Nicholson AG. IARC Press, Lyon, France.

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Contents

Scope

This protocol contains standards and guidelines for the preparation of structured reports for biopsy and resection specimens of the heart, pericardium and great vessels. It includes primary tumours of the heart, pericardium and great vessels, both benign and malignant entities, and excludes haematolymphoid neoplasms and mesothelioma.

Structured reporting aims to improve the completeness and usability of pathology reports for clinicians, and improve decision support for cancer treatment. The protocol provides the framework for the reporting of any tumours of the heart, pericardium and great vessels, whether as a minimum data set or fully comprehensive report.

Given the rarity of primary malignant neoplasms of the heart and great vessels, a number of benign tumour and tumour like entities have been included in the protocol. Furthermore, many benign cardiac lesions may be inoperable or lead to sudden death or may distally embolize.

Abbreviations

AJCC	American Joint Committee on Cancer
IHC	Immunohistochemistry
IHI	Individual health identifier
LIS	Laboratory Information System
MRN	Medical Record Number
NHI	National Health Identifier (NZ)
PBS	Pharmaceutical Benefits Scheme
RCPA	Royal College of Pathologists of Australasia
TNM	tumour-node-metastasis
UHI	Unique Health Identifier
UICC	International Union Against Cancer
WHO	World Health Organization

Definitions

The table below provides definitions for general or technical terms used in this protocol. Readers should take particular note of the definitions for 'standard', 'guideline' and 'commentary', because these form the basis of the protocol.

Ancillary study	An ancillary study is any pathology investigation that may form part of a cancer pathology report but is not part of routine histological assessment.
Clinical information	Patient information required to inform pathological assessment, usually provided with the specimen request form, also referred to as "pre-test information".
Commentary	Commentary is text, diagrams or photographs that clarify the standards (see below) and guidelines (see below), provide examples and help with interpretation, where necessary (not every standard or guideline has commentary). Commentary is used to: • define the way an item should be reported, to foster reproducibility • explain why an item is included (e.g. how does the item assist with clinical management or prognosis of the specific cancer). • cite published evidence in support of the standard or guideline • state any exceptions to a standard or guideline. In this document, commentary is prefixed with 'CS' (for commentary on a standard) or 'CG' (for commentary on a guideline), numbered to be consistent with the relevant standard or guideline, and with sequential alphabetic lettering within each set of commentaries (eg CS1.01a, CG2.05b).
General commentary	General commentary is text that is not associated with a specific standard or guideline. It is used: • to provide a brief introduction to a chapter, if necessary • for items that are not standards or guidelines but are included in the protocol as items of potential importance, for which there is currently insufficient evidence to recommend their inclusion. (Note: in future reviews of protocols, such items may be reclassified as either standards or guidelines, in line with diagnostic and prognostic advances, following evidentiary review).

Guideline	Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are unanimously agreed should be included in the dataset but are not supported by NHMRC level III-2 evidence.[1] These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management. Guidelines include key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion eg macroscopic tumour details, block identification key, may be included as either required or recommended elements by consensus of the expert committee. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail. Guidelines are not used for research items. In this document, guidelines are prefixed with 'G' and numbered consecutively within each chapter (eg G1.10).
Macroscopic findings	Measurements, or assessment of a biopsy specimen, made by the unaided eye.
Microscopic findings	In this document, the term 'microscopic findings' refers to histo-morphological assessment.
Predictive factor	A *predictive factor* is a measurement that is associated with response or lack of response to a particular therapy.
Prognostic factor	A *prognostic factor* is a measurement that is associated with clinical outcome in the absence of therapy or with the application of a standard therapy. It can be thought of as a measure of the natural history of the disease.
Standard	Standards are mandatory, as indicated by the use of the term 'must'. Standards are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level III-2 or above (based on prognostic factors in the NHMRC levels of evidence[1] document). In rare circumstances, where level III-2 evidence is not available an element may be made a Standard where there is unanimous agreement in the expert committee. An appropriate staging system eg Pathological TNM staging would normally be included as a required element.These elements must be recorded and at the discretion of the pathologist included in the pathology report according to the needs of the recipient of the report. The summation of all standards represents the minimum dataset for the cancer. In this document, standards are prefixed with 'S' and numbered consecutively within each chapter (eg **S1.02**).
Structured report	A report format which utilises standard headings, definitions and nomenclature with required information.

Synoptic report	A structured report in condensed form (as a synopsis or precis).
Synthesis	Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new. The Oxford dictionary defines synthesis as "the combination of components or elements to form a connected whole". In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more modalities to derive new information.

Introduction

Tumours of the heart, pericardium and great vessels

Cardiac tumours are rare. The proportion of primary cardiac tumours that are malignant is estimated at approximately 10%[2,3] with prevalence rates greater in tertiary referral centres. Metastatic tumours to the heart are far more common than primary malignant tumours. Malignant tumours often undergo surgical debulking rather than definitive surgical excision. The dataset to be captured is for tumours that arise primarily within the heart, pericardium and great vessels. Consideration regarding anatomical location, multiplicity, and syndromic association is required in assessing primary cardiac tumours.

Importance of histopathological reporting

The information contained within a pathology report includes prognostic information for the patient and treating clinical team. The content will assist in subsequent management, whether this may be surveillance, further surgery, radiotherapy or chemotherapy, or a combination of these modalities.

Benefits of structured reporting

The pathology report lays the foundation for a patient's cancer journey and conveys information which:

- Provides the definitive diagnosis
- Includes critical information for Tumour-Node-Metastasis (TNM) staging
- Evaluates the adequacy of the surgical excision
- Provides morphological and biological prognostic markers which determine personalised cancer therapy

However, the rapid growth in ancillary testing such as immunohistochemistry, flow cytometry, cytogenetics, and molecular studies, have made the task of keeping abreast of advances on specific cancer investigations extremely difficult for pathologists. The use of structured reporting checklists by pathologists ensures that all key elements are included in the report specifically those which have clinical management, staging or prognostic implications. Consequently minimum or comprehensive datasets for the reporting of cancer have been developed[4,5] around the world. Both the United Kingdom,[6] and United States[7] have produced standardised cancer reporting protocols or "datasets" for national use for many years.

The use of cancer reporting checklists improves completeness and quality of cancer reporting and thereby ensures an improved outcome for cancer patients. This has long term cost implications for public health by ensuring the most effective and timely treatment based on accurate and complete information.

The use of a structured reporting format also facilitates easy extraction of the necessary information by secondary users of the information ie cancer registries.

International Collaboration on Cancer Reporting

The International Collaboration on Cancer Reporting (ICCR), founded in 2011 by the Australasian (RCPA), US (CAP) and UK (RCPath) Colleges of Pathology and the Canadian Association of Pathology (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC), was established to explore the possibilities of a collaborative approach to the development of common, internationally standardised and evidence-based cancer reporting protocols for surgical pathology specimens.

The ICCR, recognising that standardised cancer datasets have been shown to provide significant benefits for patients and efficiencies for organisations through the ease and completeness of data capture[8-11] undertook to use the best international approaches and the knowledge and experience of expert pathologists, and produce cancer datasets which would ensure that cancer reports across the world will be of the same high quality – ensuring completeness, consistency, clarity, conciseness and above all, clinical utility.

Representatives from the four countries participating in the initial collaboration undertook a pilot project in 2011 to develop four cancer datasets - Lung, Melanoma, Prostate (Radical Prostatectomy), and Endometrium. Following on from the success of this pilot project, the ICCR was joined by the European Society of Pathology (ESP) in 2013 and in 2014 incorporated a not-for-profit organisation focussed on the development of internationally agreed evidence-based datasets developed by world leading experts. The ICCR Datasets are made freely available from its website www.ICCR-Cancer.org

Design of this protocol

This structured reporting protocol has been developed using the ICCR dataset on neoplasms of the heart, pericardium and great vessels as the foundation.

This protocol includes all of the ICCR cancer dataset elements as well as additional information, elements and commentary as agreed by the RCPA expert committee. It provides a complete framework for the assessment and documentation of all the pathological features of tumours of the heart, pericardium and great vessels.

ICCR dataset elements for neoplasms of the heart, pericardium and great vessels are included verbatim. ICCR required elements are mandatory and therefore represented as standards in this document. ICCR recommended elements, that is, those which are not mandatory but are recommended, may be included as guidelines or upgraded to a standard based on the consensus opinion of the local expert committee.

The ICCR elements are identified in each chapter with the ICCR logo placed before the Standard or Guideline number or bullet and the ICCR element description and commentary is boarded by a grey box as shown below:

G3.02	The intraglandular extent should be recorded as a percentage.

Additional commentary by the RCPA expert committee may be added to an ICCR element but is not included in the grey bordered area eg

G2.03	If present, the laterality of the lymph nodes submitted may be recorded as left, right or bilateral.

CS2.03a If present, record site and number. All lymph node tissue should be submitted for histological examination.

Further information on the ICCR is available at www.iccr-cancer.org

Checklist

Consistency and speed of reporting is improved by the use of discrete data elements recorded from the checklist. Items suited to tick boxes are distinguished from more complex elements requiring free text or narrative. A structured or 'atomic' approach to responses is favoured, however the pathologist is encouraged to include free text or narrative where necessary to document any other relevant issues, to give reasons for coming to a particular opinion and to explain any points of uncertainty.

Report format

The structure provided by the following chapters, headings and subheadings describes the elements of information and their groupings, but does not necessarily represent the format of either a pathology report (Chapter 7) or checklist (Chapter 6). These, and the structured pathology request form (Appendix 1) are templates that represent information from this protocol, organised and formatted differently to suit different purposes.

Key documentation

- Guidelines for Authors of Structured Cancer Pathology Reporting Protocols, Royal College of Pathologists of Australasia, 2009[12]
- ICCR Neoplasms of the heart, pericardium and great vessels Histopathology Reporting Guide 1st edition v1.0
- WHO (World Health Organization) (2015) Classification of Tumours of the Lung, Pleura, Thymus and Heart. Fourth edition 2015 Travis WD, Brambilla E, Burke AP, Marx A and Nicholson AG. IARC Press, Lyon, France.
- The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Provider[13]

Changes since the last edition

Not applicable

Authority and development

This section provides information about the process undertaken to develop this protocol.

This 1st edition of the protocol is an amalgam of two separate processes:

1. This protocol is based on the ICCR dataset Neoplasms of the heart, pericardium and great vessels Histopathology Reporting Guide 1st edition v1.0. All ICCR elements from this dataset, both required (mandatory) and recommended (optional), are included in this protocol, verbatim. (It should be noted that RCPA feedback from all Anatomical Pathology fellows and specifically the local expert committee was sought during the development process of the ICCR dataset.) Details of the ICCR development process and the international expert authoring committee responsible for the ICCR dataset are available on the ICCR website: iccr-cancer.org.

2. Additional elements, values and commentary have been included as deemed necessary by the local expert committee. In addition, the standard inclusions of our local protocols eg example reports, request information etc, have also been added.

Local expert committee

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Jenny Ma Wyatt (committee chair), pathologist

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Stakeholders

ACT Health

Anatomical Pathology Advisory Committee (APAC)

Australasian Lung Cancer Trials Group (ALTG)

Australasian Society of Cardiac & Thoracic Surgeons (ASCTS)

Australian Association of Pathology Practices Inc (AAPP)

Australian Cancer Network

Australian Commission on Safety and Quality in Health Care

Australian Lung Foundation Lung Cancer Consultative Group

Australian Society of Clinical Oncologists (ASCO)

Cancer Australia

Cancer Council ACT

Cancer Council NSW

Cancer Council Queensland

Cancer Council SA

Cancer Council Tasmania

Cancer Council Victoria

Cancer Council Victoria Clinical Network

Cancer Council Western Australia

Cancer Institute NSW

Cancer Services Advisory Committee (CanSAC)

Cancer specific expert groups – engaged in the development of the protocols

Cancer Voices

Clinical Oncology Society of Australia (COSA)

Department of Health

Health Informatics Society of Australia (HISA)

Independent Review Group of Pathologists

International Collaboration on Cancer Reporting (ICCR)

Medical Software Industry Association (MSIA)

National E-Health Transition Authority (NEHTA)

National Pathology Accreditation Advisory Council (NPAAC)

National Round Table Working Party for Structured Pathology Reporting of Cancer.

New Zealand Guidelines Group (NZGG)

NSW Department of Health

Peter MacCallum Cancer Institute

Public Pathology Australia

Pulmonary Pathology Society

Queensland Cooperative Oncology Group (QCOG)

Representatives from laboratories specialising in anatomical pathology across Australia

Royal Australasian College of Physicians (RACP)

Southern Cancer Network, Christchurch, New Zealand

Southern Melbourne Integrated Cancer Service (SMICS)

Standards Australia

The Australasian Lung Cancer Trials Group (ALTG)

The International Association for the Study of Lung Cancer (IASLC)

The Medical Oncology Group of Australia

The Royal Australasian College of Surgeons (RACS)

The Royal Australian and New Zealand College of Radiologists (RANZCR)

The Royal Australian College of General Practitioners (RACGP)

The Royal College of Pathologists of Australasia (RCPA)

The Thoracic Society of Australia & New Zealand (TSANZ)

Victorian Cooperative Oncology Group (VCOG)

Western Australia Clinical Oncology Group (WACOG)

Secretariat

Meagan Judge, Royal College of Pathologists of Australasia.

Development process

This protocol has been developed following the ten-step process set out in *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols.*[14]

Where no reference is provided, the authority is the consensus of the local expert group for local inclusions and the ICCR Dataset Authoring Committee for ICCR components denoted with the ICCR logo.

1 Pre-analytical

This chapter relates to information that should be recorded on receipt of the specimen in the laboratory.

The pathologist is reliant on the quality of information received from the clinicians or requestor. Some of this information may be received in generic pathology request forms, however, the additional information required by the pathologist specifically for the reporting of tumours of the heart, pericardium and great vessels is outlined in Appendix 1. Appendix 1 also includes a standardised request information sheet that may be useful in obtaining all relevant information from the requestor**.**

Surgical handling procedures affect the quality of the specimen and recommendations for appropriate surgical handling are included in Appendix 1.

S1.01 All demographic information provided on the request form and with the specimen must be recorded.

CS1.01a The Royal College of Pathologists of Australasia (RCPA) *The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Providers* must be adhered to.[15] This document specifies the minimum information to be provided by the requesting clinician for any pathology test.

CS1.01b The patient's ethnicity must be recorded, if known. In particular whether the patient is of aboriginal or Torres Strait islander origin. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.

CS1.01c The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Medicare number (Australia), Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).

S1.02 All clinical information as documented on the request form must be recorded verbatim.

CS1.02a The request information may be recorded as a single text (narrative) field or it may be recorded atomically.

S1.03 The pathology accession number of the specimen must be recorded.

S1.04 The principal clinician involved in the patient's care and responsible for investigating the patient must be recorded.

CS1.04a Knowledge of the clinical presentation is an essential part of the WHO classification yet it may not be available for a number of reasons:

- The clinical assessment and staging may be incomplete at the time of biopsy.
- The pathology request is often authored by the clinician performing the biopsy rather than the clinician who is

investigating and managing the patient.

- The identity of this clinician is often not indicated on the pathology request form

In practice therefore, it is important in such cases that the reporting pathologist should be able to communicate with the managing clinician for clarification.

CS1.04b The Australian Healthcare identifiers i.e. Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be included, where possible, to identify the principal clinician involved in the patient's care.

G1.01 Any clinical information received in other communications from the requestor or other clinician should be recorded together with the source of that information.

2 Specimen handling and macroscopic findings

This chapter relates to the procedures required after the information has been handed over from the requesting clinician and the specimen has been received in the laboratory.

Tissue Banking

- Pathologists may be asked to provide tissue samples from fresh specimens for tissue banking or research purposes. The decision to provide tissue should only be made if the pathologist is sure that the diagnostic process will not be compromised. As a safeguard, research use of the specimen may be put on hold until the diagnostic process is complete.

Specimen handling

- Detailed fixation and specimen handling instructions are available from the RCPA online Cut-up Manual:

  www.rcpa.edu.au/Library/Practising-Pathology/Macroscopic-Cut-Up

Macroscopic findings

S2.01 All measurements are in SI units, unless explicitly stated.

S2.02 The labelling of the specimen(s) must be clearly recorded.

ICCR	**S2.03**	**The operative procedure must be recorded.**	
ICCR		CS2.03a	Because there may be more than one approach or technique to removing or sampling a tumour at a given location within the heart, specifying the nature of the operative procedure to the extent possible is important.[16]

G2.01 Specimen weight should be recorded.

G2.02 The specimen(s) should be measured in 3 dimensions.

G2.03 Specimen orientation markers should be recorded.

G2.04 The specific anatomical components submitted should be recorded.

CG2.04a The presence or absence of epicardium, endocardium and myocardium should be noted and their dimensions recorded.

CG2.04b For biopsy specimens, the site and number of fragments per site should be recorded.

G2.05 The specimen should be described.

CG2.05a For cardiac specimens, the description may include the colour, consistency eg gelatinous, solid, rubbery, the shape or type of growth and the presence of pedicle.

CG2.05b For arterial /venous specimens, the description may include:

- Artery/endarterectomy shape
  - Fusiform
  - Saccular
  - Other, describe
- Vein diameter of wall
  - Uniform
  - Irregular
- Thrombus,
  - If present record in 3 dimensions
  - Length of vessel involved __ mm
- Stenosis dimensions
  - Diameter __ mm
  - Length __ mm
  - Background artery diameter __ mm
- Other abnormalities, if present, description
  - Purulent exudate
  - Lipid core debris
  - Calcification
  - Other, describe
- Valves, if present, describe

G2.06	The integrity of resection and explant specimens should be recorded.	
	CG2.06a	This element applies only to resection and explant specimens. If the tumour specimen is not received whole and intact, specify the nature of disruption (removed piecemeal, rupture during removal, etc.) This element has relevance to completeness of tumour removal and suitability for staging and size comparison with imaging studies.
S2.04	**The macroscopic tumour site(s) must be recorded.**	
	CS2.04a	The tumour site within the heart has implications in terms of obstruction of blood flow, valvular dysfunction and downstream vascular beds at risk of embolization and haematogenous spread.[16]
S2.05	**Tumour focality must be recorded.**	
	CS2.05a	Multiple tumours may be present at the same site (e.g. left atrium in Carney Syndrome) or at different sites. A single

		tumour may invade multiple structures and thereby also be present in multiple cardiac locations. The tumour focality element clarifies this issue.

G2.07 A description of each tumour should be recorded.

CG2.07a Description should include the colour, presence of haemorrhage, necrosis, calcifications, cystic degeneration etc.

S2.06	**The maximum dimension of primary tumour must be recorded.**	
	CS2.06a	This element is applicable to resection and explant specimens only.
	CS2.06b	This element applies only to resection and explant specimens in which the entire tumour can be measured. Reporting the size in biopsy and other incomplete tumour samples may be misleading clinically.

G2.08 Additional dimensions of the primary tumour may be recorded.

G2.09 Measurements of other tumour(s) or tumour-like lesions should be recorded in at least 1 dimension.

G2.10 The involvement of tumour in relation to adjacent normal structures should be recorded.

G2.11 The macroscopic distance of tumour to closest margin should be recorded.

S2.07	**A block identification key listing the nature and origin of all tissue blocks must be recorded.**	
	CS2.07a	The origin/designation of all tissue blocks should be recorded. This information should be documented in the final pathology report and is particularly important should the need for internal or external review arise. The reviewer needs to be clear about the origin of each block in order to provide an informed specialist opinion. If this information is not included in the final pathology report, it should be available on the laboratory computer system and relayed to the reviewing pathologist. Recording the origin/designation of tissue blocks also facilitates retrieval of blocks for further immunohistochemical or molecular analysis, research studies or clinical trials.

CS2.07b Consideration of a photograph block key should be given.

G2.12 A descriptive or narrative field should be provided to record any macroscopic information that is not recorded in the above standards and guidelines, and that would normally form part of the macroscopic description.

CG2.12a The traditional macroscopic narrative recorded at the time of specimen dissection is often reported separately from

the cancer dataset. Although this remains an option, it is recommended that macroscopic information be recorded within the overall structure of this protocol.

CG2.12b Much of the information recorded in a traditional macroscopic narrative is covered in the standards and guidelines above and in many cases, no further description is required.

CG2.12c A traditional macroscopic description may be required when the Laboratory Information System (LIS) does not allow a structured approach.

CG2.12d Where the LIS offers an electronic interface for structured data entry the need for narrative can be significantly reduced to describe only information not otherwise captured.

3 Microscopic findings

Microscopic findings relates to purely histological (morphological) assessment. Information derived from multiple investigational modalities, or from two or more chapters of this protocol, are described in Chapter 5.

S3.01	**The histological tumour type must be recorded.**	
	CS3.01a	There are a large number of additional tumours that may occur in the heart, pericardium, and great vessels.[3] Only the more common entities are specifically mentioned in this element, but other types should be entered under "other" (a complete list of histological types of primary tumours of the heart is included below). The neoplastic nature of some mass-forming lesions (lipomatous hypertrophy of the atrial septum, vascular malformations, hamartoma of mature cardiac myocytes, histiocytoid cardiomyopathy, etc.) may be in doubt.[16,17] Whether or not to require a dataset worksheet on these masses is left to the discretion of the pathologist. (Note: for pericardial mesotheliomas, please use the thoracic dataset for pleural mesothelioma; haematolymphoid tumours are not covered by this dataset and will be dealt with in a future dataset). This dataset is for tumours that arise primarily within the heart, pericardium, and great arteries. Metastatic lesions to these sites should not be recorded using this dataset.
	CS3.01b	The WHO 2015 classification system for heart neoplasms is included in Appendix 4.
G3.01	The histological grade for sarcomas should be recorded, where applicable.[3,16,18,19]	
	CG3.01a	This element only applies to malignant sarcomas of the heart, pericardium, and great vessels. This element captures information shown to be prognostically important in malignant sarcomas at other body sites. Evidence that these have the same importance in sarcomas of the heart, pericardium and great vessels is lacking.
	CG3.01b	If a pathologist is unclear how to grade, the WHO blue book and the FNCLCC paper maybe useful resources.
S3.02	**The presence and extent of necrosis must be recorded where applicable.**	
S3.03	**Mitotic count of the most proliferative area must be recorded where applicable.**	
	CS3.03a	Mitotic figure count should be expressed as "#/mm^2" owing to the fact that differing field diameters of high power (x40) objectives dramatically vary the size of a single high power field (hpf). For example the hpf area for an x40

		objective with a 0.40 mm field diameter is 0.125 mm^2 whereas for an x40 objective with a 0.69 mm field diameter, the hpf area is 0.374 mm^2. Depending on the objective used, it could take as many as 8 (for the 0.40 mm field diameter lens) or as few as 3 (for the 0.69 mm field diameter lens) hpfs to cover 1 mm^2 of tissue. Each pathologist should determine the number of hpfs in a mm^2 based on the field diameter of their x40 objective.[20]
S3.04	**The extent of invasion must be recorded.**	
	CS3.04a	For the purposes of this data element, the parietal pericardium represents the anatomic boundary between the heart tissues and adjacent organs. Tumours that extend beyond the parietal pericardium should be considered "other organ involvement". Tumours crossing tissue boundaries in the heart (e.g. one chamber to another, across a valve, or into the pericardium) should be considered "involvement of adjacent tissues".[3,16]
G3.02	The response to any neoadjuvant therapy should be recorded.	
	CG3.02a	This element is not required since it presupposes knowledge of treatment prior to tumour removal. It may not always be possible to separate spontaneous tumour necrosis from treatment related necrosis. As of yet, no established level of pathologic response to treatment has been associated with prognostic significance.[3]
S3.05	**Margin status must be recorded.**	
G3.03	The presence or absence of lymphovascular invasion should be recorded.[21]	
	CG3.03a	This element is commonly reported for malignancies, however since the majority of tumours in the heart and great vessels exist within the vasculature and have immediate access to haematogenous dissemination. This element should only be reported for pericardial tumours, such as germ cell tumours and solitary fibrous tumour, that do not arise within the vascular system. Increasingly, centres are utilizing immunohistochemistry for antigens such as CD34, CD31, and/or D2-40 (podoplanin) to assess lymphovascular invasion. This may have an effect prognostically, but further study is needed. This element is not required, but will help in providing evidence along this line.

G3.04 If present, the type of lymphovascular invasion should be recorded ie lymphatic or vascular, if possible.

CG3.04a If extensive, this should also be noted.

G3.05 The presence or absence of perineurial invasion should be recorded.

G3.06 A descriptive or narrative field should be provided to record any microscopic information that is not recorded in the above standards and guidelines.

G3.07 Any relevant co-existent pathology should be recorded.

4 Ancillary studies findings

Ancillary studies may be used to determine lineage, clonality or disease classification or subclassification; as prognostic biomarkers; or to indicate the likelihood of patient response to specific biologic therapies.

S4.01	**Any ancillary investigations pivotal in determining the diagnosis must be recorded in the pathology report.**	
	CG4.01a	Increasingly, ancillary studies are needed to confirm and clarify a diagnosis. There is also potential for these kinds of studies to identify a target for therapy or confer meaningful prognostic information.

G4.01 Any ancillary investigations used in determining therapeutic options should be recorded.

5 Synthesis and overview

Information that is synthesised from multiple modalities and therefore cannot reside solely in any one of the preceding chapters is described here.

For example. *tumour stage* is synthesised from multiple classes of information – clinical, macroscopic and microscopic.

By definition, synthetic elements are inferential rather than observational, often representing high-level information that is likely to form part of the report 'Summary' or 'Diagnosis' section in the final formatted report.

Overarching case comment is synthesis in narrative format. Although it may not necessarily be required in any given report, the provision of the facility for overarching commentary in a cancer report is essential.

G5.01 The "Diagnostic summary" section of the final formatted report should include:

a. Operative procedure (S2.03)

b. Tumour site and focality (S2.04/05)

c. Tumour type (S3.01)

d. Margin status, if applicable (S3.05)

e. Relevant coexistent pathology (G3.07)

S5.01 The reporting system must provide a field for free text or narrative in which the reporting pathologist can give overarching case comment.

CS5.01a This field may be used, for example, to:

- list any relevant ancillary tests
- document any noteworthy adverse gross and/or histological features
- express any diagnostic subtlety or nuance that is beyond synoptic capture
- document further consultation or results still pending.

CS5.01b Use of this field is at the discretion of the reporting pathologist.

G5.02 The edition/version number of the RCPA protocol on which the report is based should be included on the final report.

CG5.02a For example, the pathology report may include the following wording at the end of the report: **"**the data fields within this formatted report align with criteria as set out in the RCPA document " XXXXXXXXXX" XXXX Edition dated XXXXXXX".

6 Structured checklist

The following checklist includes the standards and guidelines for this protocol which must be considered when reporting, in the simplest possible form. The summation of all "Standards" is equivalent to the "Minimum Data Set" for heart tumours. For emphasis, standards (mandatory elements) are formatted in bold font.

S6.01 The structured checklist provided below may be modified as required but with the following restrictions:

a. All standards and their respective naming conventions, definitions and value lists must be adhered to.

b. Guidelines are not mandatory but are recommendations and where used, must follow the naming conventions, definitions and value lists given in the protocol.

G6.01 The order of information and design of the checklist may be varied according to the laboratory information system (LIS) capabilities and as described in *Functional Requirements for Structured Pathology Reporting of Cancer* Protocols.[12]

CG6.01a Where the LIS allows dissociation between data entry and report format, the structured checklist is usually best formatted to follow pathologist workflow. In this situation, the elements of synthesis or conclusions are necessarily at the end. The report format is then optimised independently by the LIS.

CG6.01b Where the LIS does not allow dissociation between data entry and report format, (for example where only a single text field is provided for the report), pathologists may elect to create a checklist in the format of the final report. In this situation, communication with the clinician takes precedence and the checklist design is according to principles given in Chapter 7.

G6.02 Where the checklist is used as a report template (see G6.01), the principles in Chapter 7 and Appendix 2 apply

CG6.02a All extraneous information, tick boxes and unused values should be deleted.

G6.03 Additional comment may be added to an individual response where necessary to describe any uncertainty or nuance in the selection of a prescribed response in the checklist. Additional comment is not required where the prescribed response is adequate.

Item descriptions in italics are conditional on previous responses.

Values in all caps are headings with sub values.

S/G	Item description	Response type	Conditional
Clinical information and surgical handling			
S1.01	**Demographic information provided**		
S1.02	**Clinical information provided on request form**	**Text** OR **Structured entry as below:**	
	Clinical information	**Text**	
	Operative procedure	**Single selection value list:** • Resection • Endovascular biopsy • Image guided percutaneous biopsy • Explantation • Other (specify)	
	Neoadjuvant therapy	**Single selection value list:** • Information not provided • Not administered • Administered (describe)	

	New primary lesion or recurrence	**Single selection value list:** • New primary • Recurrence – regional *(describe)* • Recurrence - distant *(describe)*	**If local recurrence or distant metastasis, provide details**
S1.03	**Pathology accession number**	**Alpha-numeric**	
S1.04	**Principal clinician**	**Text**	
G1.01	Comments	**Text**	
Macroscopic findings			
S2.02	**Specimen labelled as**	**Text**	
S2.03	**Operative procedure**	**Single selection value list:** • Not specified • Resection • Endovascular biopsy • Image guided percutaneous biopsy • Explantation • Other (specify)	
G2.01	Specimen weight	**Numeric**: _____g	
G2.02	Specimen dimensions	**Numeric**: __x__x__mm	
G2.03	Orientation markers	**Text**	

G2.04	ANATOMICAL COMPONENTS SUBMITTED		
	Epicardium	**Single selection value list:** • Absent • Present	**If present, consider recording dimensions**
	Dimensions	***Numeric**: __x__x__mm*	
	Endocardium	**Single selection value list:** • Absent • Present	**If present, consider recording dimensions**
	Dimensions	***Numeric**: __x__x__mm*	
	Myocardium	**Single selection value list:** • Absent • Present	**If present, consider recording dimensions**
	Dimensions	***Numeric**: __x__x__mm*	
	BIOPSY SUBMITTED	***Note: Repeat site and no. of fragments for each biopsy site submitted.*** ***Note: Complete only if applicable.***	
	Site	**Text**	
	No. of fragments	**Numeric: __**	
G2.05	Specimen description	**Text**	

G2.06	Specimen integrity *(applicable for resection and explant specimens only)*	**Single selection value list:** • Indeterminate • Intact • Disrupted *(describe)*	**Applicable for resection and explant specimens only**
S2.04	**Tumour site(s)**	**Multi select value list (select all that apply):** • Not specified • Right atrium • Left atrium • Right ventricle • Left ventricle • Ventricular septum • Atrial septum • Valve (specify) • Great vessel (specify) • Pericardium • Other submitted specimens (specify)	
S2.05	**Tumour focality**	**Single selection value list:** • Indeterminate • Unifocal • Multifocal	**If multifocal, specify the number of tumours in the specimen and their locations.**
	Number of tumours and locations	***Text***	

G2.07	Tumour description	**Text** Note: Repeat for each tumour identified in S2.05, as applicable.	
S2.06	**Maximum dimension of primary tumour** (*Applicable for resection and explant specimens only)*	Cannot be assessed OR **Numeric:** __mm	
G2.08	Additional dimensions of primary tumour	**Numeric:** __x__mm	
G2.09	Dimensions of other tumours /tumour-like lesions	**Numeric:** __x__x__mm Note: Repeat for each other ie non primary tumour identified in S2.05, as applicable.	
G2.10	Involvement of tumour in relation to adjacent structures	**Text**	
G2.11	Macroscopic distance of tumour to closest margin	**Numeric**: __mm	
S2.07	**Block identification key**	**Text**	
G2.12	Other macroscopic description	**Text**	
Microscopic findings			
S3.01	**Histological tumour type**	Value list from the World Health Organization Classification of Tumours of the Lung, Pleura, Thymus and Heart. Fourth edition (2015).	

		Single selection value list: **HEART** <u>Benign</u> • Rhabdomyoma • Myxoma • Papillary fibroelastoma • Haemangioma • Fibroma • Cystic tumour of the atrioventricular node • Other (specify) <u>Malignant</u> • Angiosarcoma • Undifferentiated pleomorphic sarcoma • Myxofibrosarcoma • Other (specify) <u>Tumours of uncertain behaviour</u> • Inflammatory myofibroblastic tumour • Paraganglioma **PERICARDIUM** • Solitary fibrous tumour	

		• Germ cell tumour • Angiosarcoma • Other (specify) **GREAT VESSELS** • Angiosarcoma ○ Intimal sarcoma subtype • Leiomyosarcoma • Other (specify)	
G3.01	Histological grade *(Applicable to sarcomas; if possible)*	**Single selection value list:** • Cannot be graded • Grade 1 • Grade 2 • Grade 3 • Ungraded sarcoma	
S3.02	**Necrosis**	**Single selection value list:** • Cannot be assessed • Not identified • Present Note: Record if applicable to the specimen/ type of lesion	**If present, consider recording extent of necrosis, if applicable.**
	Extent of necrosis	***Numeric:_____%***	

S3.03	**Mitotic count** *(most proliferative area)*	**Numeric:_____per mm^2** Note: Record if applicable to the specimen/ type of lesion	
S3.04	**Extent of invasion**	**Single selection value list:** • Cannot be assessed • No involvement of adjacent tissue(s) • Involvement of adjacent tissue(s) (specify tissues) • Other organ involvement (specify)	
G3.02	Response to neoadjuvant therapy	**Single selection value list:** • Cannot be assessed • Not identified • Present	**If positive, specify % residual viable tumour**
	Residual viable tumour	***Numeric:*** ___%	
S3.05	**Margin status**	**Single selection value list:** • Not applicable *(biopsies only)* • Cannot be assessed • Not involved • Involved (specify margin(s))	
G3.03	Lymphovascular invasion *(Applicable to solitary fibrous and germ cell tumours of the pericardium)*	**Single selection value list:** • Indeterminate • Not identified	**If present, consider recording method of evaluation and G3.04.**

		• Present	
	Method of evaluation	***Single selection value list:*** • *Routine staining (H&E)* • *Immunohistochemistry for lymphovascular endothelium (specify)*	
G3.04	Type of lymphovascular invasion	**Multi select value list (select all that apply):** • Lymphatic • Vascular	
G3.05	Perineurial invasion	**Single selection value list:** • Not identified • Present	
G3.06	Additional microscopic comment	**Text**	
G3.07	Coexistent pathology	**Text**	
Ancillary test findings			
G4.01	**ANCILLARY STUDIES**	**Single selection value list:** • Not performed • Performed	**If performed and for diagnostic purposes report the specific IHC, Molecular, Cytogenetic or other ancillary findings under S4.01.** **If performed and for therapeutic determination consider reporting the specific IHC, Molecular, Cytogenetic or other ancillary findings under G4.01.**
S4.01	**DIAGNOSTIC**		

	Immunohistochemistry	**Text *(List stains)***	
	Molecular pathology	**Text *(List test(s))***	
	Cytogenetics	**Text *(List test(s))***	
	Other ancillary findings	**Text**	
G4.01	THERAPEUTIC		
	Immunohistochemistry	**Text *(List stains)***	
	Molecular pathology	**Text *(List test(s))***	
	Cytogenetics	**Text *(List test(s))***	
	Other ancillary findings	**Text**	
Synthesis and overview			
G5.01	Diagnostic summary Include: a. Operative procedure (S2.03) b. Tumour site and focality (S2.04/05) c. Tumour type (S3.01) d. Margin status, if applicable (S3.05) e. Relevant coexistent pathology (G3.07)	**Text**	

S5.01	**Overarching comment** (if applicable)	**Text**	
G5.02	Edition/version number of the RCPA protocol on which the report is based	**Text**	

7 Formatting of pathology reports

Good formatting of the pathology report is essential for optimising communication with the clinician, and will be an important contributor to the success of cancer reporting protocols. The report should be formatted to provide information clearly and unambiguously to the treating doctors, and should be organised with their use of the report in mind. In this sense, the report differs from the structured checklist, which is organised with the pathologists' workflow as a priority. For an example pathology report, please refer to Appendix 3.

Uniformity in the format as well as in the data items of cancer reports between laboratories makes it easier for treating doctors to understand the reports; it is therefore seen as an important element of the systematic reporting of cancer. For guidance on formatting pathology reports, please refer to Appendix 2.

Appendix 1 Pathology request information and surgical handling procedures

This appendix describes the information that should be collected before the pathology test. Some of this information can be provided on generic pathology request forms; any additional information required specifically for the reporting of tumours of the heart, pericardium and great vessels may be provided by the clinician on a separate request information sheet. An example request information sheet is included below. Elements which are in bold text are those which pathologists consider to be required information. Those in non-bold text are recommended.

Also included in this appendix are the procedures that are recommended before handover of specimens to the laboratory.

Patient information

- **Adequate demographic and request information should be provided with the specimen.**
  - Items relevant to cancer reporting protocols include:
    - patient name
    - date of birth
    - sex
    - identification and contact details of requesting doctor
    - date of request
  - The patient's ethnicity should be recorded, if known. In particular whether the patient is of aboriginal or Torres Strait islander origin. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.
- The patient's health identifiers should be provided.
  - The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Medicare number (Australia), Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).
- The Australian Healthcare identifiers i.e. Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be use, where possible, to identify the requesting doctor.

Clinical Information

- Clinical information should be recorded.

- The operative procedure should be documented on the request form.

➢	Any neoadjuvant therapy should be recorded.

- **Record if this is a new primary lesion or a recurrence of a previous cancer, if known.**

  - The term recurrence defines the return, reappearance or metastasis of cancer (of the same histology) after a disease free period.

    Recurrence should be classified as distant metastases or regional (local) recurrence.

    Regional (local) recurrence refers to the recurrence of cancer cells at the same site as the original (primary) tumour or the regional lymph nodes.

    Distant metastasis refers to the spread of cancer of the same histologic type as the original (primary) tumour to distant organs or distant lymph nodes.

  - This information will provide an opportunity for previous reports to be reviewed during the reporting process, which may provide valuable information to the pathologist. This information also has implications for recording cancer incidence and evidence based research.

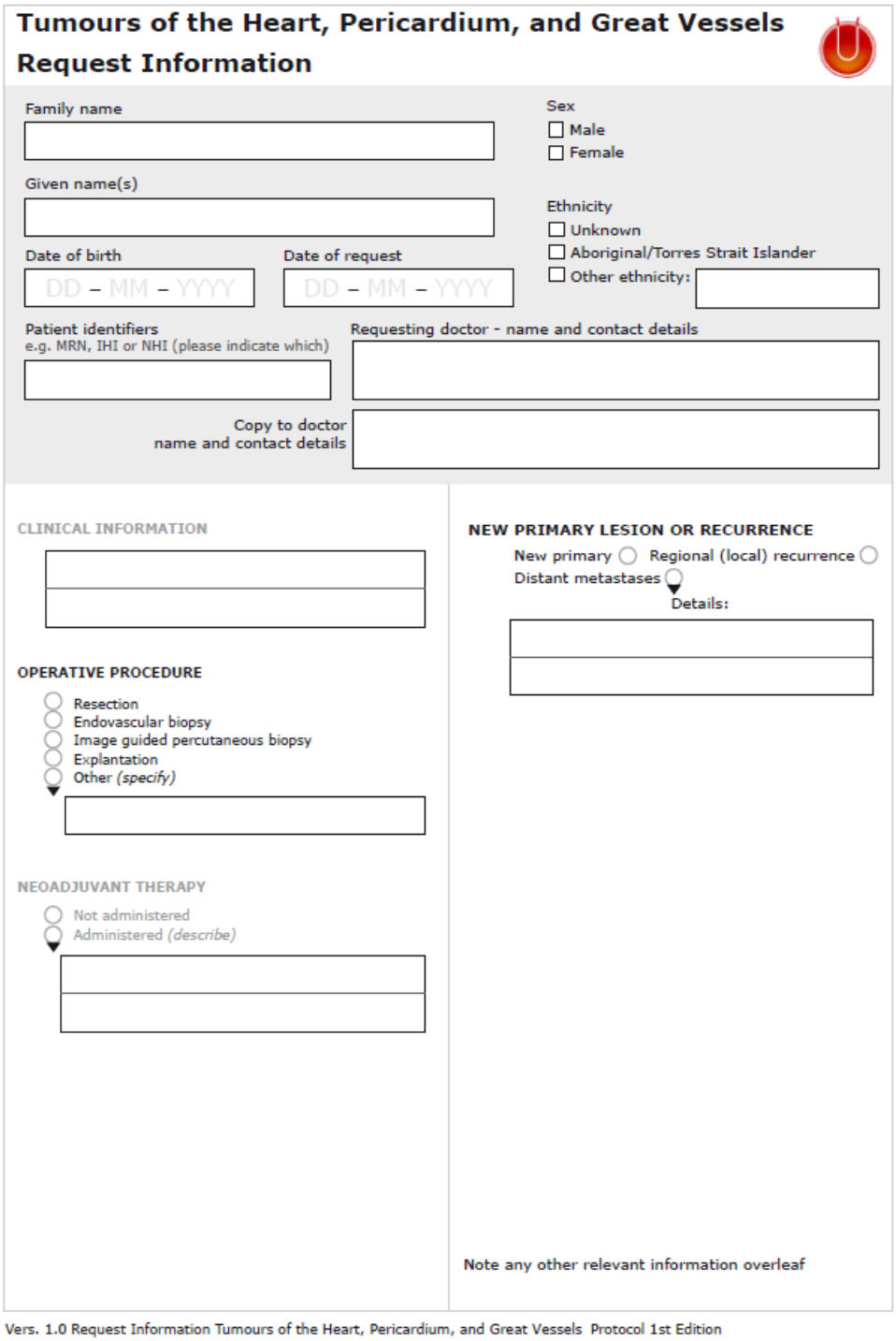
Surgical handling

- The specimen should be capable of orientation if the status of specific surgical margins is critical in determining the need for, or extent of, further surgery.

  - Where there are no anatomical landmarks, specimen orientation may be indicated with marking sutures or other techniques. If a specimen is orientated, the orientation should be indicated on the specimen request form (this may be facilitated by the use of a diagram).

- Identification of research sections should preferably be done in consultation with the pathologist in order to avoid compromising the diagnosis.

Example Request Information Sheet



Tumours of the Heart, Pericardium, and Great Vessels
Request Information

Family name

Given name(s)

Date of birth — DD – MM – YYYY

Date of request — DD – MM – YYYY

Sex
☐ Male
☐ Female

Ethnicity
☐ Unknown
☐ Aboriginal/Torres Strait Islander
☐ Other ethnicity:

Patient identifiers
e.g. MRN, IHI or NHI (please indicate which)

Requesting doctor - name and contact details

Copy to doctor
name and contact details

CLINICAL INFORMATION

OPERATIVE PROCEDURE
- Resection
- Endovascular biopsy
- Image guided percutaneous biopsy
- Explantation
- Other *(specify)*

NEOADJUVANT THERAPY
- Not administered
- Administered *(describe)*

NEW PRIMARY LESION OR RECURRENCE
New primary ○ Regional (local) recurrence ○
Distant metastases ○
Details:

Note any other relevant information overleaf

Vers. 1.0 Request Information Tumours of the Heart, Pericardium, and Great Vessels Protocol 1st Edition

The above Request Information Sheet is published to the RCPA website

Appendix 2 Guidelines for formatting of a pathology report

Headings and spaces should be used to indicate subsections of the report, and heading hierarchies should be used where the Laboratory Information System (LIS) allows it. Heading hierarchies may be defined by a combination of case, font size, style and, if necessary, indentation.

- Grouping like data elements under headings and using 'white space' assists in rapid transfer of information.[22]

Descriptive titles and headings should be consistent across the protocol, checklist and report.

When reporting on different tumour types, similar layout of headings and blocks of data should be used, and this layout should be maintained over time.

- Consistent positioning speeds data transfer and, over time, may reduce the need for field descriptions or headings, thus reducing unnecessary information or 'clutter'.

Within any given subsection, information density should be optimised to assist in data assimilation and recall.

- Configuring reports in such a way that they 'chunk' data elements into a single unit will help to improve recall for the clinician. [22]
- 'Clutter' should be reduced to a minimum.[22] Thus, information that is not part of the protocol (e.g. billing information, SNOMED codes, etc) should not appear on the reports or should be minimized.
- Injudicious use of formatting elements (e.g. too much bold, underlining or use of footnotes) constitutes clutter and may distract the reader from the key information.

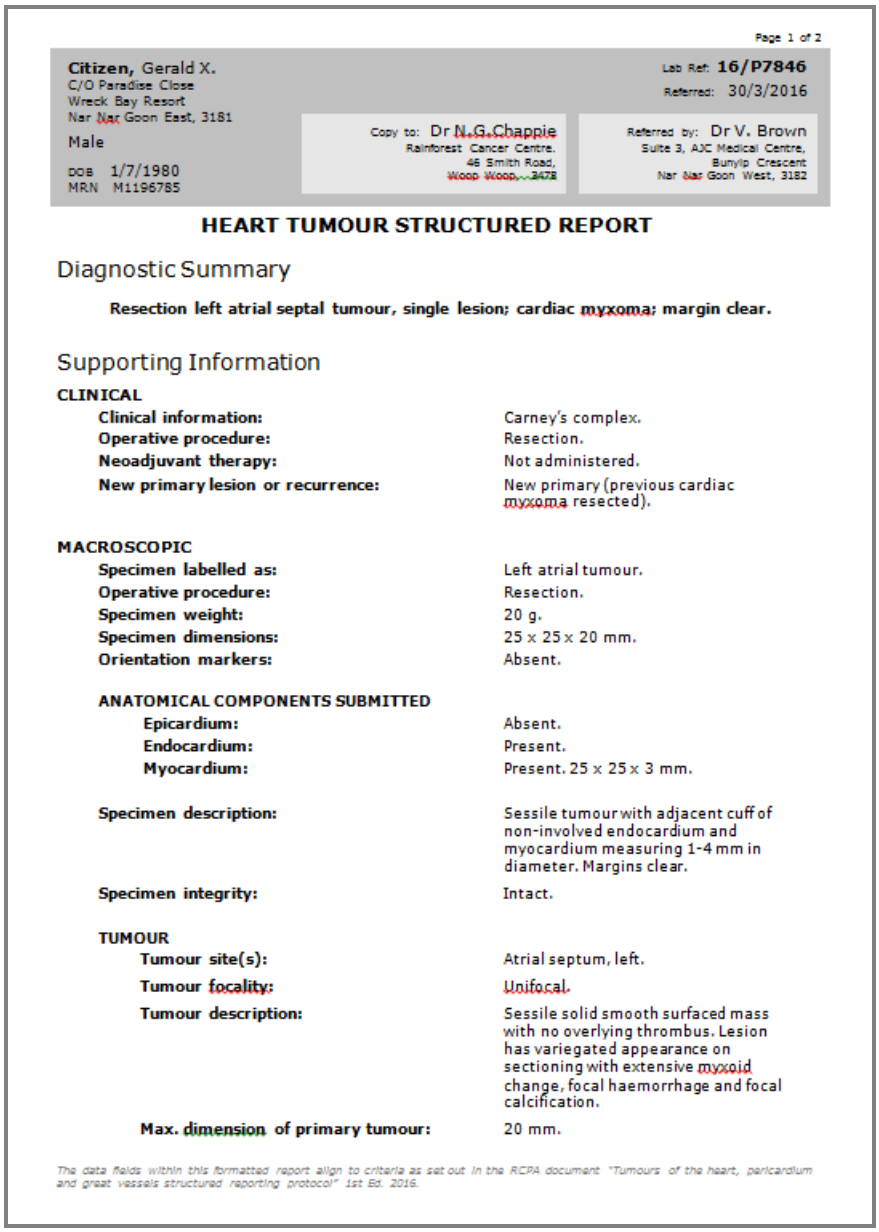
Where a structured report checklist is used as a template for the actual report, any values provided in the checklist but not applying to the case in question must be deleted from the formatted report.

Reports should be formatted with an understanding of the potential for the information to mutate or be degraded as the report is transferred from the LIS to other health information systems.

As a report is transferred between systems:

- text characteristics such as font type, size, bold, italics and colour are often lost
- tables are likely to be corrupted as vertical alignment of text is lost when fixed font widths of the LIS are rendered as proportional fonts on screen or in print
- spaces, tabs and blank lines may be stripped from the report, disrupting the formatting
- supplementary reports may merge into the initial report.

Appendix 3 Example of a pathology report



Page 1 of 2

Citizen, Gerald X.
C/O Paradise Close
Wreck Bay Resort
Nar Nar Goon East, 3181
Male
DOB 1/7/1980
MRN M1196785

Lab Ref: **16/P7846**
Referred: 30/3/2016

Copy to: Dr N.G.Chappie
Rainforest Cancer Centre.
46 Smith Road,
Woop Woop, 3478

Referred by: Dr V. Brown
Suite 3, AJC Medical Centre,
Bunyip Crescent
Nar Nar Goon West, 3182

HEART TUMOUR STRUCTURED REPORT

Diagnostic Summary

Resection left atrial septal tumour, single lesion; cardiac myxoma; margin clear.

Supporting Information

CLINICAL

Clinical information:	Carney's complex.
Operative procedure:	Resection.
Neoadjuvant therapy:	Not administered.
New primary lesion or recurrence:	New primary (previous cardiac myxoma resected).

MACROSCOPIC

Specimen labelled as:	Left atrial tumour.
Operative procedure:	Resection.
Specimen weight:	20 g.
Specimen dimensions:	25 x 25 x 20 mm.
Orientation markers:	Absent.

ANATOMICAL COMPONENTS SUBMITTED

Epicardium:	Absent.
Endocardium:	Present.
Myocardium:	Present. 25 x 25 x 3 mm.
Specimen description:	Sessile tumour with adjacent cuff of non-involved endocardium and myocardium measuring 1-4 mm in diameter. Margins clear.
Specimen integrity:	Intact.

TUMOUR

Tumour site(s):	Atrial septum, left.
Tumour focality:	Unifocal.
Tumour description:	Sessile solid smooth surfaced mass with no overlying thrombus. Lesion has variegated appearance on sectioning with extensive myxoid change, focal haemorrhage and focal calcification.
Max. dimension of primary tumour:	20 mm.

The data fields within this formatted report align to criteria as set out in the RCPA document "Tumours of the heart, pericardium and great vessels structured reporting protocol" 1st Ed. 2016.

Additional dimensions of primary tumour:	20 x 15 mm.
Involvement of tumour in relation to adjacent structures:	Nil.
Macroscopic distance of tumour to closest margin:	1 mm.
Block identification key:	Representative sections of tumour and adjacent inked margin 1A-1D.

MICROSCOPIC:

Histologic tumour type:	Cardiac myxoma.
Necrosis:	Present, focal.
Mitotic count:	Not applicable.
Extent of invasion:	No involvement of adjacent tissues.
Margin status:	Not involved. 1 mm clear of myocardial and endocardial margins.
Lymphovascular invasion:	Not applicable.
Additional microscopic comment:	'Lepidic' type cells with vasoformative rings noted. Extensive myxoid matrix. Focal degenerate change with haemosiderin deposition and calcification.
Coexistent pathology:	None noted.

ANCILLARY TESTS	Performed for diagnostic purposes.
Immunohistochemistry:	Lesional 'lepidic' cells positive for calretinin.
Molecular pathology:	Not performed.
Cytogenetics:	Not performed.

Reported by Dr Edwin Clark Authorised 4/4/2016

The data fields within this formatted report align to criteria as set out in the RCPA document "Tumours of the heart, pericardium and great vessels structured reporting protocol" 1st Ed. 2016.

Appendix 4 WHO Classification of tumours

WHO classification of tumours of the heart[a,b]

Descriptor	ICD0 codes	Descriptor	ICD0 codes
Benign tumours and tumour-like lesions		**Malignant tumours**	
Rhabdomyoma	8900/0	Angiosarcoma	9120/3
Histiocytoid cardiomyopathy		Undifferentiated pleomorphic sarcoma	8830/3
Hamartoma of mature cardiac myocytes		Osteosarcoma	9180/3
Adult cellular rhabdomyoma	8904/0	Myxofibrosarcoma	8811/3
Cardiac myxoma	8840/0	Leiomyosarcoma	8890/3
Papillary fibroelastoma		Rhabdomyosarcoma	8900/3
Haemangioma, NOS	9120/0	Synovial sarcoma	9040/3
Capillary haemangioma	9131/0	Miscellaneous sarcomas	
Cavernous haemangioma	9121/0	Cardiac lymphomas	
Cardiac fibroma	8810/0	Metastatic tumours	
Lipoma	8850/0		
Cystic tumour of the atrioventricular node	8454/0	**Tumours of the pericardium**	
Granular cell tumour	9580/0	Solitary fibrous tumour	8815/1
Schwannoma	9560/0	Malignant	8815/3
		Angiosarcoma	9120/3
Tumours of uncertain behaviour		Synovial sarcoma	9040/3
Inflammatory myofibroblastic tumour	8825/1	Malignant mesothelioma	9050/3
Paraganglioma	8680/1	Germ cell tumours	
		Teratoma, mature	9080/0
Germ cell tumours		Teratoma, immature	9080/3
Teratoma, mature	9080/0	Mixed germ cell tumour	9085/3
Teratoma, immature	9080/3		
Yolk sac tumour	9071/3		

a The morphology codes are from the International Classification of Diseases for Oncology (ICD-O). Behaviour is coded /0 for benign tumours; /1 for unspecified, borderline, or uncertain behaviour; /2 for carcinoma in situ and grade III intraepithelial neoplasia; and /3 for malignant tumours.
b The classification is modified from the previous WHO classification, taking into account changes in our understanding of these lesions.

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