health

Cancer (Reporting) Regulations 2012

Regulatory Impact Statement

State Government Victoria

Department of Health

Cancer (Reporting) Regulations 2012

Regulatory Impact Statement

This Regulatory Impact Statement (RIS) has been prepared to fulfil the requirements of the ***Subordinate Legislation Act 1994*** and to facilitate public consultation on the proposed Cancer (Reporting) Regulations). A copy of the proposed regulations is provided as an attachment to this RIS.

Public comments and submissions are invited on the proposed Regulations, in response to information provided in this RIS. All submissions will be treated as public documents.

Written comments and submissions should be forwarded by email or post no later than **11 January 2011** to:

Email Address: Cancerreporting.RIS@health.vic.gov.au

or

Kate Wilkinson

Acting Manager

Screening and Cancer Prevention

Prevention and Population Health

Department of Health

50 Lonsdale Street, Melbourne, Victoria 3000

Cancer (Reporting) Regulations 2012

Regulatory Impact Statement

State Government Victoria

Department of Health

If you would like to receive this publication in an accessible format, please phone 9096 2013 using the National Relay Service 13 36 77 if required, or email: cancerreporting.RIS@health.vic.gov.au

This document is available as a PDF on the internet at:

www.health.vic.gov.au/screening/cancer-reporting2012

Authorised and published by Victorian Government, 50 Lonsdale Street, Melbourne.

Except where otherwise indicated, the images in this publication show models and illustrative settings only, and do not necessarily depict actual services, facilities or recipients of services.

Abbreviations

Abbreviation	Explanation
AACR	Australian Association of Cancer Registries
AIHW	Australian Institute of Health and Welfare
CBA	Cost Benefit Analysis
CCV	Cancer Council Victoria
COAG	Council of Australian Governments
DH	Department of Health
ECOG	Eastern Cooperative Oncology Group
HIM	Health Information Manager
ICS	Integrated Cancer Service
IHI	Individual Health Identifier
MCA	Multi Criteria Analysis
NCSCH	National Cancer Statistics Clearing House
NIRA	National Indigenous Reform Agenda
RIS	Regulatory Impact Statement
VAED	Victorian Admitted Episode Dataset
VCCR	Victorian Cervical Cytology Registry
VCR	Victorian Cancer Registry

Table of Contents

Executive Smmary **1**

1 Introduction **5**

1.1. What is the Purpose of a Regulatory Impact Statement? 5
1.2. Background to the Current Regulations 5

2 The nature and extent of the problem **7**

2.1. Effectiveness of the current regulations 7
2.2. Data Gaps 9
2.3. Risks Associated with Non-Intervention 10

3 Policy and objectives **12**

3.1. Policy Environment 12
3.2. Objectives 14

4 Options to address the problem **15**

4.1. Options considered and rejected 15
4.2. Non-Regulatory Option 15
4.3. Regulatory Options 16

5 Cost Benefit Analysis **19**

5.1. Costs – Burden of Reporting 19
5.2. Benefits – Users of Data from the Cancer Registry 26
5.3. Multi-Criteria Analysis 28

6 The preferred option **33**

6.1. Proposal Description 33
6.2. Groups Affected by the Proposed Regulations 35
6.3. Implementation 36
6.4. Compliance with the Regulations 37
6.5. Impact on Competition 37
6.6. Evaluation Strategy 38
6.7. Consultation 39

7 Appendices **44**

8 Endnotes and References **56**

Executive Summary

The *Cancer (Reporting) Regulations 2002* (the Regulations) are scheduled to sunset on 5 March, 2012 and new regulations are required to support the *Cancer A*ct 1958. The proposed regulations will replicate the current regulations, with limited amendments.

The objective of the current Cancer (Reporting) Regulations (2002) is:

> *"…to prescribe the timing of and the forms for the reporting of cancer to the Anti-Cancer Council of Victoria*[1] *by persons required to report under the* ***Cancer Act 1958****"*

Section 60 of the *Cancer Act* (Reporting of cancer) lists the persons required to report under the Act, as well as the conditions under which such reporting must take place. The Regulations further note the particulars of what must be reported to the Council and within what time frames, for each of the listed persons.

As specified in the *Cancer Act 1958* (the Act), the Anti-Cancer Council Victoria (operating as the Cancer Council Victoria, CCV)[1] is responsible for registering all cases of cancer reported by hospitals, prescribed health services, prescribed registers and those carrying out cancer tests. Currently, approximately 250 hospitals, 40 pathology laboratories and two prescribed registries notify cancer to the Victorian Cancer Registry (VCR) via paper, web or electronic reporting.

The principal objective of the VCR is to contribute to the prevention, control and treatment of cancer in the population, through the supply of timely and accurate data based on the incidence, prevalence and outcomes of cancer in Victoria.

It is intended to bring the proposed Regulations into effect on 6 March 2012. The proposed Regulations are the subject of this Regulatory Impact Statement (RIS).

Proposed Changes to the Regulations

The first proposed change to the Regulations is an extension to require private radiotherapy centres and day oncology treatment centres to report cancer data to the VCR. This will bring the Regulations in line with the intent of the *Cancer Act 1958* and will improve the completeness of data collection from all treatment sources.

In addition, a number of changes to the data captured by the Schedules are also being proposed:

- Aboriginal or Torres Strait Islander status (if known);
- Country of birth (if known);
- Language spoken at home (if known);
- Individual Health Identifier (IHI) (if known); and
- ECOG (Eastern Cooperative Oncology Group) performance status (if known)
- Clarification to an existing data item (Staging) to note that staging data is to comply with existing accepted international standards.

Objectives of the Proposed Regulations

The aim of the proposed Regulations is:

"To capture comprehensive data on new cases of cancer diagnosed and treated in Victoria, in order to monitor best practice and be accountable for health and treatment outcomes."

The objectives of the proposed Regulations are to:

1. improve data collection, by extending the Regulations to cover private oncology and day chemotherapy centres, areas of increasing importance in the treatment pathways for people suffering from cancer, but whose data is currently not being captured in a systematic, consistent and prescribed manner;
2. enhance the collection of demographic data currently submitted under the Regulations, by explicitly calling for the reporting of ATSI status and details related to ethnicity, thereby improving the monitoring of health outcomes for specific populations groups and to better inform prevention, screening and treatment programs;
3. introduce the mandated reporting of ECOG performance status, a clinical measure of how cancer affects the daily living abilities of a patient. This will allow for improved monitoring of best practice treatment;
4. introduce the collection of Individual Health Identifier (IHI) to prepare for implementation of e-health reform. The IHI, which is an unique identifying code, gives individuals and healthcare providers confidence that the right health information is associated with the right individual at the point of care.;
5. clarify the staging data which is required to be reported with preference for the internationally accepted Tumour, Node, Metastases (TNM) site specific staging system.

Risks Associated with Non-Intervention

- Reduced integrity of the Victorian Cancer Registry
- Reduction in the type and quality of cancer data that is available**.**
- Inability to correctly participate in the National Cancer Statistics Clearinghouse activities.
- Failure to further the policy intent of the authorising Act.
- Without the information collected through the workings of the Regulations and the maintenance of the data integrity of the VCR, it would be significantly more difficult and costly to manage and plan for a range of cancer services, and to provide data for cancer research.

Impact on Stakeholders

The proposed Regulations have most impact on the three reporting groups, hospitals and prescribed health service establishments, prescribed registries and pathology laboratories, as well as those who use data from the Victorian Cancer Registry to support cancer research, policy and programs.

Options Considered

Option	Assessment
Option 1 – Retain the existing prescribed particulars for reporting to the VCR	Regulatory Option 1 does not seek to improve the current reporting to support changing practice and policies.
Option 2 - Proposed option – extension of reporting to private radiotherapy centres and day oncology treatment centres, addition of five prescribed particulars – Country of birth, language spoken at home, ATSI status, IHI, ECOG status	Regulatory Option 2 increases the cost of VCR data collection by only an incremental amount, offset by the benefits accrued.
Option 3 – Expanded clinical data collection through tailored reporting requirement by tumour stream	Regulatory Option 3 was assessed to be beneficial although it was also recognised that this would impose an additional reporting burden and would be administratively complex to collect.
Option 4 - Base case – no Regulations	Reduced integrity of the Victorian Cancer Registry. Reduction in the type and quality of cancer data that is available**.** Inability to correctly participate in the National Cancer Statistics Clearinghouse activities. Failure to further the policy intent of the authorising Act.

Costs and Benefits

The cost-benefit assessment of the impact of renewing the Cancer (Reporting) Regulations demonstrates that the benefits of maintaining the regulations outweigh the costs. Regulations impose only a marginal increase in costs compared to the base case (no regulations) as the Act requires pathology services to report cases to the VCR in the absence of regulations. The value of the benefits of VCR data to government and researchers is confirmed in the qualitative consultation statements as well as their demonstrated willingness to pay. Targeted consultation on the proposed Regulations provided many quotes from researchers, and users of cancer data within the health department, cancer screening registries and the Cancer Council, on the value of data from the Cancer Registry. Uses of the data include assessment of patterns of cancer patient care, identification of successes and areas of improvement in cancer diagnosis and treatment, assessment of potential environmental hazards, support for improved understanding of cancer, the epidemiology of cancer and cancer control, service planning and information for policy development.

The cost analysis considers average growth in cancer incidence of 2.8% per annum and cash flow using a 3.5% real discount rate. Net Present Values (NPV) for the ten year life of the various regulatory options and incremental costs are displayed in the following table. The total cost of the proposed Regulations, relative to the base case which is no regulations, is $1,725,184 over ten years (NPV).

Comparison of NPV total and incremental costs of options

Option	NPV 10 year costs	Incremental costs compared to Option 3 (status quo)	Incremental costs compared to Base Case (no regulations)
Base Case - no regulations	$ 775,199		
Option 1 - status quo	$ 1,754,418		$ 979,219
Option 2	$ 2,500,383	$ 745,965	$ 1,725,184
Option 3	$ 4,754,810	$ 3,000,392	$ 3,979,611

Multi-criteria analysis is useful where it is not possible to quantify and assign monetary values to all the impacts of a regulatory option. In this analysis it is possible to quantify many of the costs of regulation but the benefits are difficult to quantify, as they are social benefits such as those described by users of data from the cancer registry. The Multi-Criteria Analysis (MCA) considered the following four criteria and weighted them according to their importance: effectiveness (30%) (including enabling Department of Health functions), support for cancer research (20%), costs (40%), implementation and practicality (10%). The three regulatory options were compared to the base case (no regulations) which was given a score of zero.

All of the alternatives considered were preferable to the unregulated base case scenario. However, Option 2 had a score of 2.4 which is higher than Option 3 with a score of 1.3 and Option 1, the current Regulations, which had a score of 2.2. The conclusion of this analysis is that the proposed measure, Option 2 is the most effective and appropriate to achieve the required objectives. Detail on the MCA can be found in Chapter 5.2.

Conclusion

An assessment of the various regulatory and non-regulatory options available to support the policy intent of the Act has been completed as part of the RIS process and the following conclusions have been reached:

- The benefits of the proposed Regulations (Option 2) outweigh the costs;
- The proposed Regulations are considered to be superior to the alternatives in terms of meeting policy objectives;
- And the proposed Regulations do not restrict competition.

A prime function of the RIS process is to allow members of the public to comment on proposed Regulations before they have been finalised. Such public input can provide valuable information and perspectives, and thus improve the overall quality of the regulations. Targeted consultation on the regulatory options has been carried out with key groups who report data to the VCR as well as key researchers, policy and program makers who use data from the registry. Preliminary feedback has been valuable in informing this assessment.

Public comments and submissions are invited on the proposed regulations, in response to information provided in the RIS. In particular, ways in which the regulatory and administrative burden of the proposed regulations could be reduced are welcomed.

1 Introduction

1.1. What is the Purpose of a Regulatory Impact Statement?

This document is a regulatory impact statement (RIS) analysing the regulations governing the reporting of cancer incidence in Victoria. Its purpose is to examine the need for specifications surrounding reporting of cancer incidence, and based on this, draw conclusions on whether continued regulation is necessary. In doing so, the RIS will assess a draft set of regulations, the proposed *Cancer (Reporting) Regulations 2012*, against other options.

The *Subordinate Legislation Act 1994* specifies that all regulations covered by the Act will expire or 'sunset' after 10 years. In accordance with this, the *Cancer (Reporting) Regulations 2002* are scheduled to sunset on 5 March, 2012.

The renewal of regulations which are sunsetting is treated as a new legislative process, and hence requires appropriate demonstration that the regulation is still required and in the best interests of society. The *Subordinate Legislation Act 1994* also specifies that a RIS needs to be prepared where a proposed statutory rule imposes a significant burden on any sector of the public.

The review process imposed by the requirement for a RIS ensures that the regulation is still required and that adjustments are considered to better achieve the desired benefits and/or reduce the cost it imposes. This RIS has taken into account the feedback provided by key stakeholders during a targeted consultation process, both in the consideration of options to address the need for regulation as well as in the conduct of the cost benefit analysis.

1.2. Background to the Current Regulations

Cancer causes more deaths in Victoria than any other condition and is the cause of considerable morbidity in the Victorian community. Cancer affects one in three Victorians up to the age of 75 and around 70 Victorians per day are newly diagnosed with cancer. [2]

In 2009, 28,314 Victorians were diagnosed with malignant cancer and 10,397 died from cancer. This figure represents 29% of all deaths making cancer the single greatest cause of death in Victoria. There has been a steady increase in the incidence of cancer in our community, primarily associated with the increasing age of the population and population growth. From 2005 to 2009, there was a 16 percent increase in the number of Victorians diagnosed with malignant cancer (24,408 to 29,314). In contrast, cancer death rates have been decreasing over recent years by approximately 1 per cent per annum. [3] The estimated prevalence of Victorians living with cancer between 2003 and 2008 has remained constant at approximately 6.6 percent for the population as a whole. The data however, indicates an increasing prevalence with increasing age. The highest rates of cancer were seen in individuals aged 65 and over (17.6 percent).[4]

As specified in the *Cancer Act 1958* (the Act), the Anti-Cancer Council Victoria (operating as the Cancer Council Victoria, CCV)[5] is responsible for registering all cases of cancer reported by hospitals, prescribed health services, prescribed registers and those carrying out cancer tests. Currently, 250 hospitals, 40 pathology laboratories and two prescribed registries notify cancer to the Victorian Cancer Registry (VCR) via paper, web or electronic reporting. The minimum data set for reporting to the VCR is presented in Appendix A.

The existing Act and Regulations are an enabler of the system; that is, they prescribe the agencies that are required to report, they outline the minimum data set to be reported in the required time, and they support and empower one agency to be the repository of the data.

The objective of the current Cancer (Reporting) Regulations (2002) is:

> *"…to prescribe the timing of and the forms for the reporting of cancer to the Anti-Cancer Council of Victoria*[5] *by persons required to report under the* ***Cancer Act 1958****"*

Section 60 of the *Cancer Act* (Reporting of cancer) lists the persons required to report under the Act, as well as the conditions under which such reporting must take place.[6]

The Regulations further note the particulars of what must be reported to the Council and within what time frames, for each of the listed persons.[7]

Section 60(4) of the *Cancer Act* specifies that the Governor in Council may prescribe additional categories of health service establishments that must report, as well as increase the number and types of cancer tests that must be reported.[8]

The CCV established the Victorian Cancer Registry (VCR) to collect and manage information on the cancer cases reported to it. The information required to be reported to the Cancer Council, is contained in the *Cancer (Reporting) Regulations 2002* (the Regulations) and more specifically the Schedules contained within it (see D to Appendix F for details on the Schedules).

The principal objective of the VCR is to contribute to the prevention, control and treatment of cancer in the population, through the supply of timely and accurate data based on the incidence, prevalence and outcomes of cancer in Victoria. The data collected and managed by the VCR/CCV is then accessible to a range of researchers, public health practitioners, government programs and the public in order to improve our understanding and efforts to improve cancer control.

1.2.1.Rationale for Government Intervention

The rationale for government intervention in the case of cancer reporting is the provision of public goods, as defined in the Victorian Guide to Regulation 2011.[9] Public goods are goods or services which display both of the following characteristics:

- they are non-excludable, which means that anyone can have access to them once they are provided; and
- they are non-rivalrous, which means that any person can benefit from them, without diminishing anyone else's enjoyment.

Once provided, the benefits of public goods can be enjoyed by all parties, although it is not feasible to charge all users for these services. As a result, public goods may not be provided, or will be under-provided, unless governments intervene.

The cancer data provided by the VCR fits this definition of public goods. Cancer data from the VCR is used for research, cancer service planning and funding, cancer screening activities and public health investigations for public good. Cancer data is also available directly to the public through the CCV website and Cancer Information and Support Services. If the *Cancer Act* and the *Cancer (Reporting) Regulations* did not mandate the reporting of all cancer cases, a full cancer data set would not be available for use by researchers, health service providers, policy makers and the community, or deliver the flow on community benefit of improved cancer control.

2 The nature and extent of the problem

2.1. Effectiveness of the current regulations

One of the key functions of cancer registries, including the VCR, is the collection and dissemination of statistical information on cancer. The VCR information is used by a wide range of organisations to inform their research, policy and decision making for the benefit of the health of all Victorians. Table 12 (in Appendix B) summarises the data requests made to the VCR from 2007 to 2010, and provides a snapshot of the uses to which the data contained in the VCR has been put including record linkages, de-identified data provision and recruitment of participants for cancer studies.

Table 12 provides some indication of the value of the registry to thousands of users of data, particularly since the on-line data kiosk was made available in 2009 through the Cancer Council website (7,681 total data requests in 2009). In addition to these data requests, there are numerous non-recorded uses of the cancer data, which are published in the yearly CCV Canstat publication.

To adequately and efficiently perform these functions requires that the VCR:

- maintain a cancer database of high quality and accessibility;
- produce regular reports on cancer incidence, prevalence, mortality and survival;
- utilise and make data available for epidemiological and clinical research;
- utilise and make data available to inform and evaluate cancer prevention and early detection strategies; and
- make data available for use by government, health service providers, health service planners, public health/environmental health professionals, health services researchers, medical researchers and the general community.

Like all State and Territory Cancer Registries, the VCR provides data to the National Cancer Statistics Clearing House (NCSCH) at the Australian Institute of Health and Welfare (AIHW). The NCSCH produces reports of national cancer incidence, mortality and survival data. Periodically, analyses of specific cancer sites, cancer histology, differentials in cancer rates by country of birth, geographical variation, trends over time and survival are undertaken. The NCSCH also has a role in facilitating cancer research both nationally and internationally.

The regulatory approaches adopted in other jurisdictions are very similar to that which is proposed for Victoria. As the registries in all jurisdictions are part of the Australasian Association of Cancer Registries (AACR) and all jurisdictions report data to the NCSCH at the AIHW, the legislation does not vary much in intent or operation between the jurisdictions. There is a fairly standard approach to cancer data collection and management across the country and similar data is collected from state to state (see Appendix C for details). In some jurisdictions there are additional categories of notifiers to the registry such as aged care facilities. The West Australian Regulations are the most recently updated (2011) and they have added reporting of cancer by radiation oncologists and ophthalmologists.

Currently, approximately 250 hospitals and 40 pathology laboratories and two registries notify cancer to the Registry, sometimes with all three reporting on the same individual at different phases of the treatment pathway. The duplication of notification was an important principle built into the system from its inception and underpins all Australian cancer registries functioning. Notifications from several institutions may be received for the same cancer, allowing a check for completeness to be performed and the collection of additional information to occur, if necessary.[10] Computerised death certificates are also obtained from the Register of Births, Deaths and Marriages on a regular basis, in instances

where a cancer diagnosis occurs only at the time of death.[3] All of the details contained in each of the Schedules may not be reported with each VCR notification; however, the overlapping notification by hospitals and laboratories allow a complete picture of diagnosis, clinical and treatment details for each cancer to be built up in the Registry. As a result of the operation of the Regulations, the Registry is able to report incident or new cases of cancer for each year, as well as survival and mortality data.

The release of data from the VCR is two-tiered. Statistical tabulations are routinely available from the information manager and anonymous data are available at the discretion of the Director.[10] Record linkage or research proposals that require disclosure of personal details require the approval of the Cancer Council Victoria's Human Research Ethics Committee. Cancer data is available to the public via the CCV website or data kiosk and also from the Cancer Information and Support phone services. Research groups undertaking complex and time consuming participant recruitment, record linkage or data extraction are able to contract the VCR to undertake the work for a fee or charge for service. These charges are not prescribed in the Regulations but are set by CCV based on cost recovery. Further information on this is available in Chapter 5.

Notification of cancer cases in Victoria has been mandatory since 1981. Therefore, a measure of the effectiveness of the regulatory regime is the completeness and quality of the data being captured. Canstat, the Cancer Council Victoria Epidemiology Centre's publication,[3] provides information on three internationally standardised indices of the VCR data quality and completeness: death certificate only (DCO), histological verification (HV) and mortality to incidence ratio (M:I).

Death certificate only (DCO) indicates the proportion of cases registered for which no information was available other than a statement on the death certificate that the deceased died from, or with, cancer. A high DCO suggests incomplete incidence notification. *Canstat: Cancer in Victoria 2009* [3] reports a DCO percentage of 2.0% for all malignant tumours, which is well within the accepted international benchmark range of 2-3%.[11]

Histological verification (HV) indicates the proportion of cases registered which had histological verification of diagnosis. A low HV suggests incomplete registration of pathology reports and consequently poorer verification of diagnosis and incomplete registration of some cancers for which this is often the only source of notification, such as melanoma. *Canstat: Cancer in Victoria 2009* [3] reports a HV of 93% for all malignant tumours. Again, this value indicates good performance against the accepted standards.

The mortality to incidence ratio (M:I) is the ratio of the number of deaths attributed to a specific cancer against the number of new cases of the same cancer diagnosed during the same period, in the same population. If registration is complete and the incidence of the cancer is not rapidly changing, the mortality to incidence ratio should reflect long-term survival. If survival rates are comparable in two populations, a more complete case notification is suggested by a lower M:I. *Canstat: Cancer in Victoria 2009* [3] reports an M:I of 37% for all malignant tumours. This figure is consistent with recently documented survival data which reports Victorian 5 year cancer survival (2005-2008) as 63%. [3]

The three indices of quality have not varied much over the previous five years (see Table 1 below), indicating that the Regulations have been effective in achieving their aim; that is, ensuring the capture and recording of accurate and complete cancer data.

Table 1: Quality of data in the cancer registry

Year	DCO (%) all malignant tumours	HV (%) all malignant tumours	M:I (%) all malignant tumours
2005	1.8	91	40
2006	2.8	91	38
2007	2.0	92	39
2008	1.7	93	38
2009	2.0	93	37

2.2. Data Gaps

Although the data currently being captured is of high quality, there are a number of missing data elements. The draft *Cancer (Reporting) Regulations 2012* propose a number of extensions, aimed at capturing these elements.

The first proposed change is an extension to the Regulations to require private radiotherapy centres who use radiation for cancer treatment, and day oncology treatment centres to report cancer data to the VCR. This will bring the Regulations in line with the intent of the *Cancer A*ct 1958 and will improve the completeness of data collection from all treatment sources. Some private oncology providers already report data to the registry however private radiotherapy providers are not currently reporting and this treatment information is not being captured by the VCR. Cancer treatment carried out by outpatient radiation oncology services and chemotherapy centres is a rapidly growing area of cancer care.

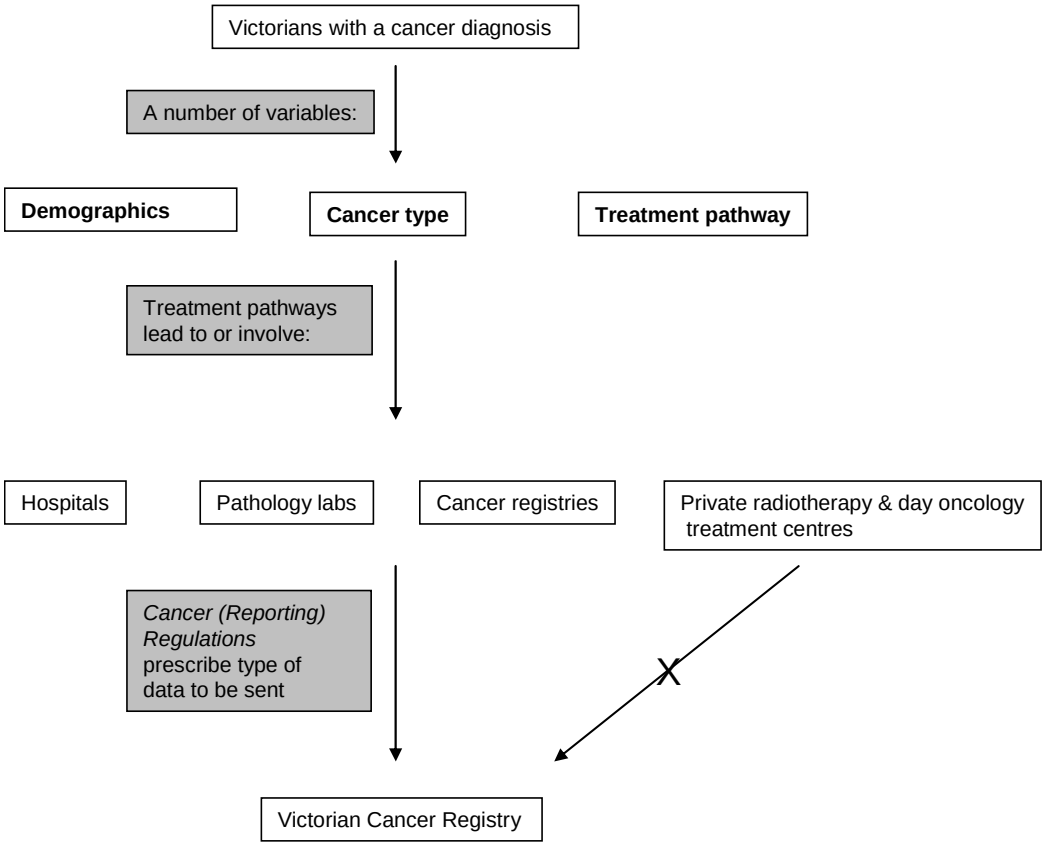
In addition, a number of changes to the data captured by the Schedules are also being proposed:

- Aboriginal or Torres Strait Islander status (if known);
- Country of birth (if known);
- Language spoken at home (if known);
- Individual Health Identifier (IHI) (if known); and
- ECOG (Eastern Cooperative Oncology Group) performance status (if known)

As with the extension to the Regulations, the additional data elements are necessary for the completeness of the data. The Department of Health argues that the improved capture and recording of data relating to Aboriginal or Torres Strait Islander status is an obligation under numerous state and national policy objectives and that the monitoring of cancer data relating to various ethnic groups that are over-represented in advanced cancer diagnosis statistics, will inform policy and service planning to support better screening and treatment outcomes. The proposed addition of IHI will ensure that the Regulations keep up to date with the projected move towards e-Health in Australia and internationally. ECOG status, as a measure of how cancer affects the daily living abilities of a patient, will be an important addition to the Regulations. Through appropriate risk adjustment, ECOG status data will support more valid epidemiological interpretation of health outcomes.

Figure 1 below illustrates the flow of information to the VCR and identifies the points at which gaps in data may arise; primarily in the lack of information from private radiotherapy and day oncology treatment centres.

Figure 1: The flow of information to the Registry and identification of data gaps



2.3. Risks Associated with Non-Intervention

Without the information collected through the workings of the Regulations and the maintenance of the data integrity of the VCR, it would be significantly more difficult and costly to manage and plan for a range of cancer services, and to provide data for cancer research. This would result in increased expense, as each group sought to undertake re-collection of the cancer data separately in an inefficient, *ad hoc* manner, as well as increased imposition of administrative burden on hospitals, pathology laboratories and other registries, who would all receive increased applications for data from the disparate groups.

In the absence of the Regulations, some data items may be derived from the data captured in the Victorian Admitted Episode Data (VAED); however, this dataset does not contain data of the same type and detail and would not allow for continued retrospective analysis against the existing dataset in the VCR. In addition, as cancer care is increasingly delivered on an ambulatory (or non-admitted) basis, the VAED would fail to capture a significant proportion of new cancer cases.

The risks associated with the absence of regulation are described in further detail below.

- **Reduced integrity of the Victorian Cancer Registry.** Without prescribing the particulars to be provided about each cancer diagnosis, and thereby detailing the minimum information requirements, there is a risk that the integrity of the register would be diminished over time. People responsible for notifying the Registry of a cancer case may either not provide adequate information to enable the case to be registered at all, or may provide incomplete information, leading to an erosion in the type, data and quality of information collected by the Registry or additional costs in following up on missing data items.
- Alternatively, reporting agencies may challenge the authority of the Registry to collect such information. A highly probable result would be the progressive reduction in the integrity of the Registry over time. This would in turn jeopardise the ability of the Registry to function as the official cancer record keeper and to provide full and accurate data to policy makers, public health practitioners, researchers, health service providers and people affected by cancer.
- **Reduction in the type and quality of cancer data that is available.** Without the cancer information collected through the workings of the Regulations, it would be significantly more difficult and costly to manage and plan a range of cancer services, and to provide data for epidemiological and cancer research. Individual cancer research studies would be obliged to collect their own data through surveys. The retrospective collection of relevant data by survey could potentially miss cases or be subject to selection error and bias. Larger sample sizes would therefore be required, at a higher collection cost.
- Without the existence of the Regulations, the ready access to population-level cancer data for service planning purposes would be lost, limiting the ability of policy makers to formulate policy options for the improvement of cancer management and treatment. In addition, the ability to evaluate public health interventions such as tobacco control measures or respond to concerns about potential disease clusters and carcinogen hazards would also be reduced, negatively impacting on the health protection obligations of the Department of Health.
- **Inability to correctly participate in the National Cancer Statistics Clearinghouse activities**. Without the existence of Regulations, and with the Victorian cancer data consequently being potentially compromised, the VCR would not be able to provide adequate information to the NCSCH, which is responsible for the monitoring and analysis of national cancer incidence and mortality. This would erode the quality and completeness of the national dataset, as well as hinder Victoria's participation in national and international research collaborations.
- **Failure to further the policy intent of the authorising Act.** The Act assumes that Regulations setting out prescribed matters will exist to support the objectives of the Act. The proposed Regulations will be made under section 60(4) of the ***Cancer Act 1958*****.** [8]

3 Policy and objectives

3.1. Policy Environment

The proposed *Cancer (Reporting) Regulations 2012* and the suggested extensions to the data elements collected align with a number of key state and federal policies, discussed in further detail below.

3.1.1. Victorian Cancer Act, 1958

As noted in Section 1.2 above, Section 60 of the *Cancer Act* (Reporting of cancer) lists the persons required to report under the Act, as well as the conditions under which such reporting must take place.[6]

The Regulations further note the particulars of what must be reported to the Council and within what time frames, for each of the listed persons.[7]

Section 60(4) of the *Cancer Act* notes that the Governor in Council may prescribe additional categories of health service establishments that must report as well as prescribe the form of any report or prescribe the time within which any report is required to be made.[8]

The proposed Regulations therefore comply with the intent and purpose of the Act.

3.1.2. Victorian Health Priorities Framework 2012 – 2022

The Victorian Health Priorities Framework[12] lists a number of principles that are of particular relevance to the proposed Regulations, namely:

- Universal access and a focus on those most in need.
- Equitable outcomes across the full continuum of health.
- Evidence-based decision making.

The proposed Regulations with the extension of the data elements to be reported, focus on collecting improved information on some of the most vulnerable and hard-to-reach members of the Victorian community, including Aboriginal and Torres Strait Islander and ethnic communities that are over represented in advanced cancer diagnosis statistics. The maintenance of, and improvement to, the data asset controlled by the VCR will serve to respond to these needs and work within the principles outlined in the Victorian Health Priorities Framework.[12]

Two health-focused outcomes, listed below, respond directly to the principle of evidence-based decision making and are of key relevance to the objectives of the proposed changes to the Regulations:

- Care is clinically appropriate and cost-effective, and delivered in the most clinically appropriate, cost-effective settings.
- The health system is highly productive and sustainable.

These outcomes are supported and enabled by the reform priorities outlined in the Victorian Health Priorities Framework,[12] in particular the statement “Utilising e-health and communications technology.” The proposed Regulations support this priority by including a requirement to report IHI (if known) in order to prepare for the move to individual controlled health records and an integrated e-health network.

3.1.3.Victoria's Cancer Action Plan 2008-2011

Victoria's Cancer Action Plan (VCAP) [2] outlines a medium-term vision for cancer reform that will offer standardised high-quality cancer care to all Victorians, regardless of where they live, and sets measurable targets across the spectrum of cancer control. The VCAP was released in December 2008 with new four-year funding for implementation of a range of initiatives across four Action Areas: Screening and Prevention, Research, Treatment and Support. The overarching target for VCAP is to increase cancer survival.

The VCAP also includes the development of a comprehensive suite of quality and service improvement initiatives and programs, such as a Cancer Services Capability Framework, clinical indicators and clinical audit, and monitoring and benchmarking of cancer treatment outcomes.

All of these initiatives are designed to ensure that Victorians with cancer can be confident of access to timely, high quality and affordable services. The data held by the VCR is critical to support and inform these initiatives and to measure VCAP targets and outcomes.

3.1.4.Closing the Gap and the National Indigenous Reform Agreement

The National Indigenous Reform Agreement (NIRA) was agreed by COAG (the Council of Australian Governments) in November 2008. The agreement:

- commits all jurisdictions to achieving the Closing the Gap targets
- spells out an integrated strategy for achieving the targets in urban and regional areas, as well as in remote Australia
- defines responsibilities and promotes accountability among governments
- notes the significant funding provided through Indigenous-specific National Partnerships to assist in meeting the targets, and
- links to other National Agreements and National Partnerships for all Australians that include elements addressing the Closing the Gap targets.[13]

One of the key schedules to the NIRA is a commitment to improve data quality, which is required in order to measure progress towards the Closing the Gap targets. The extension to the proposed Regulations is in keeping with the spirit of this Schedule and will contribute to Victoria's commitment to monitoring the Closing the Gap targets.

3.1.5.E-Health

The National E-Health Transition Authority (NEHTA) has been tasked with developing the Personally Controlled Electronic Health Record, an undertaking to which all State and Territory governments are committed. One of the first steps has been the development of the Healthcare Identifiers Service, which identifies both individual consumers as well as organisations involved in healthcare across Australia. The proposal to include the Individual Healthcare Identifier (IHI) as a data element in the proposed Regulations is part of the move to ensure that the Regulations keep pace with the rapid changes occurring in the delivery of healthcare in Victoria and across Australia.

3.2. Objectives

The existing Act and Regulations are enablers of the health system; that is:

- they prescribe the agencies that are required to report cancer cases;
- they outline the minimum data set to be reported;
- they list the time in which the report is to be made; and
- they authorise and empower one agency to be the repository of the data.

The aim of the proposed Regulations is:

"To capture comprehensive data on new cases of cancer diagnosed and treated in Victoria, in order to monitor best practice and be accountable for health and treatment outcomes."

The objectives of the proposed changes to the Regulations are to:

- improve data collection, by extending the Regulations to cover private oncology and day chemotherapy centres, areas of increasing importance in the treatment pathways for people suffering from cancer, but whose data is currently not being captured in a systematic, consistent and prescribed manner;
- enhance the collection of demographic data currently submitted under the Regulations, by explicitly calling for the reporting of ATSI status and details related to ethnicity, thereby improving the monitoring of health outcomes for specific populations groups and to better inform prevention, screening and treatment programs;
- introducing the mandated reporting of ECOG status, a clinical measure of how cancer affects the daily living abilities of a patient. This will allow for improved monitoring of best practice treatment;
- introducing the collection of IHI to prepare for implementation of e-health reform. The IHI, which is an unique identifying code, gives individuals and healthcare providers confidence that the right health information is associated with the right individual at the point of care;
- clarifying the staging data which is required to be reported with preference for the internationally accepted Tumour, Node, Metastases (TNM) site specific staging system.

4 Options to address the problem

4.1. Options considered and rejected

A broad range of options to address the problem was considered by some key stakeholders within the Department of Health and the Cancer Registry. Reporting of cancer by aged care facilities, which is carried out in NSW and Queensland, was considered as an option but rejected, as it would mean a lot of additional reporting by a large number of additional facilities. This additional reporting burden would not merit the small number of additional cancer cases which would be captured. Most cancer cases are reported when aged care patients move to a hospital for diagnosis and treatment and any cancers not reported through hospitals would be later captured through reporting from death certificates.

The additional reporting of cancer which is diagnosed through radiography was considered as an option, but this would lead to a lot of extra reporting by a large number of providers, many of which are small businesses. Key stakeholder consensus was that the additional burden of reporting by these providers and the additional effort required by the cancer registry to incorporate this complex data, would not be worth any potential benefit obtained.

Tripartite memoranda of understanding between individual hospitals, the Department of Health, and the Cancer Council regarding the reporting of cancer cases is a possible non-regulatory option which was considered. The administrative burden of setting up these agreements would be large and there would be issues related to compliance and transaction cost which would outweigh the benefits of reporting in this fashion.

The option of reducing the existing data requirements to reduce reporting obligations by some groups was considered not to be feasible as the duplication of notification is an important principle built into the system from its inception and underpins the functioning of all Australian cancer registries. Notifications to the VCR from several institutions may be received for the same cancer, allowing a check for completeness to be performed and the collection of additional information to occur, if necessary.[10] The data details also need to be collected to fulfil Victoria's obligations of reporting to the Commonwealth.

4.2. Non-Regulatory Option

4.2.1. The Base Case

In the case of regulations that are under review, it is government policy that the RIS compare the regulatory option with the so-called base case; the situation that would occur, were there to be no regulations. This non-regulatory option will be used as the base case from which to compare the regulatory options discussed in Section 4.3, below.

Under the base case, the current Regulations would sunset in March, 2012 and no further Regulations would be put in place. The *Cancer Act* states that "*the person in charge of any place where a cancer test is undertaken shall, when t*he test indicates that a person is suffering from cancer, cause a report of that test be forwarded to the Council". This provision allows that, even if no regulations exist, pathology laboratories will still be required to provide a 'report' of cancer cases. However, this will be an incomplete data set as not all cancers are diagnosed based on pathology tests: seven percent (7%) of cancers reported to the registry are not based on a pathology diagnosis. Specific data items captured under the current regulations will also be missing under this base case, including clinically determined information, such as date of diagnosis and extent of disease (non-histologically defined). As reporting of cancer by hospitals, prescribed health service establishments and prescribed registers

is further specified by the Regulations, it would not be obligatory for these notifying bodies to report to the VCR, in the absence of Regulations.

To access data regarding the incidence of cancer in Victoria, the demographics of those individuals suffering from cancer, and the particulars of their diagnosis and treatment, it would be necessary to combine pathology report notification with other data sources such as the VAED or data from individual hospitals and registries. To replicate a population registry under this approach would incur significantly greater cost to the Department of Health and funded agencies. The alternative would be that the government would only collect *ad hoc* data to support specific functions on a case by case basis. It is likely that researchers would seek improved access to the VAED and any other relevant data collections held by the Department, which would be an added burden to the Department.

The VAED does not hold patient names with the coded data. Details of treating doctors are missing as well as the date of cancer diagnosis, the laterality, grade and staging details of the cancer. Thus the data that it would be possible to extract from the VAED is markedly inferior to that which is available from the VCR.

This option would compromise the continued integrity of the VCR data collection and consequently the national cancer data collection, impeding the ability to track and monitor trends over time. In addition, this option would also compromise the integrity of research activities which rely on having a whole of population dataset and require increased sample sizes to account for potential bias.

4.3. Regulatory Options

4.3.1. Regulatory Option 1 – current Regulations

Regulatory Option 1 proposes the retention of the Regulations as they are currently drafted, with all of the existing provisions and the existing prescribed particulars for reporting to the Registry.

This option would maintain the status quo for data collection, without seeking to improve the data in the Registry, or modernise it consistent with contemporary policy and cancer control objectives.

4.3.2. Regulatory Option 2 – proposed Regulations

The scope of the proposed Regulations is similar to that of the existing Regulations. Regulatory Option 2 proposes to extend reporting Schedule 2 (Appendix D) to include private radiotherapy centres and day oncology treatment centres. A new Schedule will also be added to the Regulations in order to prescribe specific health service establishments carrying out treatment of cancer patients. This will bring the Regulations in line with the intent of the *Cancer Act 1958* which is that reporting of cancer data includes reporting by hospitals and prescribed health service establishments. This will improve the completeness of data collection from all treatment sources. Cancer treatment carried out by outpatient radiation oncology services and chemotherapy centres is a rapidly growing area of cancer care. The option also includes one clarification to an existing data item (Staging) to note that staging data is to comply with existing accepted international standards.

The specific provisions of the proposed Regulations largely replicate the existing Regulations. There is some reordering of the current Regulations (Schedule 2) in relation to cancer staging information to clarify the preferred reporting format. Under the changes the internationally accepted Tumour, Node, Metastases (TNM) site specific staging system is listed first, as the format most preferred, and the simplified ‘degree of spread’ staging system is ordered last, as the least preferred.

The additional data elements proposed in this iteration of the Regulations will be prescribed for one or more of the reporting groups; hospitals (Schedule 2), prescribed health service establishments (Schedule 2), prescribed registries (Schedule 3), and pathology groups (Schedule 4) (See Appendices

D, E and F for a description of the particulars in each of the existing Schedules). Three of the data elements are general patient details and one seeks clinical information. The proposed elements are:

- Language spoken at home (if known) to be added to Schedules 2, 3 and 4 (for reporting by all notifiers);
- Country of Birth (if known) to be added to Schedule 3 and 4 (for reporting by prescribed registries and pathology services);
- Aboriginal or Torres Strait Islander status (if known) to be added to Schedule 4 (for reporting by pathology services); and
- Individual Health Identifier (if known) to be added to Schedules 2, 3 and 4 (for reporting by all notifying bodies).

As with the extension to the Regulations, the additional data elements are necessary for the completeness of the data. The enhanced collection of demographic data, through the reporting of ATSI status and details related to ethnicity, will help to improve the monitoring of health outcomes for specific population groups and will better inform prevention, screening and treatment programs. Introducing the collection of IHI will help to prepare health services, registries and pathology services for the implementation of e-health reform.

ECOG performance status (if known) will also be added to Schedule 2 for reporting by hospitals and prescribed health service establishments. ECOG performance status uses scales and criteria to:

- assess how a patient's disease is progressing;
- assess how the disease affects the daily living abilities of the patient; and
- determine appropriate treatment and prognosis.

The addition of ECOG status will allow for improved monitoring of best practice treatment. The ECOG scale is presented in Table 2 below.[14]

Table 2: ECOG status definitions

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

4.3.3.Regulatory Option 3

Regulatory Option 3 proposes that the Regulations change so that the data which is reported to the Registry is supplemented with a series of additional data items reported for separate tumour streams, similar to the inclusion of Clark's level and thickness for melanoma cases in the current Regulations. This would require the inclusion of a series of additional data items within the Schedules of the Regulations to prescribe which additional data attributes should be reported for the different tumour

types where applicable. These additions would be limited to the most common tumour types (breast, prostate, colorectal and lung cancers) and may include up to an additional four data items for each. These data items will be ones which provide significant prognostic value of health outcomes and where the data are not readily available from other routine data sources. For example, based on current evidence of prognostic value, two additional items would be relevant for prostate cancer cases, Gleason grade and pre-biopsy Prostatic Specific Antigen (PSA) level (if known). Although not captured elsewhere, it is highly likely that these two data items would be recorded in a patient's medical record for the former item or within the pathology report for the latter.

Option 3 was proposed through the targeted consultation process, by a group of academic and clinical researchers, in order to improve the clinical applicability of the cancer dataset as a research tool. This approach was considered to be consistent with current work being undertaken by Cancer Australia.

The data collected under this option would provide more clinically useful information, however the time taken to provide the additional items to the VCR would increase as would the time taken by the registry to process the information. The prognostic importance of these additional data items would assist in the relevant risk adjustment and epidemiological interpretation of health outcomes for Victorians with these specific cancers and assist research of various sub-populations.

Currently there is significant work being undertaken by Cancer Australia to explore ways in which existing and additional cancer data could be more effectively used or linked, to provide information that will enhance service provision, treatments and outcomes for people affected by cancer. Part of this work includes the development of a range of national Cancer (clinical) Data Set Specifications (DSS) which will be submitted to the National Health Information Standards and Statistics Committee (NHISSC) for endorsement for use Australia wide. Victoria can position itself to be ready and able to incorporate key data elements from the DSS on endorsement consistent with its objective of contributing to national data collections and research. Refer to the Cancer Australia website for additional information on the 'National Cancer Data Strategy for Australia' (http://canceraustralia.gov.au/cancer-data/national-cancer-data-strategy).

5 Cost Benefit Analysis

5.1. Costs – Burden of Reporting

5.1.1. Option 1: Current Regulations – Costs of Existing Reporting

The major burden of reporting falls on the largest hospitals treating cancer patients and the largest pathology laboratories carrying out cancer tests. These hospitals and pathology groups have been asked to provide information on the burden of reporting through the targeted consultation.

Nine of the largest health services that provide cancer care were consulted in the development of this RIS. These accounted for approximately 32% of all hospital notifications to the VCR in 2010.

Additionally, some smaller health services were contacted as part of the targeted consultation to inform this document and were asked to advise on the average time taken and cost of reporting cancer cases under the Regulations. In hospitals, cancer notification is predominantly undertaken by Health Information Managers (HIM) or other trained staff involved in clinical coding activities following a patient's discharge from hospital.

This approach was taken based on the fact that there are three methods of reporting routinely used by health services; paper, web and electronic, via reporting software. The majority (85%) of health services notify electronically via their internal Information Technology (IT) Patient Administration Systems, where cancer notifications are a by-product of usual clinical coding activities. This electronic notification method is highly efficient. In total this group contains 94 separate health services (campuses) and in 2009 they reported a total of 34,667 cases (85% of all notifications). Informants advised that, on average, the notification process by the Clinical Coder takes between 2 to 5 minutes per case, with some economies of scale achieved by the largest notifiers.

A small proportion of medium sized notifying health services (15%) use a web-based e-form which facilitates direct transfer of data to the VCR, although it does not link with internal health service IT systems necessitating additional data entry. This group includes 83 notifying organisations and in 2009 they reported a total of 6,117 cases (15% of all notifications). Informants advised that, on average, the notification process using this method takes 5 minutes per case.

The remaining 192 notifications (0.5%) are received from 11 very small health services and involve the completion of a paper form, which is then mailed or faxed to the VCR. Informants advised that, on average, the notification process using this method takes 5 minutes per case.

Similarly, pathology laboratories are grouped based on their method of reporting where they either print and forward to the VCR a paper copy of the relevant pathology report or where they transmit their information to the VCR in electronic form.

Table 3 below presents the average time and costs involved with reporting to the registry on a per agency basis.

Costing assumptions include:

- For hospital notifiers, salary costs are calculated based on a Grade 1, Year 1 Health Information Manager (HIM) as per the VHIA Salary Circular (Number 491, 4 November 2010) – [$877.50 per week].
- Information on costs for the prescribed registers is as reported by the informants within these organisations.

- Pathology costs are estimated based on reported time taken, with salary costs based on a Grade 1 Year 3 Medical Laboratory Technician salary as per the VHIA Salary Circular (Number 491, 4 November 2010) – [$843.30 per week].
- All costs adjusted by overhead multiplier of 1.75 as provided in the Victorian Guide to Regulations.
- No costs are included for the current operation of the VCR as these are unlikely to be impacted under any of the options considered due to the ongoing legislative requirement for pathology reporting. Thus this funding is being treated as a fixed cost. Please refer to the detailed discussion below.

Table 3: Cost burden of reporting to the VCR

Reporting agency	Number of agencies *	Current reported average time taken per report (in minutes)	Current average number of reports received by VCR per annum	Current average cost per report (based on relevant hourly $wage of responsible person)	Current average total cost per agency type (number of reports x cost per report) / number of agencies) per annum or as reported*
Hospital:			40,976		
Small[i]	11	5 min.	192	$3.37	$646.58
Medium[ii]	83	5 min.	6,117	$3.38	$20,669.34
Large[iii]	94	2-5 min.	34,667	$2.36	$81,721.18
Registries:	2		4,052		$1,435
Pathology laboratories:			41,420		
Paper[iv]	24	9 min.	13,914	$5.80	$81,055
Electronic[v]	9	0.1 min.	27,506	$0.06	$1,650.36
TOTALS			86,448		$187,177.46

i – defined as a hospital submitting paper reports to the VCR

ii – defined as a hospital submitting data via VCR website

iii – defined as a hospital submitting data using health software

iv – defined as a pathology laboratory submitting paper reports to the VCR

v – defined as a pathology laboratory reporting to the VCR electronically

* *This represents the number of agencies who reported to the VCR in 2009. There are number of small hospitals and health services who may report cancer cases only once every three or four years and the number of laboratories reporting varies year to year as services amalgamate and close.*

Cancer incidence is growing at an average rate of 2.8% and adjusting these current costs by this factor over the 10 years of the Regulations (as currently framed, i.e., Regulatory Option 1) and analysing cash flow using a 3.5% real discount rate calculates the net present value (NPV) as $1,754,418.

Regulatory Option 1 proposes the retention of the Regulations as they are currently drafted, with all of the existing provisions and the existing prescribed particulars for reporting to the Registry.

This option would maintain the status quo for data collection with the current costs of reporting costs of reporting as outlined in Table 3 adjusted for average yearly growth in cancer incidence giving a NPV over the 10 years of $1,754,418 (refer to Appendix G, Table 16).

5.1.2. Regulatory Option 2: Proposed Regulations - Cost of proposed reporting

Consultation indicates that, if the proposed additional data elements (that is, patient details) proposed under Regulatory Option 2 are captured through existing hospital admission, and/or pathology test requesting processes, then the reporting related additional marginal costs at the time of notification, will be negligible. However, there would be some software modification costs associated with the changes to ensure data capture, plus some minor staff costs associated with understanding any changes to the regulations.

In the case of hospitals using the Department of Health *HealthSmart* products, software modification costs are funded by the Department. The proposed implementation date of Regulatory Option 2 (1 July 2013) is designed to coincide with the Department of Health's usual schedule for the implementation of any changes to hospital's reporting requirements and software modifications. This proposal enables any software and implementation costs associated with Regulatory Option 2 to leverage off normal Departmental change processes. It should also be noted that the administrative costs of clinical coding, hospital VAED reporting and cancer notifications is incorporated into the costing data used to determine activity based funding (ABF) prices paid to public hospitals to fund their operations.

The addition of the private Radiotherapy Centres will impose a cost burden on the private provider. Currently, the only analogous notifying service is the William Buckland Radiotherapy Centre which reported that their estimated cancer notification costs are approximately $500 per annum for 1,350 cases treated on 4 linear accelerators. The private Radiotherapy Centres will likely incur a higher cost than this estimate due to the expectation that the level of activity across the multiple sites (6 sites with a total of 11 linear accelerators) will be higher (currently an unknown number). However, it is likely that these costs would be a multiple of the costs incurred by the William Buckland Radiotherapy Centre commensurate with their additional linear accelerator stock. Given the private radiotherapy centres have 2.75 times the number of linear accelerators compared to William Buckland, but may be treating less complex patients we have assumed their costs will be 3 times greater. Based on this assumption the private Radiotherapy Centres will incur notification costs of an estimated $1,500 per annum. It is assumed that this estimate will not vary significantly with increasing cancer incidence as activity is constrained by the linear accelerator stock. A more detailed discussion of the applied growth factor and underlying assumptions is provided below. The Department will monitor impacts once reporting commences.

The two private Day Oncology Centres which would be added to the Regulations under Option 2 are already reporting to the VCR and this change to the Regulations will have no additional cost impact.

Consultations also suggest that the capture of ECOG status would involve negligible additional notification related costs, but does rely on the relevant clinician documenting this clinical detail in the patient medical record to enable it to be extracted by clinical coders. Similar to the collection of additional patient details, there would be a need to modify software to enable ECOG status to be recorded as part of the electronic notification process.

A number of those consulted indicated that the main difficulty associated with ECOG status relates to their experience that it is not routinely documented in the patient medical record by clinicians. The Department of Health, through its Integrated Cancer Services (ICS) program, is working with hospital based cancer services and clinicians to improve the recording of patient clinical details such as cancer stage and ECOG status as part of routine practice. This work will be on-going and will support the improved recording of patient clinical details relating to cancer and incidentally support improved

cancer notification. The department's ICS program funds quality and service improvement infrastructure based on geographic regions as part of its cancer care improvement reforms.

However, it is assumed that the addition of ECOG status to the Schedule 2 will require some additional effort and cost by clinicians in hospitals recording ECOG status in the medical record so that it can be abstracted by clinical coders at the time of notification. For this analysis it is assumed that an estimated 50% of cancer cases notified will currently have ECOG recorded by clinicians as part of good clinical care or associated with patient involvement in clinical trials. As noted above, the Department of Health is working with clinicians to improve relevant clinical data recording and capture and it is anticipated that there will be improvement in this documentation over the life of the proposed regulations. The calculations relating to the cost of clinicians' time recording ECOG status, factor in this assumed improvement in documentation over time from 50% gradually reducing to 0% by year 9.

Based on the above analyses of costs, the following comments can be made about the impact of the Regulatory Option 2 relative to the Non-Regulatory Option:

- Costs incurred at the time of reporting cancer cases are likely to be negligibly increased above current costs incurred (estimated at $103,037) for hospitals and prescribed registries (estimated at $1,435). An additional 30 seconds per case notified is factored into the analysis for hospitals reporting additional items (estimated at $17,302) from 2013 (adjusted for cancer incidence growth). These incremental costs will only apply from 2013 when the regulatory changes would come into effect.
- The private Radiotherapy Centres (one group of six practices) will incur additional costs, estimated to be $1,500 per annum. This amount will not mirror the growth in cancer incidence over the life of the regulations as radiotherapy (linear accelerator) machine capacity determines their activity levels more than cancer incidence. Radiotherapy service planning parameters incorporate the assumption that radiation treatment is estimated to only be of benefit in 50% of cancer cases.[15] Also new linear accelerators require a licence from the Australian Government to enable access to Medicare Benefit payments[16] which are considered necessary to ensure commercial operating viability. New linear accelerator machines must be imported and can take up to 18 months in installation and commissioning. Realistically unless new licences have already been issued it will be a few years before additional capacity would become operational. For these reasons growth in the number of private radiotherapy centres or capacity is expected to be quite limited over the 10 year life of the regulations. For the purposes of this costing analysis a 50% proportion of average annual cancer incidence growth is applied from the fourth year of the 10 year cycle. This is potentially an over-estimate.
- The two private oncology centres are already reporting and therefore their costs are included in the estimated hospital reporting costs (noted above).
- Costs incurred by pathology groups would be predominantly unchanged as they will still be required under the Act to forward reports to the VCR (see section 4.1.1). However, the pathology groups are being asked to supply some additional information where available. This data will be provided by the clinician or service requesting pathology tests, or at the point of specimen collection for example by a nurse provider, and may require some modification to a pathology services 'request slip' formats. Request slips signed by a qualified medical practitioner are a legal requirement for the ordering of pathology and other diagnostic tests. It should be noted that most hospital patients will have patient identification (adhesive) labels used to complete patient details on request slips. Patient identification labels generally record demographic details such as name, date of birth, address, ATSI status, country of birth and language spoken (for interpreter services as relevant) taken from hospital patient administration IT systems. It is expected that as IHI becomes a national standard then these details will also be included in routine patient administration IT systems. Also where pathology

laboratories are integrated with hospitals, they will share patient administration IT systems, which will generally have these additional data items electronically recorded. An estimate of 5% of the total pathology reporting costs ($4,135 per annum) is included to cover any additional costs associated with the additional reporting requirements.

- Costs incurred at the time of reporting cancer cases are likely to be negligibly increased above current costs incurred prescribed registries (estimated at $1,435) as, similar to pathology services; these details are generally available to the person referring the test or cancer case and will be included in local patient administration IT systems. An estimate of 5% of the total reporting costs is included to cover any additional costs associated with the additional reporting requirements. These costs will only apply from 2013 when the regulatory changes would come into effect.
- If changes are made to the regulations there will be some (one-off) effort and cost incurred by the notifying agencies in understanding the new regulations. These have been estimated at 30 minutes for a small agency (less than 200 hospital notifications), 60 minutes for a medium sized agency (200 – 1000 hospital notifications or less than 1200 pathology notifications) and 120 minutes for a large agency (more than 1000 hospital notifications or 1200 pathology notifications). The total cost for hospitals are estimated to be $5,294 and $1,748 for pathology groups and $155.34 for prescribed registers.
- There is some suggestion from the VCR that they may require additional staff resources to process the additional notifications from the private radiotherapy centres (estimated as one full time equivalent staff member) to maintain timeliness of the registry collection. Consideration of this investment will require a business case but is estimated to impose a very modest burden on the department, assumed to be a base cost of $65,000 ($113,750 adjusted by 1.75 overhead multiplier) based on the example cited by the VCR in relation to recruitment of a data manager for specific research projects (refer following section).
- There will be software modification costs incurred but these cannot be estimated in advance with any certainty and would require the development of detailed data specifications to allow software vendors to quote on the required changes. However, a best estimate of software costs is included in the analysis based on $50,000 for *HealthSmart* software (covers a significant number of public health services), $10,000 for modification of the VCR web-based e-form (covering all e-form notifiers) and an additional $90,000 to cover the cost of software modifications at the residual hospitals, prescribed registers and pathology services. This estimate is based on nine $10,000 system modifications allowing for the large number of residual notifying hospitals and laboratories covered by private health groups such as Healthscope, Ramsay Health Care, St John of God Health Care and St Vincent's and Mercy Private where software costs would be shared. These are fixed costs, incurred once and offset against benefits accruing over the life of the Regulations (10 years).

Given that the Regulations will last for 10 years, relevant cash flow analyses have been undertaken applying a 3.5% real discount rate and factoring in an annual average 2.8% increase in cancer incidence (unless specified). This analysis is provided in Appendix G, Table 14. The total NPV of Regulatory Option 2 is estimated to be $2,500,383 over the 10 years.

5.1.3. Regulatory Option 3: Separate tumour streams - Cost of proposed reporting

Costs associated with Regulatory Option 3 relative to the base case of the Non Regulatory Option will be higher than those associated with Regulatory Option 2 although the order of magnitude is unknown as total costs will depend on the number of additional data items and related software modification costs. It is known that the cancer cases for the four nominated cancer tumour streams make up a

significant proportion of all cancer incidence. In the most recently published cancer incidence data (2009) these four tumour streams accounted for 53% of total new cancer cases. [3]

Cancer Type	Male	Female	Persons	% of Total
Bowel	1,992	1,627	3,619	13%
Lung	1,387	987	2,374	8%
Breast	30	3,264	3,294	12%
Prostate	5,609	n/a	5,609	20%
Subtotal	9,018	5,878	14,896	53%
All Cancers (2009)	**16,237**	**12,077**	**28,314**	**100%**

For the purposes of this RIS it is assumed that the costs of data collection and notification for hospitals will double under this option (related predominantly to the time taken for clinical coders to locate, interpret and report the additional clinical items) due to the high proportion (approximately half) of all cancer cases affected under this option. As noted under section 4.3.2 many of the anticipated data items (such as smoking status and history for lung cancer patients and Prostate Specific Antigen level and Gleason Score for patients with prostate cancer) should and hopefully will have been documented in patient medical records or pathology reports as part of routine clinical care. However, the documentation of some of the required data items by clinicians may be sub-optimal in some instances. As an estimate to account for this possibility the clinician time commitment to record the additional clinical information has been doubled under this option. A gradual improvement in documenting by clinicians is also included for option 3 as once defined and reported to the VCR, there will be the opportunity to determine the extent of missing data, provide appropriate feedback to notifying organisations and so improve compliance over time. This may be an underestimate and comment is invited on the appropriateness of this estimated growth factor.

Understanding the regulations under this option is assumed to require more effort due to the differential nature of the datasets needed for different tumour sites and has been tripled compared to option 2 ($21,591). This growth factor (triple) has been applied not just to hospitals but also to prescribed registers and pathology laboratories as some clinical information may be sourced from these two latter sources (particularly in relation to the follow up of missing data) and they will need to understand the impact of the regulations even if directly applied to hospitals rather than to themselves.

It is also assumed that the software modification costs for hospital notifiers will be triple those associated with option 2 (from $150,000 to $450,000) and that the registry will require a total of two additional full time equivalent data managers to process the additional information. Again this latter assumption relates to the high proportion of notified cancer cases being impacted (approximately half) and the fact that the VCR staff may need to abstract or follow up on any missing data (for example to abstract Gleason score from pathology reports). The software modifications are estimated to triple as they will not simply involve the addition of a few data fields but would require more sophisticated business rules that link the primary cancer site codes with the specific additional data items relevant to that tumour. This may be an underestimate and comment is invited on the appropriateness of this estimated growth factor.

Detailed analysis of this option is provided in Appendix G, Table 15. The total NPV of Regulatory Option 3 is estimated to be $4,754,810 over the 10 years, $2.2 million greater than Option 2.

5.1.4. Non Regulatory Option (Base Case)

As noted above under Non Regulatory Option, there will still be some costs associated with pathology notifications to the VCR under the Base Case. Also as noted below, the Department investment in the operation of the VCR is assumed 'fixed' for all options including this base case and is not explicitly

included here. The costs associated with pathology reporting are estimated to be $82,705 per annum for pathology notifications (refer to Table 3. above) with a NPV over the 10 years of $775,199 (refer to Appendix G, Table 17).

The quality of data available would be lower under the base case due to the missing clinical information from hospitals, prescribed health services and prescribed registers. Work required by the VCR would therefore involve processing and matching notified cases and following-up with hospitals and other services to source missing information or confirm unique identifying data.

Comparison of the incremental cost impact of the range of options is provided in the following table. Table 4 shows that the incremental NPV cost of the preferred option (Regulatory Option 2) is $1,725,184 ($2,500,383 minus the base case cost of $775,199).

Table 4: Comparison of NPV total and incremental costs of the regulatory options and the base case

Option	NPV 10 year costs	Incremental costs compared to Option 1 (status quo)	Incremental costs compared to Base Case (no regulations)
Base Case - no regulations	$ 775,199		
Option 1 - status quo	$ 1,754,418		$ 979,219
Option 2	$ 2,500,383	$ 745,965	$ 1,725,184
Option 3	$ 4,754,810	$ 3,000,392	$ 3,979,611

Cost of Maintaining and Operating the Cancer Registry

The Department of Health provides $508,000 funding per annum to the Cancer Council for the operation of the Cancer Registry. Pathology reporting would continue with or without reporting regulations. An estimated 93% of all cancer notifications currently include pathology reports so, although there would be less individual cancer notification records received by the VCR in the absence of regulation, there would still be significant work to be done. Whilst the majority of cancer incident cases could be captured under this base case, the lack of clinical and demographic details would require the VCR to undertake additional work to obtain the necessary level of detailed data and to resolve any inconsistencies (confusion as to the primary cancer site or to resolve person 'matches'). The quality of data available would be lower due to the missing clinical information from hospitals, prescribed health services and prescribed registers. This work would involve processing and matching notified cases and following-up with hospitals and other services to source missing or confirm unique identifying data. Assuming that Births Deaths and Marriages still provide death certificates to the VCR then there would also be ongoing work in processing cancer death data. On this basis it is not considered possible to reduce the current level of government investment in the VCR and this is therefore assumed to be a 'fixed cost' that applies for all considered options. The 10 year Net Present Value (NPV) of this investment in the VCR applying a 3.5 % real interest rate and factoring average yearly cancer incidence growth of 2.8% would be $4,761,495. This cost will not be explicitly applied to any of the options analysed but could be included in each.

	Year 1 (2012)	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	NPV
Government investment in VCR	$508,000	$522,224	$536,846	$551,878	$567,331	$583,216	$599,546	$616,333	$633,590	$651,331	$4,761,495

5.2. Benefits – Users of Data from the Cancer Registry

The Regulations create the parameters of the Registry, which is a highly valued data asset. Table 12 (Appendix B) provides some indication of the value of the registry to thousands of users of data, particularly since the on-line data kiosk was made available in 2009 through the Cancer Council website (7,681 total data requests in 2009). In addition to these data requests, there are numerous non-recorded uses of the cancer data, which are published in the yearly CCV Canstat publication.

The benefit and value of the registry can be assessed in a number of different ways, including quantitative. For example, research groups undertaking complex and time consuming participant recruitment, record linkage or data extraction are able to contract the VCR to undertake the work for a fee or charge. These charges are not prescribed in the Regulations but are set by CCV based on cost recovery. The following case studies demonstrate the (minimum) dollar value cancer researchers have placed on the data held by the VCR.

- Recruitment of 1,000 participants for a research project. This was charged at $65,000, as it required recruitment and training of a dedicated data manager.[17]
- Record linkages carried out for the notifying hospitals are provided free of charge. Linkages carried out for researchers or occupational cohorts are charged at $1,200 per day, with approximately 10,000 records requiring one day to link.
- Data extraction for researchers is calculated as for record linkage.
- Tullamarine cancer cluster analyses (conducted on behalf of the Department of Health's, Environmental Health Unit and the Environmental Protection Agency) were costed at $15,000 for provision and preparation of data (including geo-coding addresses and obtaining small area population data from ABS) and statistical analysis.

These values can be used as a de facto measure of the value of the Registry as a research and policy resource. In each of the examples above, the costs charged to researchers by the VCR to identify and recruit a 'study' participant from the registry database (e.g. fee of $65) represents what researchers are willing to pay. Assuming that an average of three notifications per cancer case is received by the VCR (each at an estimated cost of $3.37) then this 'fee' is well in excess of the estimated total cost burden of an individual case notification ($10.11).

The benefits of the Registry can also be expressed qualitatively. The targeted consultation with users of the Registry data revealed a number of key themes, presented in more detail below, with quotes from users of data to illustrate the theme. (Refer to table 9, page 39 for more information on data users consulted.)

1. The extension of the Schedule to cover radiation oncology and outpatient ambulatory chemotherapy centres will allow for better, more comprehensive ascertainment and assessment of patterns of care.

   "The changes to incorporate reporting from prescribed health services addresses an area of a growing blind spot…completely missed in the inpatient data (such as VAED) that many people take as prime indicators of cancer service workload. So access to cancer notifications from such services would provide a better assessment of the patterns of care for cancer patients." Clinician Researcher, Alfred Health

2. The Regulations ensure consistency with national and international reporting guidelines

   "Regulations work by defining and requiring specific data collections and have been fundamental to tracking and identifying successes and areas for improvement in cancer since the initiation of the register in Victoria. The Victorian Cancer Register processes and outputs are in line with best

practice throughout Australia and in key countries around the world." Academic Researcher, Victorian Comprehensive Cancer Centre

3. The Regulations are necessary to ensure quality and consistency of data capture.

   "Uniform requirements through regulations are important and are needed to aggregate mandatory key data to accurately report cancer outcomes to the public, health professionals and researchers." Academic Researcher, Victorian Comprehensive Cancer Centre

4. The VCR provides data to a range of public health practitioners, in particular environmental health, serving to protect the health of the community and address community concerns about environmental hazards generally and cancer clusters in particular.

   "Over time, there has been increasing community concern about potential hazards and exposure events and the possibility of perceived cancer clusters being caused by the hazard/exposure. Currently, Environmental Health receives one to two initial queries each week. Most of these can be dealt with through a desk-top review and assessment processes, but some require a more detailed assessment, which in the first instance requires use of the data from the VCR." Senior Medical Advisor, Environmental Health, DH

5. The VCR provides data to a range of researchers to support improved understanding of cancer, the epidemiology of cancer and cancer control, including cancer prevention programs.

   "…updated melanoma trend data and age-based declines suggest that sun protection messages are having a positive effect on incidence rates. There are positive correlations with melanoma incidence rates and the younger generations who grew up with the Slip! Slop! Slap! campaign and SunSmart messages, whereas older Victorians are still experiencing higher incidence rates". SunSmart, CCV

   "In the absence of cancer registries (including the VCR), reliable data on cancer occurrence, treatment and outcomes would not be available. Data gathered in other ways, such as from hospital inpatient data, is incomplete in both case ascertainment and in details about the diagnosis, type, and outcome for each person with cancer. Gathering similar data to compare cancer incidence, diagnosis and survival for Indigenous with non-Indigenous populations would require data collection from hospital inpatient data, supplemented by collection from pathology laboratory and in many cases from clinicians, which in effect would duplicate most of the VCRs data collection process for each research project but with less complete and accurate data." Academic Researcher, Menzies School of Health Research and Health Gains Planning Branch, NT Department of Health and Families

6. The VCR provides data to a range of Department of Health officers, policy makers and service planning consultants to inform policy development, service planning and program evaluation.

   "The Victorian Cancer Action Plan sets a target for improving cancer survival by 2015, the VCR produced survival data is critical to our ability to monitor our progress against this government set target." Cancer Strategy and Development, Department of Health

   Recent departmental publications demonstrate the use of cancer incidence and projections data in support of health planning activities. One such example is the Victorian Medical Radiations: Workforce Supply and Demand Projections (2010-2030) which relies on cancer incidence to project future workforce needs. These functions are critical to ensuring the ongoing efficient functioning of the Victorian health system.

7. All respondents emphasised the longevity of the Registry as a data asset, enabling studies across time in a defined geographical area.

"Without the existence of the VCR, we would not be able to gather similar data. We would be forced to use data collected in other states/countries which we believe have a similar disease profile to that of Victoria." Health Intelligence Unit, DH

8. The data from the VCR is also used routinely by screening programs as illustrated by the following comments from BreastScreen Victoria and the Victorian Cervical Cytology Registry.

   "Data from the VCR is used by BreastScreen Victoria to identify women who are diagnosed with an invasive breast cancer before the next scheduled screening episode. These are referred to as Interval Cancers and are reviewed by Service Radiologists to meet the BreastScreen Australia National Accreditation Standard (2.4.2a and 2.4.2 b)."

   In addition, BreastScreen Victoria undertakes cancer matching for women recruited into the Program via the Victorian Electoral Roll. This process ensures that women diagnosed with breast cancer are not invited to participate in the Program."

   "The VCR provides a valuable and essential service to both the Victorian Cervical Cytology Registry (VCCR) and to the Cervical Cancer Screening Program. The data collected on cervical cancers by the VCR is used to indicate the success of the screening program in terms of the number of cervical cancers reported and to demonstrate the importance of regular screening by reviewing the screening patterns of women diagnosed."

5.3. Multi-Criteria Analysis

Multi-criteria analysis is useful where it is not possible to quantify and assign monetary values to all the impacts of a regulatory option. In this analysis it is possible to quantify many of the costs of regulation but the benefits are difficult to quantify, as they are social benefits such as those described by users of data from the cancer registry in section 5.2 above.

- Option 1 – Retain the existing prescribed particulars for reporting to the VCR
- Option 2 –Proposed option – extension of reporting to private radiotherapy centres and day oncology treatment centres, addition of five prescribed particulars – Country of birth and language spoken at home, ATSI status, IHI, ECOG status
- Option 3 – Tailored reporting requirement by tumour stream
- Base Case – no Regulations

5.3.1. Criteria weightings and the values assigned to the alternatives

The criteria below have been used to assess the Regulatory options. These criteria have been chosen as they reflect the identified problem which is the requirement for cancer data to support research, cancer prevention activities, cancer control programs and policy development. The criteria also address the objectives of the proposed Regulations.

A weighting, which adds up to 100%, is assigned to each criterion. Based on the assessment of the identified options, discussed in Chapter 4, a score (-10 for negative outcomes to 10 for positive outcomes) is given to each option for all criteria, with the understanding that:

A high score means that the alternative partially achieves the regulatory objectives.

A low score means that the proposal does not achieve the regulatory objectives.

A score of zero for any criterion means that the option has been assessed as having a neutral impact in that area.

The weighted scores for each identified option are summed to provide an estimate of the highest ranking option.

Table 5: MCA Criteria weighting

MCA Criteria	Weighting
1. Effectiveness Supports the policy intent of the authorising legislation Preserves the integrity of the Cancer Register – maintaining a cancer database of high quality and accessibility Enables the Health Department to carry out functions related to cancer control	30 % - This is a very important criterion as it measures the critical function of reducing the burden of cancer and protecting the health of the community. The VCR is a vital resource for data to support policy, programme planning and funding, evaluation of health prevention and cancer control programs, epidemiological reports of burden of disease and investigation of potential environmental hazards
2. Support for Cancer Research- Enables the VCR to support relevant cancer research with provision of data, record linkages and the recruitment of cancer patients for research studies	20% - The registry supports important epidemiological, behavioural and & clinical cancer research to help determine the causes of cancer and improve health outcomes.
3. Costs - refers to the cost of providing data to the registry, the efficiency with which the Registry data are used and the desire to minimise unnecessary administrative costs in managing the Registry's functions.	40% - The provision of data by those reporting to the register has been costed in Table 3. Data from the registry is used by researchers, service planners, policy officers, cancer organisations, hospitals and clinicians, allied health, the general public, students, pharmaceutical companies, legal cases, national reports (AIHW), international requests and the media.
4. Implementation & Practicality	10% - it is important to assess any additional burden imposed by each Option and look at the implementation issues

Explanation of the Scoring

The scores assigned to each criteria as part of the qualitative assessment for each option, reflect the analysis of each option in the costs and benefits section of this RIS (refer to 5.1 and 5.2).

Option 1 – current Regulations

- scores well on the effectiveness criteria as it maintains the integrity of the cancer registry in providing high quality data to support the Department of Health functions
- scores very well in enabling cancer research by provision of high quality data
- costs of this option would be only slightly more than the base case as discussed in 5.1
- implementation will not require any software upgrades or changes to data collection and storage

Option 2 – the preferred Option

- scores well on the effectiveness criteria as it maintains the integrity of the cancer registry in providing high quality data to support the Department of Health functions
- scores well in enabling cancer research by provision of high quality data, enabling data linkages and recruiting subjects for research studies
- costs of this option would be only slightly more than the base case as discussed in 5.1
- implementation will require some software upgrades and changes to data collection

Option 3 – tumour stream specific reporting

- scores well on the effectiveness criteria as it maintains the integrity of the cancer registry in providing high quality data to support the Department of Health functions
- scores very well in enabling cancer research by provision of high quality data, enabling data linkages and recruiting subjects for research studies
- the costs of this option would be significantly more than the base case due to the need for collection of additional data as discussed in 5.1
- implementation will require software upgrades and significant changes to data collection and storage

Base Case

- This is considered to be the null case with no impact
- There would still be reporting under the Cancer Act without any regulations operating.

The table at 5.3.2 shows that all three options received a positive score. This implies that all of the alternatives considered are believed to be preferable to the unregulated base case scenario. However, Option 2 has a score of 2.4 which is higher than Option 3 with a score of 1.3 and Option 1, the current Regulations, which has a score of 2.2. The conclusion of this analysis is that the proposed measure, Option 2 is the most effective and appropriate to achieve the required objectives.

5.3.2.Analysis of Options or Weighted Scorecard

Criteria	Weighting	Base Case*		Option 1		Option 2		Option 3	
		Assigned Score	Weighted Score	Assigned Score	Weighted Score	Assigned Score	Weighted Score	Assigned Score	Weighted Score
1. Effectiveness/ Benefits	30%	0	0	8	2.4	10	3	10	3
2. Enabling Cancer research	20%	0	0	7	1.4	8	1.6	10	2
3. Costs	40%	0	0	-4	-1.6	-5	-2	-8	-3.2
4. Implementation and Practicality	10%	0	0	0	0	-2	-0.2	-5	-0.5
TOTAL	100%		0		2.2		2.4		1.3

* Note: The Base Case has been assigned scores of zero for comparison purposes, although it is known that there are costs and benefits associated with the base case.

5.3.3.Conclusion

The cost-benefit assessment of the impact of renewing the Cancer (Reporting) Regulations demonstrates that the benefits of maintaining the regulations (Regulatory Option 1) outweigh the costs. Regulations impose only a marginal increase in costs compared to the base case (no regulations) as the Act still requires pathology services to report cases to the VCR in the absence of regulations. The value of the benefits of VCR data to government and researchers is confirmed in the qualitative consultations as well as their demonstrated willingness to pay.

Regulatory Option 3, expanded clinical data collection by tumour stream, was assessed to be beneficial although it was also recognised that this would impose an additional reporting burden and would be administratively complex to collect, at much greater cost.

Regulatory Option 2 increases the cost of VCR data collection by only an incremental amount, predominantly in up-front fixed costs associated with modifications to information technology software. However, it was assessed that the ongoing benefits accrued across the life of the regulations, in terms of improved completeness, quality and access would offset these incremental costs. Based on these analyses Regulatory Option 2 is the preferred option.

6 The preferred option

6.1. Proposal Description

The scope of the proposed Regulations is similar to that of the existing Regulations with an extension that will improve the operation of the *Cancer Act 1958*. It will require private radiotherapy centres and day oncology treatment centres to report to the VCR, bringing the Regulations in line with the intent of the Act and improve the completeness of data collection from all treatment sources.

The existing Regulations (Schedule 2, See Appendix D) prescribe the following details outlined in the following table (Table 6) to be reported by hospitals to the Cancer Council. The table also includes comments on the rationale for retaining the reporting of these data elements, some of which are also reported by prescribed registries and pathology laboratories, as specified in Schedule 3 and Schedule 4.

Table 6. Schedule 2 Reporting and the rationale for retention of data items

Schedule 2 Reporting	Data detail reported to the Cancer Council by Hospitals	Rationale for retaining this data element
Hospital details	Name of hospital, Hospital ID number and UR number	Required to accurately match up reports on the patient from multiple sources
Patient identification details	Medicare number, name, address, postcode, DOB	Required to accurately match up reports on the patient from multiple sources
Patient demographic details	Sex, occupation, country of birth, ATSI status	Enables epidemiological analysis of burden of disease for planning and evaluation purposes
Details of the doctor in charge of the case and of the general practitioner	Contact details of treating doctors	Enables follow up with medical practitioners
Date of admission and diagnosis of cancer	Date of admission and diagnosis of cancer	Enables incidence data to be calculated and epidemiological analyses of survival
Vital status	Dead or alive	Enables mortality data to be calculated and epidemiological analysis of survival.
Investigations relevant to the diagnosis of cancer	Test results	Allows cross checking with pathology reports
Laterality of primary cancer	Laterality of primary cancer	Required to distinguish between recurrent and multiple cancers of the same organ
Morphology	Morphology of primary tumour	Allows cross checking with pathology reports. Enables cancer research and epidemiological analyses by type of cancer

Schedule 2 Reporting	Data detail reported to the Cancer Council by Hospitals	Rationale for retaining this data element
Grade	Grade/differentiation of primary tumour	Enables cancer research and epidemiological analysis by type of cancer and assessment of prevention activities
Staging details for the cancer	Degree of spread, TNM	Enables cancer research, and epidemiological analysis of prevention activities
Treatment and recurrence details	Treatment details and cancer recurrence	Enables cancer care studies
Notifier details	Name of person notifying and date	Enables follow up to ensure data quality

The existing Regulations (Schedule 3, See Appendix E) prescribe the following details to be reported by prescribed registers to the Cancer Council:

- register details
- patient identification details
- details of the doctor in charge of the case
- date of diagnosis of cancer
- vital status
- investigations relevant to the diagnosis of cancer
- laterality
- morphology
- grade
- staging details for the cancer.

The existing Regulations (Schedule 4, See Appendix F) prescribe the following details to be reported by pathology groups to the Cancer Council:

- pathology group details
- patient identification details
- details of the doctor in charge of the case
- name of the reporting pathologist
- date of report
- diagnosis in words including morphology
- where available staging, size, morphology, grade and differentiation details for the cancer.

The specific provisions of the proposed Regulations largely replicate the existing Regulations. There is some reordering of the current Regulations (Schedule 2) in relation to cancer staging information to clarify the preferred reporting format. Under the changes the internationally accepted Tumour, Node, Metastases (TNM) site specific staging system is listed first (as the format most preferred) and the simplified ‘degree of spread’ staging system is ordered last, as the least preferred.

The changes proposed include the reporting of five additional prescribed particulars by one or more of the reporting groups; hospitals, prescribed health service establishments, registries, and pathology groups (that is, Schedules 2, 3 and 4). Four of the data elements are general patient details and one seeks clinical information. The proposed elements are:

- Language spoken at home (if known) to be added to Schedules 2, 3 and 4;
- Country of birth (if known) to be added to Schedules 3 and 4 for reporting by prescribed registries and pathology services;
- Aboriginal or Torres Strait Islander status (if known) to be added to Schedule 4 for reporting by pathology services; and
- Individual Health Identifier (if known) to be added to Schedules 2, 3 and 4;
- ECOG performance status (if known) to be added to Schedule 2 for reporting by hospitals and prescribed health service establishments.

The ECOG scale is used to assess a patient's disease progression and how it affects daily living abilities of the patient, and assists in determining appropriate treatment and prognosis.

Table 7: ECOG status definitions

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

6.2. Groups Affected by the Proposed Regulations

6.2.1. Hospitals / Prescribed Health Service Establishments

The proposed Regulations will require public and private hospitals and prescribed health service establishments to provide information to the VCR on any patient who is suffering or commences to suffer from cancer. Hospitals have already been reporting to the Registry and the transfer of data is usually carried out electronically, so additional reporting burden will be minimal apart from establishment costs. The proposed additional data elements to be reported are language spoken at home (if known), Individual Health Identifier (if known) and ECOG performance status (if known).

In order to capture data from private oncology treatment services, there will be the addition of the term 'prescribed health service establishments' to Schedule 2 and a list of prescribed health service establishments will be added to the Regulations as a new Schedule. The inclusion of reporting from these treatment centres will improve the completeness of the data recorded in the VCR. Two of the private oncology services have already been reporting data to the VCR so there is no additional burden in prescribing them.

6.2.2. Prescribed Registers

The proposed Regulations will require prescribed registers to provide information to the VCR on any patient who is suffering or commences to suffer from cancer. Prescribed Registers already report to the Registry and the transfer of data is usually carried out electronically, so additional reporting burden will be minimal. The proposed additional data elements to be reported are Country of birth (if known), Language spoken at home (if known), Aboriginal or Torres Strait Islander status (if known) and IHI (if known). BreastScreen already collect and report ethnicity (country of birth and language spoken at home) and ATSI status. The Victorian Cervical Cytology Registry (VCCR) can capture ATSI status and ethnicity (country of birth and language spoken at home), if it is reported to them. Both registries will need to add IHI as a data element to be collected and reported to the VCR.

The VCCR state that the collection of additional data elements would require the engagement of Pap test providers and laboratories to collect the data and forward it to the VCCR. Changes to the VCCR information system would also be required, but this would be a one off cost and would have minimal impact on the routine reporting time.

6.2.3. Places where cancer tests are undertaken: Pathology laboratories

The *Cancer Act 1958* requires that the person in charge of any place where a cancer test is undertaken shall, when the test indicates that a person is suffering from cancer, cause a report to be forwarded to the Cancer Council.[6] The report may be on the prescribed form or it may be a copy of the pathology report or the part of the pathology report that contains material relevant to the cancer test.

The proposed Regulations provide the data detail which must be included in a report from pathology. In reality, most pathology reporting to the VCR takes the form of automatic electronic reporting of the whole pathology report for any specimen in which there is a positive cancer test result. The addition of the data elements as proposed in these Regulations does not, therefore, add any additional significant burden to the reporting requirement. It does however require that pathology laboratories collect the additional data elements.

In the case of smaller pathology laboratories who currently report using paper based reports, there will be additional data attributes to be recorded, such as country of birth, language spoken at home and ATSI status, if they are known. This will also require the collection of these particulars from patients when pathology samples are collected or from the requesting doctor on the specimen request form.

6.3. Implementation

The implementation of any additional reporting as proposed in the *Cancer (Reporting) Regulations 2012*, will require upgrades to hospital, prescribed registry and pathology software, which is used for coding of data and transfer to the VCR.

Phased in implementation has been proposed to allow time for the software changes to be implemented and for the collection of new data elements such as the IHI, which has not yet been rolled out nationally, to become routine. (See Section 5.1 for a discussion of the costs associated with reporting, including software.)

In the case of hospitals using the Department of Health *HealthSmart* products, software modification costs are funded by the Department. The proposed implementation date of the proposed regulatory changes is designed to coincide with the Department of Health's usual schedule for the implementation of any changes to hospital's reporting requirements to the VAED and software modifications. This proposal enables any software and implementation costs associated with the regulatory changes to leverage off normal Departmental change processes. The Cancer (Reporting) Regulations 2012 have been drafted to reflect this phased in approach for the reporting changes with the additional data elements being added to Schedules 2, 3 and 4 from 1 July 2013.

Adding the specification 'if known' after the new data items will reduce the burden associated with these reporting requirements, as they may not be available in a patient's medical record. Increasingly over time, with the implementation of a co-ordinated communication strategy, these data items will be collected, recorded in medical records and reported to the VCR.

The Department of Health, through its Integrated Cancer Services (ICS) program, is working with hospital based cancer services and clinicians to improve the recording of patient clinical details such as cancer stage and ECOG status as part of routine practice. This work will be on-going and will support the improved recording of patient clinical details relating to cancer and incidentally support improved cancer notification.

6.4. Compliance with the Regulations

As outlined above in 2.1, there is almost 100% compliance of hospitals, registries and pathology services in providing some data to the registry, even if certain individual reports are incomplete. The VCR reports that, generally, compliance issues relate to problems surrounding software and data extraction (personal communication from the VCR). VCR electronic notifications staff spend whatever time and resources are necessary (in terms of supplying specifications, testing submitted files and providing feedback) to assist in resolving such issues.

One example given is of a large metropolitan hospital in which VCR staff worked to set up automated cancer extractions in 2007. The hospital continued to have issues in reporting and VCR agreed to accept substandard files and to manually check all in-coming records and report back errors to the hospital for correction. This iterative process was very time consuming, but was seen as necessary to ensure complete data supply during the prolonged process of developing the electronic solution. This example demonstrates the efforts undertaken by the VCR to ensure the objectives of the Act and existing regulations are met. It also demonstrates the level of support provided to notifiers to mitigate any undue reporting burden.

6.5. Impact on Competition

The Victorian Guide to Regulation (2011) states that, 'as a matter of good public policy, it is a fundamental principle in Victoria that any legislation (both primary and subordinate) will not restrict competition. Based on the questions asked in the Victorian Guide to Regulation, Table 8 below assesses the Regulations in the context of their impact on competition.

Table 8: Competition assessment

Potential Nature of Impact	Evaluation
Is the proposed measure likely to affect the market structure of the affected sector(s) – i.e. will it reduce the number of participants in the market, or increase the size of incumbent firms?	No
Will it be more difficult for new firms or individuals to enter the industry after the imposition of the proposed measure?	No
Will the costs/ benefits associated with the proposed measure affect some firms or individuals substantially more than others (for example, Small firms, part-time participants in occupations etc)?	No- See Impact on small business, Section 6.5.1

Potential Nature of Impact	Evaluation
Will the proposed measure lead to higher ongoing costs for new entrants that existing firms do not have to meet?	No. Rather than higher costs there may be some benefit initially to new entrants who are not prescribed in the regulations and therefore would not be required to report.
Is the ability or incentive to innovate or develop new products or services likely to be affected by the proposed measure?	Not adversely affected. There would be improvement opportunities enabling notifiers and software vendors to prepare for e-health and 'Close the Gap' requirements, support record linkage and improve efficiency for Government research.

6.5.1.Impact on small business

The lack of economies of scale and/or resources may impact on small businesses, such as smaller pathology laboratories and hospitals who report to the VCR. These data reporters may not have the ability to report electronically to the Registry portal, so they will report the positive test results manually, using the prescribed form. Whilst this is a lengthier and more time consuming process, targeted consultation has shown that even paper/manual lodgement to the Registry is a relatively minor time imposition (see Table 3 for a discussion of timing and costs associated with reporting). In addition, VCR data indicates that smaller reporters report very infrequently. The time taken to report each case will therefore be longer than for larger reporters, however the number of results required to report will be comparatively less, meaning that the overall burden of reporting is quite low.

6.6. Evaluation Strategy

The aim of the proposed Regulations is:

"To capture comprehensive data on new cases of cancer diagnosed and treated in Victoria, in order to monitor best practice and be accountable for health and treatment outcomes."

The objectives proposed in order to achieve this aim are to:

- develop capacity in reporting bodies to report on ATSI, country of birth, language spoken at home, IHI and ECOG status;
- capture a fuller picture of cancer treatment in Victoria, by receiving treatment notifications from radiation oncology facilities and outpatient ambulatory chemotherapy centres;
- improve the evidence base for screening and treatment programs;
- strengthen monitoring and accountability surveillance systems;
- encourage a move to e-reporting;
- generate quality reports on the data captured by the VCR; and
- foster linkage with national and international cancer data sets and population registries.

It is proposed that the Department of Health and the VCR assess the extent to which these objectives have been met as a result of the new Regulations through a review five years after implementation. The Department of Health has prepared a program logic (a picture of why and how it is believed that a policy will work) to support future evaluation. Refer to Appendix G for a schema of the program logic.

Outcomes to be measured in the evaluation would include any increased reporting of the new data items; ATSI status, country of birth, language spoken at home, IHI and ECOG status by hospitals, pathology laboratories and prescribed registries and increased reporting by private radiotherapy and day oncology treatment centres.

6.7. Consultation

Targeted consultation has been carried out with key stakeholders, listed in the following tables (Table 9, Table 10, Table 11), along with a summary of their comments. There was wide support for the importance of the continuation of the Regulations and for the minor changes proposed. There was some concern over additional costs for software changes and for encouraging the collection of ECOG status by clinicians. Refer to Chapter 5 for discussion on the consultancy in the cost benefit analysis.

This RIS is being released for a public consultation period of 28 days, as required by the *Subordinate Legislation Act 1994*. The sunsetting date for the existing regulations is fixed and there is a need to ensure that the replacement regulations are implemented effectively. As noted above, prior consultation has already been undertaken with a wide range of interested parties.

Table 9: Researchers and other stakeholders responding to targeted consultation October 2011

Organisation	Title	Summary of View
Cancer Council Victoria (CCV)	Director, Victorian Cancer Registry	Supports Option 2
CCV	Cancer Control Information Manager	Supports Option 2
CCV	CEO	The Victorian Cancer Registry is a key part of cancer prevention, research and support in Victoria. Data collated and analysed by the Victorian Cancer Registry is used to generate knowledge about the impact of cancer in Victoria. This information is used to inform each of the program areas within the Cancer Council Victoria from the Cancer Information and Support Service supporting cancer patients and their families to prevention messages within all our campaigns.
CCV	Former CEO CCV Professorial Fellow Uni Melb	In addition to the Victorian Cancer Registry's essential and primary purpose to measure the incidence of cancer in the population, the Cancer Registry is a uniquely valuable platform for research. In fact, cancer registries are of enormous benefit to cancer prevention at the primary, secondary and tertiary levels.
CCV	Director, Cancer Prevention Centre	The Victorian Cancer Registry provides vitally important data to help inform our prevention programs. The data is used to measure the impact of our initiatives and as a vehicle to raise awareness through public relations activities.
CCV	Manager SunSmart	Victorian Cancer Registry melanoma data assists us with the evidence for why prevention is important and assists us to identify priority areas for action.

Organisation	Title	Summary of View
CCV	Acting Executive Officer, Victorian Co-operative Oncology Group	The Victorian Cancer Registry provides a centralised repository for data. The impartiality of the Victorian Cancer Registry is greatly valued by the clinical community in Victoria.
CCV	Deputy Director, Centre for Behavioural	An important use of the Registry is to conduct 'patterns of care' studies that can examine whether cancer care is deviating from guidelines or evidence based recommendations and can also highlight any variations in cancer care, including differences between healthcare providers and between different patient groups.
CCV	Deputy Director, Cancer Information and Support Service	The team at the Cancer Information and Support Service use data from the Cancer Registry to support and shape program delivery. As we provide support to any Victorian diagnosed with any cancer at any stage in their treatment and recovery, it is vital that we have up to date information on incidence and surveillance to support our evidence based approach to the delivery of information and support.
Department of Health (DH)	Senior Medical Advisor, Environmental Health	Cancer registry data is indispensible to our work of investigating cancer clusters. This is important work in terms of public confidence and reassurance about health protection. From a public health perspective, the VCR is helpful in highlighting differentials in access and cancer burden across the community supporting the development of research questions and policies to reduce burden and address inequalities.
DH	Acting Director , Prevention and Population Health	Supports Option 2
DH	Acting Senior Advisor, Health Development	Supports Option 2
DH	Acting Manager, Screening and Cancer Prevention	Supports Option 2
DH	Manager, Cancer Strategy and Development	Supports Option 2
DH	Data Custodian, Assistant Director – Health Information, DH	Supports Option 2
DH	Manager Health Intelligence Unit	Without the existence of the VCR we would not be able to gather similar data. Option 2 will improve the catchment of relevant data to support planning of cancer prevention and therapeutic services.

Organisation	Title	Summary of View
Alfred Health	Director of Radiation Oncology, Head of Bracytherapy Services	The data available from the VCR contributes by allowing comparison across time and geographic location and with external data sources on incidence in cancer and mortality from cancer. This provides information to inform policy, and to generate hypotheses and questions. Supports Options 2 & 3.
VCCC	Exec Director	Regulations work by defining and requiring specific cancer data collections and have been fundamental to tracking and identifying successes and areas for improvement in cancer.
Southern Melbourne Integrated Cancer Services	Manager	Regulatory Option 2 will provide a more complete picture of the journeys of cancer patients and provide long term outcome data. The inclusion of ECOG performance status will provide greater depth to the data.
Menzies School of Health Research + NT Dept of Health and Families	Academic Researcher,	Supports Regulatory Option 2. In the absence of cancer registries (including the VCR), reliable data on cancer occurrence, treatment and outcomes would not be available. Data gathered in other ways, such as from hospital inpatient data, is incomplete in both case ascertainment and in details about the diagnosis, type, and outcome for each person with cancer.
Victorian Cervical Cytology Registry		The VCR provides a valuable and essential service to both the Victorian Cervical Cytology Registry (VCCR) and to the Cervical Cancer Screening Program. The data collected on cervical cancers by the VCR is used to indicate the success of the screening program in terms of the number of cervical cancers reported and to demonstrate the importance of regular screening by reviewing the screening patterns of women diagnosed.
BreastScreen Victoria		Data from the VCR is used by BreastScreen Victoria to identify women who are diagnosed with an invasive breast cancer before the next scheduled screening episode. These Interval Cancers and are reviewed by Service Radiologists to meet the BreastScreen Australia National Accreditation Standard (2.4.2a and 2.4.2b). The cost of replicating the data provided by VCR is difficult to estimate as it would rely on being able to access the required data and extract the required subset of women. BSV would not have capacity within current funding /resources to consider this option. Potential for BSV to be non compliant with Commonwealth directed standards.

Table 10: Reporting hospitals response to targeted consultation October 2011

Organisation	Title	Summary of View
Southern Health	Health Information Manager (HIM)	ECOG - Requires collection of data by clinicians. Software changes required
Barwon Health	Director Information Services	Additional costs of collecting ECOG status would be minimal provided that it is correctly recorded by the clinician.
Cabrini Health	HIM	Additional cost to extract data for Option 2 and for Option 3 even higher costs.
Peter Macallum Cancer Centre	Coding Manager Manager Health Information Services	ECOG would be time consuming to collect. Costs of software enhancement. Required. Base case – removal of unneccesary burden of replicated reporting to VAED and the VCR
The Women's Hospital	HIM	Supports options 2 & 3. Feels that the non-regulatory option is not a good idea. Without regulation the data collected would be poor and the time to collect would be very time consuming. Has been in place so long that it is part of the normal coding process.
Austin Health	HIM	Software changes would be required. Supports Option 2 more than Option 3 which would make electronic reporting near impossible.
The Royal Melbourne Hospital	HIM	Requires modification to software. ECOG would require a clinician to document status and the HIM to extract the information. Non-regulatory option – time saving for hospitals but lack of detail on laterality of cancer and histological diagnosis.
St Vincent's and Mercy Hospital	HIM	Software change required. Additional costs in collecting data – new forms and staff costs.

Table 11: Pathology Services response to targeted consultation October 2011

Organisation	Title	Summary of View
Dorevitch Pathology	Head typist - Histopathology	Reports are sent automatically to VCR. The computer system recognizes the SNOMED codes and extracts relevant reports which are sent electronically. Changes to data – no additional reporting time.
Melbourne Pathology	Histopathology office	Computer system extracts copies of reports based on SNOMED codes and a report to VCR is sent once a fortnight. Changes to particulars will not affect what is sent.
Alfred Hospital	Managing Scientist – Pathology & Secretary, Anatomical Pathology	Reporting to VCR is ad-hoc. Electronic reporting would require substantial lab computer upgrade. Paper reporting of copies of pathology reports to VCR takes half an hour a day.
Austin Hospital	Principle Scientist-Anatomical pathology	When cancer is diagnosed a copy to the VCR is generated by pathologist or data entry person.

7 Appendices

Appendix A Victorian Cancer Registry Minimum Data Set

The minimum data set collected for each cancer consists of:

- registry identification number
- name(s) of person with cancer
- residential address
- date of birth
- indigenous status
- country of birth
- sex
- vital status
- date of last contact
- number of primary tumours
- date of diagnosis
- site of cancer
- cancer histology
- tumour grade
- method of diagnosis
- Information about the notifying institution(s) and person's doctor(s).

Appendix B Data Requests to the VCR

Table 12: Data requests to the VCR (2007 – 2010)*

	2007		2008		2009		2010	
Data Request	**External**	**CCV**	**External**	**CVV**	**External**	**CVV**	**External**	**CVV**
Record Linkages								
Undertaken by VCR	17	5	16	5	19	6	11	5
Undertaken by AIHW (VCR approved)	4		5		4		10	
HREC approved Data requests								
Undertaken by VCR	1		3		3		8	
Undertaken by AIHW (VCR approved)	1		2		1		6	
Data requests (de-identified)	284	81	277	85	159	114	256	144
Recruitment for studies	3	2	1	1	2	1	3	4
On-line data kiosk (Tardis) requests	Had not been implemented				7,493		6,863	
Total	310	88	304	91	7,681	121	7,157	153

CCV = Cancer Council Victoria; AIHW = Australian Institute of Health and Welfare; HREC = Human Research Ethics Committee; VCR = Victorian Cancer Registry

***** Note: Numbers are estimates. Very brief requests (<10 minutes) are often not documented and will be undercounted. In addition, CCV's Cancer Information and Support Services regularly supply basic VCR incidence and mortality statistics to callers using Canstat and/or Tardis (on line data kiosk) figures. These are not included in this table.

Appendix C Cancer Reporting Regulations in other Jurisdictions

Table 13: Comparison of Cancer Reporting Regulations in selected Jurisdictions

Jurisdiction	Authorising legislation	Objective of the Regulations	Reporting groups	Reporting elements that are different to Victoria's
NSW	Public Health Act 2010	The relevant objects of this Act include: (a) to promote, protect and improve public health, (b) to control the risks to public health …	Pathology laboratories Radiotherapy and medical oncology departments Hospitals Multi-purpose services Forensic medicine Residential aged-care facilities Day procedure centres	Notification is to the Department of Health Director General An extended range of reporting groups based on definitions in the Act No regulations as Act allows for the Director General to approve the 'approved form' used for notifying
WA	Health (Western Australia) Cancer (Register) Regulations 2011	The register is to be kept for the following purposes — (a) to monitor the number of cases of cancer in Western Australia; (b) to plan, monitor and evaluate services for the control of cancer and the care of cancer patients in Western Australia; (c) to compile and publish general or statistical information relating to cancer (d) to carry out research into the causes, prevention, screening and treatment of cancer .	Medical specialists including; pathologists, haematologists and clinical biochemists Radiation oncologists Ophthalmologists Hospitals	Notification is to the Department of Health EDPH An extended range of reporting groups based on definitions in the Regulations Two additional data items; Date of admission or outpatient consultation, and; Outcome of screening tests (where known to have been carried out) Penalties of $100 for first offence, $200 for second offence and $500 for third offence. Total fine of $1000.

Jurisdiction	Authorising legislation	Objective of the Regulations	Reporting groups	Reporting elements that are different to Victoria's
QLD	Public Health Act 2005	The purposes for establishing the register are as follows-- (a) to collect data to help in-- (i) monitoring and analysing the outcomes and patterns of cancer; and (ii) monitoring cancer mortality; and (iii) increasing public awareness of cancer; (b) to help in the planning of services and strategies for the prevention and management of cancer.	Pathology laboratories Hospitals Residential aged-care facilities	Notification is to the Department of Health CEO (Director General) Addition of aged-care facilities to reporting groups CEO can require the information or further information from notifiers 20 penalty points for each offence.

Appendix D Schedule2

SCHEDULE 2

Regulation 5

Cancer (Reporting) Regulations 2002

Name of hospital

Hospital identification number

Hospital unit record number

Patient details:

- Medicare number (*if known*)
- Surname
- Given name(*s*)
- Maiden name (*if applicable*)
- Address
- Postcode
- Date of birth
- Sex
- Occupation
- Country of birth
- Aboriginal or Torres Strait Islander

Name of doctor in charge of case

- Address
- Telephone number

Name of general practitioner

- Address
- Telephone number

Date of first admission for this cancer

Date of diagnosis of this cancer

Vital status

Date of death/Date last known to be alive

Investigations relevant to diagnosis of cancer

Laterality of primary cancer

Morphology of primary cancer

Grade/differentiation of primary cancer

Staging details (*if available*):

- Degree of spread of cancer
  - Localised to the tissue of origin
  - Invasion of adjacent tissue or organs
  - Regional lymph nodes
  - Distant metastases
- Staging Tumour Nodes Metastasis (T.N.M.), Federation Internationale de Gynecologie et D'Obstetrique (FIGO)
- If melanoma—
  - Melanoma thickness
  - Melanoma level of invasion

Treatment details for each primary tumour:

- Details of initial treatment
- Details of treatment of recurrence(*s*) (*if any*)

Cancer recurrence information:

- Date of cancer recurrence
- Site(*s*) of cancer recurrence

Name of person completing form

Date of completing form

Appendix E Schedule 3

SCHEDULE 3

Regulation 6

Cancer (Reporting) Regulations 2002

Name of prescribed register

Prescribed register identification number

Patient details:

- Surname
- Given name(*s*)
- Address
- Postcode
- Date of birth
- Sex
- Aboriginal or Torres Strait Islander (*if known*)

Name of doctor in charge of case:

- Address
- Telephone number

Date of diagnosis of cancer

Vital status

Date of death/Date last known to be alive

Investigations relevant to diagnosis of cancer

Diagnosis in words (*site, morphology and grade/differentiation*)

Laterality (*if known*)

Staging system (*if known*)

Name of person completing form

Date of completing form

Appendix F Schedule 4

SCHEDULE 4

Regulation 7

Cancer (Reporting) Regulations 2002

Name of pathology group

Pathology group identification number

Laboratory case reference number

Patient details:

- Medicare number (*if known*)
- Surname
- Given name(*s*)
- Address
- Postcode
- Date of birth
- Sex

Name and address of doctor responsible for this case

Name of reporting pathologist

Date of report

Diagnosis in words (*site and morphology, including thickness and level of melanomas*)

Where available—

- Staging Tumour Nodes Metastasis (T.N.M.)
- Size
- Grade
- Differentiation

Name of person completing form

Date of completing form

Appendix G Costings of Regulatory Options 1, 2 & 3 and the Base Case

Table 14: Regulatory Option 2

Regulatory Option 2: Costs	Year 1 (2012)	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	NPV
Hospital reporting costs (current)	$ 103,037	$105,922	$108,888	$111,937	$115,071	$118,293	$121,605	$125,010	$128,510	$132,109	$ 965,769
Hospital reporting costs - coding time (incremental)*		$ 17,302	$ 17,787	$ 18,285	$ 18,797	$ 19,323	$ 19,864	$ 20,420	$ 20,992	$ 21,580	$ 146,446
Hospital costs of understanding the Regulations	$ 5,294										$ 5,115
Clinician documentation of ECOG+	$ 45,188	$ 46,453	$ 38,203	$ 34,364	$ 30,279	$ 25,939	$ 21,333	$ 16,447	$ -	$ -	$ 227,281
Prescribed registers reporting costs (current)	$ 1,435	$ 1,475	$ 1,516	$ 1,559	$ 1,603	$ 1,647	$ 1,694	$ 1,741	$ 1,790	$ 1,840	$ 13,450
Prescribed registers (incremental) reporting costs (+5% on current)		$ 74	$ 76	$ 78	$ 80	$ 83	$ 85	$ 87	$ 90	$ 92	$ 626
Prescribed Register costs of understanding the Regulations	$ 155										$ 150
Pathology (incremental) reporting costs (+5% on current costs)		$ 4,251	$ 4,370	$ 4,492	$ 4,618	$ 4,747	$ 4,880	$ 5,017	$ 5,158	$ 5,302	$ 35,981
Pathology costs of understanding the Regulations	$ 1,748										$ 1,689
ICT Software changes^	$ 150,000										$ 144,928
New Radiotherapy Centres#	$ 1,500	$ 1,500	$ 1,500	$ 1,521	$ 1,542	$ 1,564	$ 1,586	$ 1,608	$ 1,630	$ 1,653	$ 12,935
VCR Data Manager costs	$ 113,750	$113,750	$113,750	$113,750	$113,750	$113,750	$113,750	$113,750	$113,750	$113,750	$ 946,014
TOTAL COSTS											**$2,500,383**

*includes an additional 30 seconds per case for the additional work once option implemented (2013)

+based on Registrar salaries for 1 minute per case for 50% of notifications in year 1, year 2 and for 40% of cases in years 3, 35% in year 4, 30% in year 5 and 25% in years 6, 20% in year 7 & 15% in year 8.

^ includes $50,000 for HealthSmart changes, $10,000 for e-form changes (VCR), $60,000 for residual hospital sites, $20,000 for pathology labs and $10,000 for prescribed registers

average annual growth of 50% of cancer incidence growth (ie. 0.014%) applied from year 4 onwards

Table 15: Regulatory Option 3

Regulatory Option 3: Costs	Year 1 (2012)	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	NPV
Hospital reporting costs (current)	$103,037	$105,922	$108,888	$111,937	$115,071	$118,293	$121,605	$125,010	$128,510	$132,109	$ 965,769
Hospital reporting costs- coding time (incremental)*		$109,145	$112,201	$115,343	$118,573	$121,893	$125,306	$128,814	$132,421	$136,129	$ 923,816
Costs of understanding the Regulations	$ 15,882										$ 15,345
Clinician documentation of additional clinical data for tumour streams	$ 90,376	$ 92,907	$ 76,406	$ 68,728	$ 60,559	$ 51,879	$ 42,665	$ 32,895	$ -	$ -	$ 454,563
Prescribed registers reporting costs (current costs)	$ 1,435	$ 1,475	$ 1,516	$ 1,559	$ 1,603	$ 1,647	$ 1,694	$ 1,741	$ 1,790	$ 1,840	$ 13,450
Prescribed registers (incremental) reporting costs (5% on current)		$ 74	$ 76	$ 78	$ 80	$ 83	$ 85	$ 87	$ 90	$ 92	$ 626
Prescribed Register costs of understanding the Regulations	$ 466										$ 450
Pathology (incremental) reporting costs (5% on current costs)		$ 4,251	$ 4,370	$ 4,492	$ 4,618	$ 4,747	$ 4,880	$ 5,017	$ 5,158	$ 5,302	$ 35,981
Pathology costs of understanding the Regulations	$ 5,243										$ 5,066
ICT Software changes^	$450,000										$ 434,783
New Radiotherapy Centres#	$ 1,500	$ 1,500	$ 1,500	$ 1,521	$ 1,542	$ 1,564	$ 1,586	$ 1,608	$ 1,630	$ 1,653	$ 12,935
VCR Data Manager costs	$227,500	$227,500	$227,500	$227,500	$227,500	$227,500	$227,500	$227,500	$227,500	$227,500	$1,892,028
TOTAL COSTS											**$4,754,810**

*includes an doubling the time taken per case for the additional work once option implemented (2013)
+based on Registrar salaries for 2 minutes per case for 50% of notifications in year 1, year 2 and for 40% of cases in years 3, 35% in year 4, 30% in year 5 and 25% in years 6, 20% in year 7 & 15% in year 8.
^ includes $150,000 for HealthSmart changes, $30,000 for e-form changes (VCR) and $180,000 for residual sites plus option 1 pathology and register costs of $30,000
# average annual growth of 50% of total cancer incidence growth (ie. 0.014%) applied from year 4 onwards

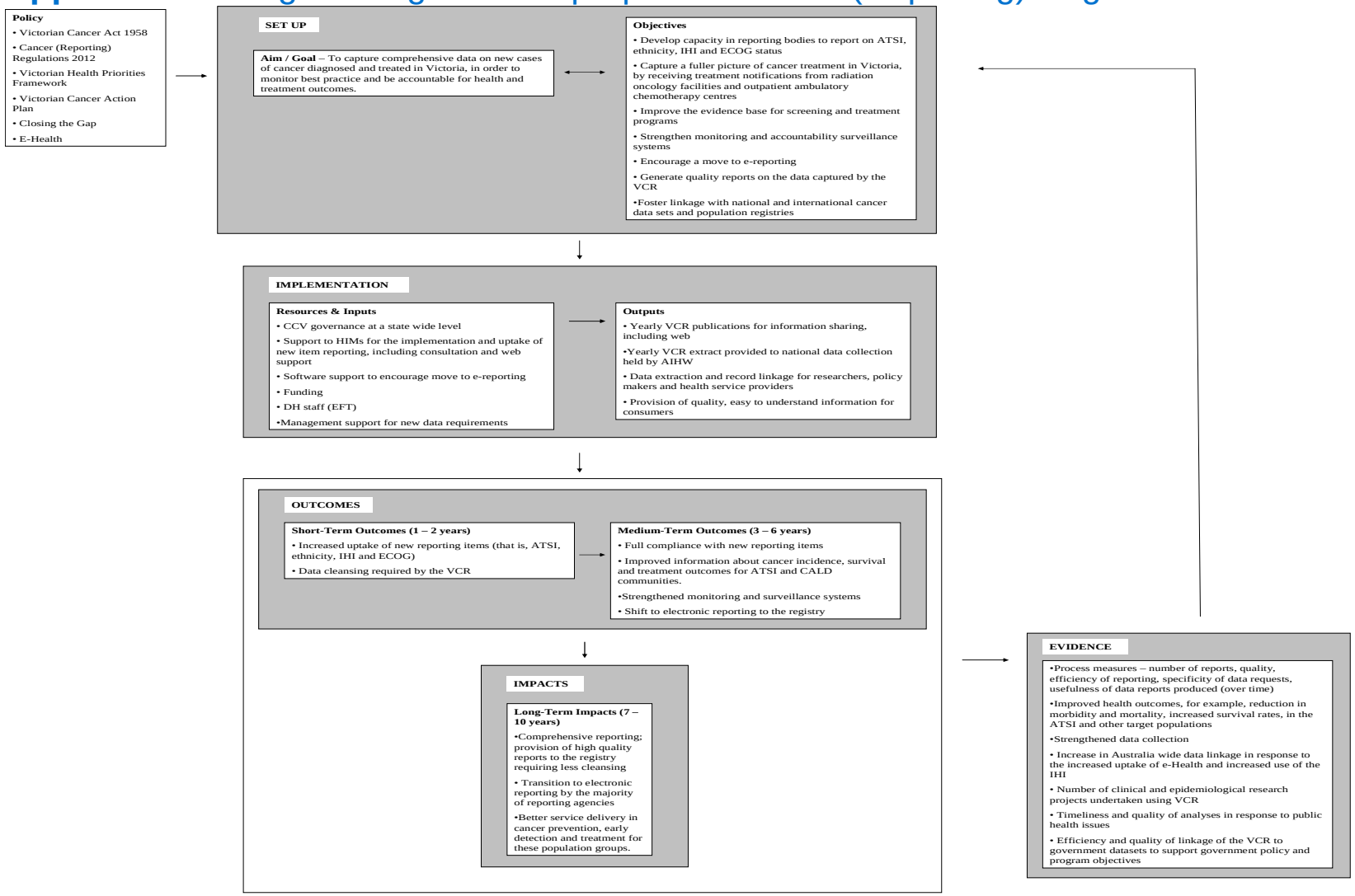
Table 16: Regulatory Option 1

Regulatory Option 1 (ISQ): Costs	Year 1 (2012)	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	NPV
Hospital reporting costs (base)	$ 103,037	$ 105,922	$ 108,888	$ 111,937	$ 115,071	$ 118,293	$ 121,605	$ 125,010	$ 128,510	$ 132,109	$ 965,769
Prescribed registers reporting costs	$ 1,435	$ 1,475	$ 1,516	$ 1,559	$ 1,603	$ 1,647	$ 1,694	$ 1,741	$ 1,790	$ 1,840	$ 13,450
Pathology reporting costs	$ 82,705	$ 85,021	$ 87,402	$ 89,849	$ 92,365	$ 94,951	$ 97,610	$ 100,343	$ 103,152	$ 106,040	$ 775,199
TOTAL COSTS											**$1,754,418**

Table 17: Base Case (No Regulations)

Non Regulatory Option Base Case: Costs	Year 1 (2012)	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	NPV
Pathology reporting costs	$ 82,705	$ 85,021	$ 87,402	$ 89,849	$ 92,365	$ 94,951	$ 97,610	$ 100,343	$ 103,152	$ 106,040	$ 775,199
TOTAL COSTS											**$ 775,199**

Appendix H Program Logic for the proposed Cancer (Reporting) Regulations 2012



8 Endnotes and References

[1] The Cancer Council Victoria is the new business name of the Anti-Cancer Council Victoria. The name change occurred in 2002, along with the daffodil logo to be consistent with the Cancer Council Australia and other state based members. See: http://www.cancervic.org.au/about/70-years/history-2000s

[2] Victoria's Cancer Action Plan 2008-2011. Victorian Government Department of Human Services. State of Victoria 2008.

[3] Cancer Council Victoria Epidemiology Centre; CANSTAT No. 50:Cancer in Victoria 2009 (2011) and CANSTAT No 45: Cancer in Victoria 2005 (2008). Available from: http://www.cancervic.org.au/about-our-research/registry-statistics/canstats.

[4] Pp. 108-87; Department of Health, Victoria; *Self-reported Health and Selected Health Conditions*. Available from: http://docs.health.vic.gov.au/docs/doc/F45784DB821C0C18CA257868007B2A81/$FILE/2008-ch03.pdf Accessed on 12 October 2011

[5] The Cancer Council Victoria is the new business name of the Anti-Cancer Council Victoria. The name change occurred in 2002, along with the daffodil logo to be consistent with the Cancer Council Australia and other state based members. See: http://www.cancervic.org.au/about/70-years/history-2000s

[6] S60 Reporting of cancer

"(1) The proprietor of a hospital, private hospital, prescribed registered funded agency or prescribed health service establishment must, within the prescribed time and in the prescribed form, report to the Council on any patient who, to the knowledge of the proprietor, is suffering or commences to suffer from cancer.

(1A) The person in charge of an organisation that maintains a prescribed register must, within the prescribed time and in the prescribed form, report to the Council on any person whose information is included in that prescribed register and who, to the knowledge of the person in charge, is suffering or commences to suffer from cancer.

(2) The person in charge of any place where a cancer test is undertaken shall, when the test indicates that the person is suffering from cancer, cause a report on that test to be forwarded to the Council."

[7] *"For the purposes of section 60(1) of the* ***Cancer Act 1958 –***

- *(a) the prescribed time to report is 30 days from the date the proprietor becomes aware that a patient is suffering or commences to suffer from cancer; and*
- *(b) the prescribed from form for a report is the form set out in Schedule 2." (See Appendix B)*

For the purposes of section 60(1A) of the ***Cancer Act 1958*** *–*

- *(a) the prescribed time to report is within 90 days from the date the person in charge of an organisation that maintains a prescribed register becomes aware that a patient, whose information is included in the prescribed register maintained by the organisation, is suffering or commences to suffer from cancer; and*
- *(b) the prescribed form for the report is set out in Schedule 3." (See Appendix C)*

For the purposes of section 60(2) of the ***Cancer Act 1958*** *–*

- *(a) the prescribed time to report is within 30 days from the date the person in charge of a place where cancer tests are undertaken becomes aware that a cancer test indicates that a person upon whom the test was conducted is suffering from cancer; and*
- (b) the prescribed from for a report is the form set out in Schedule 4." (See Appendix D)

[8] *"The Governor in Council may make regulations for or with respect to –*

- *(a) prescribing the form of any report required to be made to the Council under this section;*
- *(b) prescribing the time within which any report required to be made to the Council under this section shall be made; and*
- *(c) generally prescribing any matter or thing which is by this section authorized or required to be prescribed or is necessary or expedient to be prescribed for giving effect to the provisions of this section."*

[9] Victorian Guide to Regulation. Edition 2.1 August 2011. Department of Treasury and Finance. State of Victoria 2011.

[10] Canstat No 37, August 2002. A Guide to the Victorian Cancer Registry. The Cancer Council Victoria 2002.

[11] National Program of Cancer Registries; *Program Manual, Version 1.0*; United States Department of Health and Human Services. Available from: http://www.cdc.gov/cancer/npcr/pdf/program_manual.pdf Accessed on 12 October 2011

[12] Victorian Health Priorities Framework 2012-2011. Victorian Department of Health. Available from http://intranet.health.vic.gov.au/our-organisation/plans-and-strategies/victorian-health-priorities-framework-2012-2022/VHPF-Key-Elements-Summary.pdf Accessed 17 October 2011

[13] *Closing the Gap: National Indigenous Reform Agreement*; FACS. Available from: http://www.facs.gov.au/sa/indigenous/progserv/ctg/Pages/NIRA.aspx Accessed on 14 October 2011

[14] As published in Am. J. Clin. Oncol.: Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.; *Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group*. Am J Clin Oncol; 5:649-655, 1982.

[15] Victorian Radiotherapy Service Plan. Department of Health July 2007. http://www.health.vic.gov.au/radiotherapy/radiotherapy-service-plan06-11.pdf p.7

[16] Department of Health and Ageing. Australian Government. Website http://www.health.gov.au/internet/main/publishing.nsf/Content/health-roi-aboutus.htm

[17] Costs for recruitment are negotiated with researchers on a study by study basis depending on the complexity and the number of subjects required. The cost is based on EFT and on-costs for data management staff and do not currently include any supervision costs.