



AUSTRALIAN PROSTATE CANCER CLINICAL REGISTRY

REQUEST FOR PROPOSALS
FOR APCCR CUSTODIAN

TABLE OF CONTENTS

1	INTRODUCTION TO AUSTRALIAN PROSTATE CANCER CLINICAL REGISTRY	3
1.1	SUMMARY OF THE RESULTS WE SEEK	3
1.2	REQUEST FOR PROPOSALS TO IMPLEMENT AND UNDERTAKE CUSTODIANSHIP OF THE APCCR	3
1.3	THE APPROACH TO ESTABLISHING APCCR.....	3
1.4	SUPPORT FOR THE APCCR	4
1.5	KEY DATES.....	4
2	ABOUT MOVEMBER.....	5
3	ABOUT APCCR.....	6
3.1	DESIGN OF THE APCCR	6
3.2	THE PURPOSE AND AIMS OF THE APCCR.....	6
3.3	GOVERNANCE OF APCCR.....	6
3.4	RESPONSIBILITIES OF THE APCCR STEERING COMMITTEE	7
3.5	RESPONSIBILITIES OF THE APCCR CUSTODIAN	8
3.6	LOCAL RESPONSIBILITIES OF PARTICIPATING STATE/TERRITORY ORGANISATIONS....	9
3.7	MINIMUM CLINICAL DATA SETS.....	9
3.8	PATIENT REPORTED OUTCOMES DATA SETS	9
3.9	DATA OWNERSHIP.....	10
3.10	APCCR DATABASE.....	10
3.11	ANNUAL APCCR REPORT.....	10
3.12	STRUCTURE OF APCCR CUSTODIAN	11
3.13	ELIGIBILITY.....	11
4	EVALUATION CRITERIA FOR APCCR CUSTODIAN AND PEER REVIEW.....	12
4.1	EVALUATION CRITERIA	12
5	FUNDING ARRANGEMENTS.....	14
5.1	FUNDING OF APCCR CUSTODIAN	14
5.2	FUNDING OF LOCAL RESPONSIBILITIES	14
6	RFP SUBMISSION GUIDELINES AND TERMS AND CONDITIONS OF RFP	16
6.1	RFP SUBMISSION GUIDELINES.....	16
6.2	TERMS AND CONDITIONS OF RFP	17
7	CONTACT DETAILS FOR THIS RFP	19
	GLOSSARY.....	20
	ANNEXURE 1.....	21
	ANNEXURE 2.....	22
	ANNEXURE 3.....	23
	ANNEXURE 4.....	32

1 INTRODUCTION TO AUSTRALIAN PROSTATE CANCER CLINICAL REGISTRY

1.1 SUMMARY OF THE RESULTS WE SEEK

Movember seeks to improve health outcomes for men living with prostate cancer, together with their partners, carers and families. The key physical and mental health indicators that Movember seeks to improve are detailed in Annexure 1.

We plan to fund the establishment of an Australian Prostate Cancer Clinical Registry (referred to in this document as APCCR) to:

- Monitor, benchmark and publicly report annually on the outcomes of prostate cancer treatment and care
- Provide risk adjusted, evidence based data to clinicians, hospitals and decision makers on prostate cancer clinical practice that fosters and evaluates improved quality of treatment and care for men diagnosed with prostate cancer
- Foster research leading to improvement in care and survival; ideally enabling comparisons across countries

Movember recognises and acknowledges the clinical leadership in Australia that has already resulted in the establishment of a number of state-based prostate cancer clinical registries. In supporting the establishment of APCCR, Movember seeks to build on the foundations already laid in many parts of Australia.

Separate but relevant to this initiative, Movember anticipates supporting prostate cancer clinical registries in other countries where we conduct the Movember campaign. As far as practical, Movember would wish to see alignment on critical features of these registries.

1.2 REQUEST FOR PROPOSALS TO IMPLEMENT AND UNDERTAKE CUSTODIANSHIP OF THE APCCR

This RFP invites suitably qualified and experienced organisations to submit a proposal to be the APCCR Custodian and to undertake all of the responsibilities detailed in Section 3.

The Evaluation Criteria in Section 4 of this RFP set out the key capabilities and experience required to successfully undertake the responsibilities of the APCCR Custodian.

Following an evaluation of applications, a suitably qualified organisation will be appointed to be the APCCR Custodian. Through a separate, but parallel process, Preferred State/Territory Organisations will be selected in each state and territory.

1.3 THE APPROACH TO ESTABLISHING APCCR

APCCR will be established through a three-step process:

Step 1

Select Preferred State/Territory Organisations through an EOI process. These organisations will undertake all the Local Responsibilities identified in Section 3.6 of this RFP.

Step 2

Through this Request for Proposals, invite, review and select an organisation to be the APCCR Custodian to operate the APCCR and directly undertake the tasks and responsibilities detailed in Section 3 of this RFP.

Step 3

The selected APCCR Custodian will work with the Preferred State/Territory Organisations to quickly finalise an implementation plan for the APCCR.

In its final form, Movember will contract with the organisation selected to be the APCCR Custodian. The APCCR Custodian will contract with Preferred State/Territory Organisations, who will undertake the Local Responsibilities.

1.4 SUPPORT FOR THE APCCR

The following organisations have advised Movember that they support the APCCR.

- Urological Society of Australia and New Zealand (USANZ)
- The Royal Australian and New Zealand College of Radiologists (RANZCR)
- Faculty of Radiation Oncology Genito-Urinary Group of The Royal Australian and New Zealand College of Radiologists (FROGG)
- Medical Oncology Group of Australia (MOGA)
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
- Prostate Cancer Foundation of Australia (PCFA)

1.5 KEY DATES

Key dates in the process are provided in the table below.

Key Activity	Date
EOI released	31 May 2013
Intent to apply submissions due	14 June 2013
EOI closing date	2pm, 12 July 2013
Notification of Preferred State/Territory Organisations	30 August 2013
Selection of APCCR Custodian	30 August 2013
Finalisation of implementation plans between APCCR Custodian and each Preferred State/Territory Organisation	1 November 2013
Contract finalisation, funding and commencement of Australian Prostate Cancer Clinical Registry	22 November 2013

2 ABOUT MOVEMBER

During November each year, Movember is responsible for the sprouting of moustaches on thousands of men's faces, in Australia and around the world. With their "Mo's", these men raise vital funds and awareness for men's health, specifically prostate cancer, testicular cancer and men's mental health initiatives.

On Movember 1st, guys register at movember.com with a clean-shaven face. For the rest of the month, these selfless and generous men, known as Mo Bros, groom, trim and wax their way into the annals of fine moustachery. Supported by the women in their lives, Mo Sistas, Movember Mo Bros raise funds by seeking out sponsorship for their Mo-growing efforts.

Mo Bros effectively become walking, talking billboards for the 30 days of November. Through their actions and words, they raise awareness by prompting private and public conversation around the often ignored issue of men's health.

This initiative represents an initial investment of \$3.5 million by Movember and has been made possible with the support of Australian Mo Bros and Sistas.

3 ABOUT APCCR

3.1 DESIGN OF THE APCCR

Following extensive consultation with relevant stakeholders, in December 2011 Movember established a Working Group to oversee the design of APCCR. The members of this group are detailed in Annexure 2, and Movember would like to acknowledge the significant effort and contribution that these members have made.

The primary role of the group was to guide the development of an Australian prostate cancer clinical registry that addresses the following objectives:

- Assess relevant existing registry models, evaluating options and making recommendations for a feasible and sustainable model;
- Determine an optimal model for registry's operations, management, organisation, scope, development, funding and governance, taking into account appropriate National Standards for Clinical Registries;
- Determine a minimalist data set to achieve the objectives, taking account of established standards, definitions, and recommendations;
- Determine how data is going to be shared, if existing and collected if not existing;
- Determine how it is to be compiled, reported and used; acknowledging that different practices and processes exist across states and territories.

3.2 THE PURPOSE AND AIMS OF THE APCCR

The purpose of APCCR is to:

- (a) Monitor, benchmark and publicly report annually on the outcomes of prostate cancer treatment and care
- (b) Provide risk adjusted, evidence based data to clinicians, hospitals and decision makers on prostate cancer clinical practice that fosters and evaluates improved quality of treatment and care for men diagnosed with prostate cancer
- (c) Foster research leading to improvement in care and survival; ideally enabling comparisons across countries

The APCCR is expected to meet the Australian Commission on Safety and Quality in HealthCare (ACSQHC) Strategic and Operations Principles for a National Approach to Australian Clinical Quality Registries as endorsed by Australian Health Ministers Conference (November 2010).

The APCCR is intended to be population-based and therefore over time we would like to see over 90% of newly diagnosed prostate cancer cases collected.

3.3 GOVERNANCE OF APCCR

Prior to contract signing and commencement of implementation, Movember will put in place an interim Governance Committee. This Governance Committee will oversee negotiations and the development of implementation plans between the APCCR Custodian and the Preferred State / Territory Organisations. This interim committee will be dissolved upon contract finalisation.

To oversee the successful implementation and operation of the APCCR, Movember will contract with the APCCR Custodian. Through its funding agreement, Movember will require the APCCR Custodian to establish a Steering Committee to govern the APCCR.

The structure of the APCCR Steering Committee will be specified in the contract with the APCCR Custodian and will initially comprise:

1. A clinical representative nominated by each Participating State / Territory Organisation.
2. An epidemiologist
3. A quality of care expert
4. A representative of men living with prostate cancer
5. A representative of funders (initially Movember)
6. Two representatives of APCCR Custodian
7. A medical administrator

Clinicians managing prostate cancer will be required to comprise at least 50% of committee membership.

The Chairperson of the Committee will be suitably qualified person to provide professional leadership.

It is recognised that strong and effective relationships with the clinical community will be fundamental to the success of APCCR. The APCCR Steering Committee will need to build and maintain strong working relationships with key clinical representative organisations.

3.4 RESPONSIBILITIES OF THE APCCR STEERING COMMITTEE

The APCCR Steering Committee will be responsible for:

- Strategic development of the APCCR
- Finalisation of APCCR Terms of Reference
- Monitoring performance
- Review and endorse policies, standard operating procedures (SOPs) and terms of reference of sub committees
- Monitoring data quality and compliance with ethical requirements
- Budgeting and registry funding
- Receiving and acting (where appropriate) on reports from sub committees
- Receiving and acting (where appropriate) on feedback from Participating State/Territory Organisations
- Liaising, as appropriate, with international bodies, collecting similar data to enable international comparisons, particularly for Patient Reported Outcomes.

Other responsibilities

The APCCR Steering Committee will establish sub committees as required to undertake and oversee the data quality/access and clinical quality responsibilities.

(a) Clinical quality responsibilities

The APCCR Steering Committee will have final responsibility for:

- Determining procedures for risk adjustment
- Reviewing and interpreting registry data concerning quality and benchmarking
- Identifying and referring back to Participating State/Territory Organisations on opportunities for quality improvement evident from the data
- Reporting and referring back to Participating State/Territory Organisations on clinical matters (including outliers) arising from data review
- Developing policies in consultation with Participating State/Territory Organisations in relation to presentation and distribution of quality and benchmarking data
- Determining the format of quality and benchmarking reports

(b) Data access responsibilities

Access to information collected by the APCCR must be subject to strict protocols and procedures to ensure that privacy, confidentiality and ethical principles are maintained at all times. The provision of data will be subject to an agreed ethics protocol that will be submitted to relevant organisations such as hospitals and cancer registries.

The APCCR Steering Committee will:

- Propose policies and procedures to monitor and improve data quality
- Develop and review data access, data use and publication policies. The publication policy should address the need for acknowledgment of the registry and need for appropriate authorship. Access to data by researchers must be equal with minimal cost and restraints. Policies on use of data will be transparent and account for input from Participating State/Territory Organisations
- Specify data quality reporting requirements, recognising that Participating State/Territory Organisations will be responsible for local data management
- Review and provide comments and feedback on routine data quality reports to Participating State/Territory Organisations

3.5 RESPONSIBILITIES OF THE APCCR CUSTODIAN

The APCCR Custodian will be contracted by Movember to manage the APCCR.

The APCCR Custodian will be responsible for:

- Compiling a national data repository through its partnership arrangements with Participating State/Territory Organisations and producing regular reports based on this data
- Developing collaborative links in order to extend the registry with the goal of achieving national coverage
- Playing a mentoring role with Participating State/Territory Organisations where required in the development and implementation of the Local Responsibilities, particularly where no current registry exists
- Assisting Participating State/Territory Organisations with ethics and regulatory issues, drawing on precedents where appropriate and providing the documentation that states/territories may require.
- In consultation with Participating State/Territory Organisations, establishing administrative and organisational procedures and policies that might be workable in any state/territory, with a view to standardising and making more efficient data-collection, patient follow-up, and associated IT functions
- Where unique clinical, data or regulatory conditions occur in a state/territory, assisting with making changes needed to gain participation in the national data collection
- Establishing a national data-audit process
- Supporting the APCCR Steering Committee
- Operating and maintaining the APCCR collection
- Providing tools to support audit of registry activity within jurisdictions
- Managing administrative processes necessary to support a centralised national prostate cancer data collection, while establishing agreements with Participating State/Territory Organisations and securing a fair and balanced exchange of benefits in these agreements
- Publishing an Annual Report as detailed in Section 3.11.

3.6 LOCAL RESPONSIBILITIES OF PARTICIPATING STATE/TERRITORY ORGANISATIONS

The contract between the APCCR Custodian and each Participating State/Territory Organisation will fund the following Local Responsibilities as part of APCCR:

- Developing a local steering committee and progressing to a population-based state-wide coverage, committing to the principles and targets agreed as part of the APCCR
- Local data collection and management of the minimum clinical data set (T1) (Annexure 3) and Patient Reported Outcomes (Annexure 4)
- Arranging for appropriate institutional ethics review for data collection and for data transfer to the APCCR
- Securing collaboration of local surgeons, radiation oncologists, medical oncologists and health institutions. (Note: in order to achieve the population based aims of the registry the goal would be to secure collection of over 90% of newly diagnosed prostate cancer cases in each state / territory over time.) An opt-out consent process is recommended although it is recognized that circumstances may present where an alternative approach might be necessary to achieve the participation target
- Liaising with local ethics committees with regard to state/territory issues that might arise with APCCR function
- Obtaining patient-reported outcome data, (via the approach agreed by the APCCR Steering Committee), with data collection being organised either by the Participating State/Territory Organisations, or by delegation to the APCCR Custodian
- Undertaking local audit of registry activity, including accuracy and completeness of data.
- Identifying and acting on opportunities for quality improvement evident from the data
- Receiving, and where appropriate acting on clinical matters (including outliers) arising from data review
- Contributing to the development of policies in relation to presentation and distribution of quality and benchmarking data
- Submitting data to the APCCR within two months of the end of each reporting period
- Reviewing and providing feedback to the APCCR Custodian on routine data quality reports received
- Providing input to the APCCR deliberations through representation on APCCR Steering Committee.

3.7 MINIMUM CLINICAL DATA SETS

Participating State/Territory Organisations will need to agree to collect the Minimum Clinical Data set, either directly or through arrangements with the APCCR Custodian, as detailed in T1 of Annexure 3 to be eligible to participate in the APCCR.

It is acknowledged that in several states and territories the minimum clinical data set is already being collected. In some cases, more information is currently being collected. In this situation, the APCCR Custodian will be expected to discuss and work, wherever possible and practical, with existing local arrangements for data collection and transfer, rather than require new systems or practices to be put in place.

3.8 PATIENT REPORTED OUTCOMES DATA SETS

Annexure 4 details a draft set of Patient Reported Outcomes (PRO) instruments to address the health outcomes indicators (Annexure 1) that Movember wishes to see addressed in the Annual Report. Movember will require the APCCR Steering Committee to consider and finalise the PRO data set, taking into account Movember's desire to ensure that there is a consistent minimum set of health outcome data sets across other countries where Movember has supported similar initiatives.

Participating State/Territory Organisations will need to agree to collect the PRO data, either directly or through arrangements with the APCCR Custodian.

To support long term sustainability of the APCCR, the APCCR Custodian will be required to achieve the most efficient and effective strategies to collect PRO data. Separate, but related to this RFP, Movember will provide funding support for the design and implementation of electronic PRO collection.

3.9 DATA OWNERSHIP

It is not contemplated that APCCR Custodian will own the data collected as part of the operation of the registry. As part of finalising arrangements with Preferred State/Territory Organisations, the APCCR Custodian and Participating State/Territory Organisations will agree on Data Ownership consistent with Australian Commission on Safety and Quality in Health Care (ACSQHC) Strategic and Operating Principles for a National Approach to Australian Clinical Quality Registries as endorsed by Australian Health Ministers Conference (November 2010).

3.10 APCCR DATABASE

The APCCR Custodian will establish, operate and maintain a database that must be capable of:

- Storing the agreed minimum data sets required to achieve the objectives of the registry
- Enabling direct data entry and access where requested by Participating State/Territory Organisations
- Enabling data transfer where requested by Participating State/Territory Organisations
- Inter operating with existing databases maintained by Participating State/Territory Organisations to support the transfer of data, where this is the preferred data exchange method
- Not incorporating identifiable patient data unless otherwise agreed with Participating State/Territory Organisations
- Complying with the Australian Commission on Safety and Quality in Health Care' (ACSQHC) Strategic, Operational and Technical Principles.

Each Participating State/Territory Organisations may elect to:

- Use an existing database the organisation has in place.
- Directly enter data into the APCCR database; (details available when APCCR Custodian is selected)
- Use an existing database from another Participating State/Territory Organisation

It is a matter for each Participating State/Territory Organisation to determine whether they wish to contribute identifiable or de-identifiable data to the APCCR database.

The APCCR Custodian must, in the event of receiving identifiable patient data:

- Maintain all identifiable data under highly secure conditions and in accordance with applicable data policies, accreditation standards and Human Research Ethics Committees (HREC) requirements.
- Not release identifiable patient data without agreement from the relevant Participating State/Territory Organisations, HREC, the individual concerned and endorsement by the Steering Committee.

As part of finalising the Implementation Plan, the APCCR Custodian will work closely with each Preferred State/Territory Organisations to address local considerations in relation to data exchange.

3.11 ANNUAL APCCR REPORT

An annual report must be published by the APCCR Steering Committee that reports on the experience of men living with prostate cancer, as described in Annexure 1 (Movember Health Outcomes Indicators for Prostate Cancer).

This report will also address the quality of treatment, care and survival for men diagnosed with prostate cancer, where appropriate data is available.

As APCCR will be established to prospectively collect data, it is likely that it will take some years to have a national population-based report.

To generate reports of the lived experience of men diagnosed with prostate cancer in the interim, Participating States / Territory Organisations that have already collected population based data of a similar nature to the APCCR data sets will be invited to submit a collaborative research project on the outcomes of prostate cancer treatment and care, including the health outcome indicators detailed in Annexure 1. The proposal will be reviewed and approved by the APCCR Steering Committee. Movember will fund \$250,000 per annum for two years to support this collaborative research effort.

Any reports funded through this must be publicly accessible as part of the APCCR annual report.

3.12 STRUCTURE OF APCCR CUSTODIAN

Applicants must nominate an organisation that is capable of contracting with Movember to undertake the functions of the APCCR Custodian. The organisation may have any of the following structures:

- Organisations established through a specific piece of Commonwealth or State/Territory legislation (eg, universities);
- Incorporated Associations or Cooperatives (incorporated under State/Territory legislation)
- Not for Profit Organisations

3.13 ELIGIBILITY

Tobacco, gambling organisations, pharmaceutical or device companies are ineligible.

An organisation or academic institution that has a funding relationship (such as a prostate clinical trial or meeting sponsorship) with a pharmaceutical company is eligible to apply provided that this relationship does not cause any perceived or real conflict of interest.

Please disclose any potential conflicts of interest involving pharmaceutical companies in the “Conflict of Interest” section of the online application form.

4 EVALUATION CRITERIA FOR APCCR CUSTODIAN AND REVIEW PROCESS

4.1 EVALUATION CRITERIA

EC 1. Ability to perform the responsibilities of the APCCR Custodian

The Applicant's Proposal to implement and operate the APCCR demonstrates a sound understanding of, and the ability to perform all of the responsibilities, outputs and outcomes of the APCCR Custodian.

The Applicant demonstrates experience in implementing and operating a national initiative of a similar nature to APCCR.

The Applicant demonstrates the ability to comply with Australian Commission on Safety and Quality in HealthCare (ACSQHC) Strategic and Operations Principles for a National Approach to Australian Clinical Quality Registries.

The Applicant demonstrates appropriately qualified and skilled personnel to implement and operate the APCCR.

The price and budget for undertaking the APCCR, including oversight and working with Participating State/Territory Organisations, is competitive, and, where applicable, sensitive to volume and activity.

EC 2. Ability to build strong collaborative partnerships

The Applicant's experience in establishing and maintaining strong collaborative partnerships with multiple stakeholders across states and territories.

EC 3. Ability of software / solution to support APCCR and interoperate with other systems

The Applicant demonstrates an ability to provide a software solution that meets the needs of APCCR.

The Applicant demonstrates an ability to provide a software solution that can receive and store agreed data from Participating State/Territory Organisations in a range of different formats.

The Applicant demonstrates compliance with applicable technical standards, including :

- International Organization for Standardization (ISO) 27001.
- Australian Commission on Safety and Quality in Health Care' (ACSQHC) Infrastructure & Technical Standards - Australian Clinical Quality Registries [May 2012].*
- Australian Commission on Safety and Quality in Health Care' (ACSQHC) Requirements Specification for Australian Clinical Quality Registries - Final Consultation Draft [October 2011].*
- Australian Commission on Safety and Quality in Health Care' (ACSQHC) Logical Design - Australian Clinical Quality Registries [March 2012].*
- Australian Commission on Safety and Quality in Health Care' (ACSQHC) Security Certification Framework - Australian Clinical Quality Registries - Final consultation draft - Version 1.4 [March 2013].*

The Applicant demonstrates appropriately qualified and skilled personnel to implement and operate the APCCR software solution.

* The ACSQHC Technical Resources are available for reference at:

<http://www.safetyandquality.gov.au/our-work/information-strategy/clinical-quality-registries/technical-resources/>

4.2 SCORING

Each of the Evaluation Criteria will be scored separately against the following scale:

Outstanding - Exceeds all aspects of the evaluation criterion	4 – 4.9
Excellent - Exceeds some aspects of evaluation criterion (and meets all other aspects of the selection/evaluation criterion)	3 – 3.9
Good - Meets the evaluation criterion	2 – 2.9
Below average - Fails some aspects of the evaluation criterion	1 – 1.9
Not acceptable - Fails all aspects of the evaluation criterion.	0 -0.9

4.3 REVIEW PROCESS

Applications will be subject to an independent review process. The evaluation panel will comprise experts in clinical registries, mostly drawn from Australia. This review is likely to require a site visit for shortlisted candidates.

5 **FUNDING ARRANGEMENTS**

Movember has allocated and will make an initial investment of up to \$3 million to at least fund the first 3 years of APCCR. This amount will be available to support the function of the APCCR Custodian as well as the Local Responsibilities undertaken by Participating State/Territory Organisations.

Final funding will be determined between Movember and the APCCR Custodian following the completion of discussions with Preferred State/Territory Organisations taking into account the number of states/territories participating and the number of participating clinical sites.

On the basis that the APCCR is achieving the results we seek, Movember will consider extending the funding of the APCCR for a further period of 3 years.

Movember welcomes and will actively seek to persuade other funders to support the initiative.

In addition, as noted in this RFP, to generate reports of the lived experience of men diagnosed with prostate cancer in the interim, Participating States / Territory Organisations that have already collected population based data of a similar nature to the APCCR data sets will be invited to submit a collaborative research project on the outcomes of prostate cancer treatment and care, including the health outcome indicators detailed in Annexure 1. The proposal will be reviewed and approved by the APCCR Steering Committee. Movember will fund \$250,000 per annum for two years to support this collaborative research effort.

5.1 **FUNDING OF APCCR CUSTODIAN**

In its final form APCCR funding will be provided to cover relevant costs for:

- (a) Undertaking APCCR Custodian functions as described in Section 3
- (b) Participating State/Territory Organisations undertaking the Local Responsibilities, as described in Section 3.6

The Applicant's proposal will need to address the costs associated with performing the APCCR Custodian functions as described in Section 3. Given some costs are variable based on scope (e.g. the number of participating states and territories) and scale (the number of prostate cancer cases) the Applicant's Proposal will be expected to detail unit costs where relevant.

5.2 **FUNDING OF THE LOCAL RESPONSIBILITIES**

The level of funding to be provided to undertake the Local Responsibilities will be determined in discussions between Preferred State/Territory Organisations and the APCCR Custodian.

As part of their response, Applicants will be requested to detail their current level of relevant activity, and planned scale of activity over the next 3 years.

The principles that will apply to the funding structure for performing the Local Responsibilities are:

- The costs associated with undertaking the Local Responsibilities and collecting the minimum clinical data (T1) described in Annexure 3 and PRO in Annexure 4 will be funded. Costs associated with collecting additional data beyond the specified data sets, or undertaking activities that are not part of the Local Responsibilities, will not be eligible for APCCR funding.
- Costs that are variable in nature based on the level of activity (eg. data collection and undertaking PRO interviews) will be funded on the basis of level of activity undertaken.
- In states and territories that have a relatively small number of prostate cancer cases, it may be practical to fund an existing resource to undertake the Local Responsibilities, or share the cost of the required resources with other organisations. Where such opportunities are relevant and appropriate, applicants are encouraged to include them in their proposal.

-
- Where an existing prostate cancer clinical registry is in operation, APCCR funding is intended to strengthen rather than substitute existing funding sources. APCCR funding should support identified activities associated with Local Responsibilities.
 - Where an EOI Applicant currently undertakes functions similar to APCCR, and elects to use its own database, the costs of transferring data to the APCCR will be funded. The costs associated with operating and maintaining an existing database will not be funded.

6 RFP SUBMISSION GUIDELINES AND TERMS AND CONDITIONS OF RFP

Each Application must comply with the RFP Submission Guidelines set out below. On submitting a proposal, applicants are deemed to have accepted the Terms and Conditions of RFP, set out below.

Applications must nominate:

- The organisation that would contract with Movember if the application is successful.
- A primary contact person, who would be the key clinical leader responsible for the RFP application.

6.1 RFP SUBMISSION GUIDELINES

- All applicants must follow the instructions in this section. Applications that do not comply with these instructions may not be accepted for review.
- By submitting an application, the Applicant is deemed to have accepted the Terms and Conditions set out below.
- Applicants are requested to email prostateregistry@movember.com an intent to apply. This is an administrative process to help develop the review panel. The notice should simply detail the organisation name, the intention to submit an RFP response and a contact person, their email address and phone number.
- The application must then be submitted electronically via Movember online portal system, which can be accessed via <https://registry.myreviewroom.com>. Hardcopy and emailed applications will not be accepted.
- Applicants will need to create an account through the Movember online portal, which will then allow them to complete application.
- The application can be edited any number of times up until the closing date and time of **2pm AEST, Friday 12 July 2013**.
- The application must be submitted by **2pm AEST, Friday 12 July 2013**.
- The project proposal should be a MAXIMUM of 30 pages (excluding cover pages, table of contents, budget and any CVs).
 - Microsoft Word or PDF format preferred.
 - One (1) page for the table of contents.
 - A4 size, 210 X 297mm
 - Arial font (regular), minimum 11-point
 - Single-spaced text
 - 1 " (2.54 cm) margin on all sides of each page; and
 - A header on each page with the organisation and primary contact person's name in top left-hand corner, and the page number in the top right-hand corner.
- Movember is not obliged to consider applications received after the closing time but may do so at its sole discretion. If a late application is considered, Movember must be satisfied that accepting a late application will not compromise the integrity of the application process. Late applications may be considered when it can be clearly demonstrated that exceptional circumstances have arisen such as downtime in the online software portal (which will be separately validated by Movember before accepting a late application). If an applicant considers that their application will be late they should email the Shannyn Merlo via prostateregistry@movember.com prior to the RFP Closing Time (2pm, 12 July 2013) advising of the circumstances for the lateness which will be independently considered.

- All correspondence and questions relating to this RFP are to be submitted to Shannyn Merlo via email at prostateregistry@movember.com. All questions will be answered in a timely manner. Movember may provide responses to any question to all applicants.
- After the closing time the applicant waives the right to withdraw and replace, or amend, their application unless requested to do so by Movember or prior approved by Movember.
- Movember may request further information from applicants during the RFP process.

6.2 TERMS AND CONDITIONS OF RFP

6.2.1 General Terms

1. Movember does not make any representation that it will, and disclaims any obligation to, proceed with or to commit to any particular future actions in relation to the subject matter of this RFP (the **Project**), including without limitation:
 - a. accepting any RFP or shortlist any Applicant; and
 - b. considering, not considering, accepting or rejecting any RFP.
2. Applicants acknowledge and agree that, if they are chosen to be the APCCR Custodian, they will be requested to work closely with the Preferred State / Territory Organisations to discuss and agree on an implementation plan, consistent with the terms of this RFP.
3. Movember reserves the right, in its sole discretion, to initiate another selection process, enter into negotiations with a person or persons who have not been invited to respond to this RFP or to cancel the Project.
4. Applicants must pay their own costs and expenses incurred in preparing and submitting an RFP. Movember will provide funding to the APCCR Custodian to develop and finalise the implementation plan
5. To the extent permitted by law, Movember excludes all liability for any loss, costs (including legal costs) or damages, suffered or incurred by an Applicant or any other person, arising out of the Applicant's participation in this RFP process and (except as set out in paragraph 4 above) any subsequent phase of the process of selecting the APCCR Custodian or establishing the APCCR, including without limitation the cost of preparing and submitting an RFP or any further documents or information (however that loss, cost or damage arises).
6. The RFP Applicant warrants that it has no actual or potential conflict of interest in relation to its participation in this RFP process or its delivery of the Project other than that it has disclosed in its RFP.
7. No legal or other obligation arises between an Applicant and Movember in relation to the outcome of the RFP process, unless and until Movember executes a contract with the Applicants.
8. Movember is not obliged to:
 - a. accept any RFP; or
 - b. enter into any contract with any Applicant; or
 - c. give reasons for not considering or accepting or rejecting all or any part of any RFP or for cancelling the RFP process.

Movember may, in its sole discretion, consider for acceptance a response that does not comply with the requirements of this Request for RFPs.

9. Movember will advise the outcome of the RFP process to all Applicants
10. The Applicant grants Movember a non-exclusive licence to use for the purpose of this RFP process any information, processes, sketches, calculations, drawings or other data or information submitted with, or included in, the response submitted by the Applicant.

11. Each Applicant agrees to indemnify Movember against third party claims arising out of any use of any proprietary information submitted with, or included in, an RFP.
12. Should the Applicant find any material discrepancy, error or omission in this Request for RFP, the Applicant must immediately notify Movember in writing of the nature of the discrepancy, error or omission.
13. The Applicant and each of the key personnel acknowledge that their details, including any personal details may be disclosed to third parties including the evaluation panel, for the purposes of this RFP process and any related purposes.

6.2.2 Variations

Movember may vary the requirements set out in this Request for RFP and seek further information from the Applicants. Applicants shall supply this information upon reasonable request.

6.2.3 Movember's Rights

Movember reserves the right to subject the Applicants to a "due diligence" enquiry, which may comprise:

- verifying whether the represented resources and skills are actually available; and
- assessing experience and integrity, including a possible site visit.

Movember, in its sole discretion, reserves the right to depart from any method of evaluation set out in this RFP.

6.2.4 Reliance on Information

Movember will rely on information provided by, or on behalf of the Applicants at all stages of the RFP process. In providing information, Applicants represent to Movember that the information is complete and accurate in all material respects, that it is not misleading and that in preparing the information reasonable skill and care has been exercised by the Applicant and its personnel and acknowledges that Movember may rely upon that information.

6.2.5 Publicity

Applicants are not to make any public statement in relation to, the RFP process, their response, or their participation in the RFP process or contract negotiation process without Movember's prior written consent.

6.2.6 Governing Law

This RFP process and the Terms and Conditions set out in Section 6 are governed by the laws in force in Victoria, Australia.

7 CONTACT DETAILS FOR THIS RFP

If you have any questions in relation to the RFP, please contact Shannyn Merlo on (03) 8416 3900 or prostateregistry@movember.com.

GLOSSARY

APCCR Custodian	The organisation contracting with Movember to manage the Australian Prostate Cancer Clinical Registry
Australian Prostate Cancer Clinical Registry (APCCR)	An Australian, quality clinical registry, initially funded by Movember, that contains population based, clinical and patient reported data of men diagnosed with prostate cancer in Australia.
Local Responsibilities	The Participating State / Territory Organisations will need to undertake a number of responsibilities (either directly or through arrangements with the APCCR Custodian) within their state / territory. Those responsibilities are referred to as the Local Responsibilities, and are listed in Section 3.6
Movember Health Outcomes Indicators for Prostate Cancer	A set of statements or indicators for quality of life outcomes for men diagnosed with prostate cancer, together with their partner, carers and family.
Movember online portal	https://registry.myreviewroom.com is the portal where all EOI and RFP applications must be submitted.
Participating State / Territory Organisations	State and Territory Organisations that have contracted with the APCCR Custodian to undertake the Local Responsibilities
Patient reported outcomes	Participating men will be asked to complete the patient reported outcomes questionnaires, either via interviews with appropriately qualified personnel, or through a secure online survey tool as detailed in Annexure 4
Preferred State/Territory Organisation	State and Territory Organisations, selected through an EOI process, to be the preferred organisations to undertake the Local Responsibilities. Upon contract finalisation with the APCCR Custodian, the Preferred State / Territory Organisations will become the Participating State / Territory Organisations.

ANNEXURE 1

MOVEMBER HEALTH OUTCOMES INDICATORS FOR PROSTATE CANCER

Results we seek for men from our investment in Survivorship Programs

Result	Indicator	Baseline
A I am satisfied with the information, care and treatment I received	A1 I had access to well-coordinated advice and care	TBC
	A2 I made a well-informed treatment decision that I do not regret	TBC
	A3 I had access to the treatment of my choice	TBC
B I am physically well	B1 I have fully recovered from any urinary dysfunction that I had	TBC
	B2 I am satisfied with the level of sexual function that I have	TBC
	B3 I have fully recovered from any bowel dysfunction that I had	TBC
	B4 I am effectively managing any pain, fatigue, nausea and other symptoms that I experience	TBC
C I am mentally well	C1 I know what to expect during and after treatment, including when and where to seek help if specific issues arise	TBC
	C2 I am able to live a meaningful life in the community of my choice	TBC
	C3 I have accepted and am prepared for the possible consequences and possible outcomes of my cancer and my treatment(s)	TBC
	C4 I am not depressed or anxious	TBC

Results we seek for the partners, families and carers of men living with prostate cancer

Result	Indicator	Baseline
D My partner, family and carers are mentally well	D1 My partner, family and carers know what to expect during and after treatment, including when and where to seek help if specific issues arise	TBC
	D2 My partner, family and carers have accepted and are prepared for the possible consequences and possible outcomes of my cancer and my treatment(s)	TBC
	D3 My partner, family and carers are not depressed or anxious	TBC
E I am physically well	E1 My partner is satisfied with the level of sexual function that I have	TBC
	E2 My partner, family and carers are effectively managing any fatigue and other symptoms	TBC

ANNEXURE 2**PROSTATE CANCER CLINICAL REGISTRY WORKING GROUP**

Dr Joanne Aitken
Dr Siddhartha Baxi
Dr Jenny Broering
Professor David Currow
Dr Sue Evans
Dr Raj Gogia
Professor Dickon Hayne
Dr Peter Heathcote
Dr Anthony Lowe
Professor John McNeil AM
Associate Professor Jeremy Millar
Dr Kim Moretti
Professor Ian Olver AM
Dr Carol Pinnock AM
Professor David Roder
Dr Ian Roos OAM
Dr Tom Shannon
Dr David Smith

ANNEXURE 3

AUSTRALIAN PROSTATE CANCER CLINICAL REGISTRY DATA SET SPECIFICATION

T1 – Minimum list items (required for participation)

T2 –Additional core items (core)

T3 – Additional items (value adding)

T1 – Minimalist items (required for participation)	T2 –Additional core items (core)	T3 – Additional items (value adding)
PERSON:		
Family name	Family name	Family name
Given name(s)	Given name(s)	Given name(s)
	Address line	Address line
Postcode	Postcode	Postcode
Date of birth	Date of birth	Date of birth
	-AIHW Birth-date Accuracy Estimator	-AIHW Birth-date Accuracy Estimator
	ATSI status	ATSI status
		Country of birth
		Main language spoken at home
	Individual Healthcare Identifier (IHI)	Individual Healthcare Identifier (IHI)
	Medical Record Number	Medical Record Number
	Medicare Card Number	Medicare Card Number
Vital status	Vital status	Vital status
Date of death	Date of death	Date of death
Cause of death	Cause of death	Cause of death
FAMILY HISTORY:		
		1 st degree members diagnosed
		-1 st degree members diagnosed (text)
		-1 st degree member age at diagnosis
PROVIDER (organization):		
	Healthcare Provider Identifier (HPI-O)	Healthcare Provider Identifier (HPI-O)
DIAGNOSIS:		
	Most valid basis of diagnosis	Most valid basis of diagnosis
Diagnosis date	Diagnosis date	Diagnosis date
	-AIHW Diagnosis-date Accuracy Estimator	-AIHW Diagnosis-date Accuracy Estimator
ASSESSMENT AT DIAGNOSIS:		
		Performance status (ECOG)
	Symptoms	Symptoms
PSA (last PSA pre-biopsy):	PSA (last PSA pre-biopsy):	PSA (last PSA pre-biopsy):
-Date	-Date	-Date
-Level (ng/mL)	-Level (ng/mL)	-Level (ng/mL)
	Imaging investigations	Imaging investigations
	Biopsy type	Biopsy type
<i>Biopsy core results</i>	<i>Biopsy core results</i>	<i>Biopsy core results</i>
-Summary Results (all specimens):	-Summary Results (all specimens):	-Summary Results (all specimens):
		-Region of prostate with highest Gleason score
-Presence of tumour	-Presence of tumour	-Presence of tumour
-Histology type	-Histology type	-Histology type
-Number of core specimens:	-Number of core specimens:	-Number of core specimens:
--Number examined	--Number examined	--Number examined
--Number positive for tumour	--Number positive for tumour	--Number positive for tumour

	-Total length of tissue in cores:	-Total length of tissue in cores:
	-Total linear length of cores examined-(all cores) (mm)	-Total linear length-of cores examined (all cores)(mm)
	-Total linear length of tumour (all cores) (mm)	-Total linear length of tumour (all cores) (mm)
	-Percentage of tissue positive for tumour (derivable)	-Percentage of tissue positive for tumour (derivable)
-Gleason grade:	-Gleason grade:	-Gleason grade:
-Primary (dominant/most prevalent)	-Primary (dominant/most prevalent)	-Primary (dominant/most prevalent)
-Highest grade	-Highest grade	-Highest grade
-Specified grade (for unusual histology types)	-Specified grade (for unusual histology types)	-Specified grade (for unusual histology types)
		-Gestalt pattern
		-Dominant (most common)
		-2 nd most common
		-Higher tertiary
	Other:	
	-Perineural invasion	-Perineural invasion
	-Lymphatic/vascular invasion	-Lymphatic/vascular invasion
		-PIN (high grade)
<i>Clinical TNM assessment</i>	<i>Clinical TNM assessment</i>	<i>Clinical TNM assessment</i>
-T	-T	-T
-N	-N	-N
-M	-M	-M
-TNM-overall grouping	-TNM-overall grouping	-TNM overall grouping
-TNM text	-TNM text	-TNM text
	-M sites	-M sites
-Staging scheme edition	-Staging scheme edition	-Staging scheme edition
CLINICAL MANAGEMENT (initial round):		
	Intent (curative/non-curative)	Intent (curative/non-curative)
TREATMENT:		
-Surgery	-Surgery	-Surgery
-Radiotherapy	-Radiotherapy	-Radiotherapy
-ADT (Chemical)	-ADT (Chemical)	-ADT (Chemical)
-ADT (Surgical)	-ADT (Surgical)	-ADT (Surgical)
-Chemotherapy	-Chemotherapy	-Chemotherapy
-Other systemic therapies	-Other systemic therapies	-Other systemic therapies
-Other treatments	-Other treatments	-Other treatments
-Watchful waiting	-Watchful waiting	-Watchful waiting
-Active surveillance	-Active surveillance	-Active surveillance
	TRIAL:	TRIAL:
	-Trial entry status	-Trial entry status
	-Experimental agent/protocol	-Experimental agent/protocol
	-Trial name/number	-Trial name/number
	-Entry date	-Entry date
	-Completion date	-Completion date
SURGERY:	SURGERY:	SURGERY:
-Date	-Date	-Date
-Type	-Type	-Type
-Approach	-Approach	-Approach
		-Nerve sparing
		-Pelvic lymph node dissection
Surgical pathology:	Surgical pathology:	Surgical pathology:
-Histology type	-Histology type	-Histology type
-Gleason grade:	-Gleason grade:	-Gleason grade:

-Primary	-Primary	-Primary
-Secondary	-Secondary	-Secondary
-Tertiary (if applicable)	-Tertiary (if applicable)	-Tertiary (if applicable)
	Other:	Other:
		-Multifocal
		-Prostate region (highest Gleason score)
	-Lymphatic/vascular invasion	-Lymphatic/vascular invasion
-Extra-prostatic extension:	-Extra-prostatic extension:	-Extra-prostatic extension:
-Status (no/yes)	-Status (no/yes)	-Status (no/yes)
	-Extent	-Extent
		-Location1
		-Location2
		-Seminal vesicle invasion:
		-Occurrence (y/n)
		-Region involved (R/L/both)
	Regional nodes:	Regional nodes:
	-Number examined	-Number examined
	-Number positive	-Number positive
Pathological TNM assessment:	Pathological TNM assessment:	Pathological TNM assessment:
-T	-T	-T
-N	-N	-N
-M	-M	-M
-TNM grouping	-TNM grouping	-TNM grouping
-TNM text	-TNM text	-TNM text
-Staging scheme edition	-Staging scheme edition	-Staging scheme edition
Surgical outcome:	Surgical outcome:	Surgical outcome:
-Margin involvement:	-Margin involvement:	-Margin involvement:
-Clear/involved/equivocal	-Clear/involved/equivocal	-Clear/involved/equivocal
	-Involvement (<3mm/3+mm)	-Involvement (<3mm/3+mm)
		-Involvement (mm)
		-Surgical complications:
		-Clavian grade
		-Specific
		-Text
		-Medical complications:
		-Occurrence
		-Text
RADIOTHERAPY:		
-Radiotherapy type	-Radiotherapy type	-Radiotherapy type
-External beam	-External beam	-External beam
--Occurrence	--Occurrence	--Occurrence
--Start date	--Start date	--Start date
--Completion date	--Completion date	--Completion date
	--Dose (Gy)	--Dose(Gy)
	--Fractions	--Fractions
	--Delivery code	--Delivery code
		--Radiotherapy institution
-Brachytherapy	-Brachytherapy	-Brachytherapy
--Occurrence	--Occurrence	--Occurrence
--Start date (first implant)	--Start date (first implant)	--Start date (first implant)
--Completion date (last implant)	--Completion date (last implant)	--Completion date (last implant)
	Dose (Gy)	Dose (Gy)
	Dose rate (HDR/LDR)	Dose rate (HDR/LDR)

	Fractions	Fractions
ANDROGEN DEPRIVATION THERAPY:	ANDROGEN DEPRIVATION THERAPY:	ANDROGEN DEPRIVATION THERAPY:
		If neoadjuvant/adjuvant:
		-Agent 1
		-Agent 2
		-Agent 3
		If palliative:
		-Agent 1
		-Agent 2
		-Agent 3
		-Surgical
-Agent start date	-Agent start date	-Agent start date
	-Delivery	-Delivery
-Agent stop date	-Agent stop date	-Agent stop date
-Surgical ADT date	-Surgical ADT date	-Surgical ADT date
CHEMOTHERAPY:	CHEMOTHERAPY:	CHEMOTHERAPY:
	-Agent/protocol 1	-Agent/protocol 1
	-Agent/protocol 2	-Agent/protocol 2
	-Agent/protocol 3	-Agent/protocol 3
	-Agent/protocol 4	-Agent/protocol 4
	-Agent/protocol 5	-Agent/protocol 5
-Start date	-Start date	-Start date
-End date	-End date	-End date
-Text field	-Text field	-Text field
OTHER SYSTEMIC THERAPIES (e.g., hormone therapy):		
	-Agent/protocol 1	-Agent/protocol 1
	-Agent/protocol 2	-Agent/protocol 2
	-Agent/protocol 3	-Agent/protocol 3
	-Agent/protocol 4	-Agent/protocol 4
	-Agent/protocol 5	-Agent/protocol 5
-Start date	-Start date	-Start date
-End date	-End date	-End date
-Text field	-Text field	-Text field
OTHER TREATMENTS:		
-Text field	-Text field	-Text field
RELAPSE/RECURRENCE:		
-Clinical relapse:		
--Occurrence	--Occurrence	--Occurrence
	--Region	--Region
		--Distant recurrence site
--Date of initial event	--Date of initial event	--Date of initial event
-Biochemical relapse:		
--Occurrence	--Occurrence	--Occurrence
--Date of initial event	--Date of initial event	--Date of initial event
-Castrate resistance:		
	Occurrence	Occurrence
	Date of initial event	Date of initial event
Treatment of Relapse/Recurrence:		
	Treatment occurrence	Treatment occurrence
	Treatment type	Treatment type
	Text field	Text field
FOLLOW-UP	FOLLOW-UP	FOLLOW-UP
Last contact date	Last contact date	Last contact date

Last known cancer status	Last known cancer status	Last known cancer status
	PSA LOG (including sentinel follow-ups)	
	During treatment	During treatment
	Date	Date
	Level (ug/L)	Level (ug/L)
	At end of treatment	At end of treatment
	Date	Date
	Level (ug/L)	Level (ug/L)
	Follow-up 1 (e.g., at 12 months)	Follow-up 1 (e.g., at 12 months)
	Date	Date
	Level (ug/L)	Level (ug/L)
	Follow-up 2 (e.g. at 24 months)	Follow-up 2 (e.g. at 24 months)
	Date	Date
	Level (ug/L)	Level (ug/L)
	Follow-up 3 (e.g., at 36 months)	Follow-up 3 (e.g., at 36 months)
	Date	Date
	Level (ug/L)	Level (ug/L)
	Follow-up 4 (e.g., at 48 months)	Follow-up 4 (e.g., at 48 months)
	Date	Date
	Level (ug/L)	Level (ug/L)
	Follow-up 5 (e.g., at 60 months)	Follow-up 5 (e.g., at 60 months)
	Date	Date
	Level (ug/L)	Level (ug/L)

AUSTRALIAN PROSTATE CANCER CLINICAL REGISTRY DATA ITEM CHARACTERISTICS AND VALUES

DATA ITEM	CHARACTERISTICS	VALUES
PERSON:		
Family name	String	Text
Given name(s)	String	Text
Address line	String	Text
Postcode	Numeric	NNNN
Date of birth	Date	DDMMYYYY
-AIHW birth-date accuracy estimator	Numeric	1 Estimated; 2 Not estimated; 9 Not known
ATSI status	Numeric	1 Aboriginal; 2 TSI; 3 Aboriginal & TSI; 4 Neither; 9 Not known
Country of birth	Numeric	NNNN (Standard Australian Classification of Countries)
Main language spoken at home	Numeric	1 Not English; 2 English; 9 Not known
Individual Healthcare Identifier(IHI)	String	Unique NEHTA code (16 digit)
Medical Record Number	String	Hospital URN
Medicare Card Number	String	Medicare Number
Vital status	Numeric	1=Alive; 2 Dead; 5=Dead (not confirmed); 9 Not known
Date of death	Date	DDMMYYYY
Cause of death	Numeric	1 Prostate cancer; 2 Other; 9 Not known
FAMILY HISTORY:		
1 st degree members diagnosed	Numeric	1 Grandchild; 2 Parent; 3 Sibling; 4 Child; 5 Grandchild; 9 Not known (note: allow for multiples)

1 st degree members diagnosed (text)	String	Narrative
1 st degree member youngest age at diagnosis	Numeric	1 <65 yrs; 2 65+ yrs; 9 Not known
PROVIDER (organization):		
Healthcare Provider Identifier (HPI-O)	String	Unique NEHTA code (16 digit)
DIAGNOSIS:		
Most valid basis of diagnosis (score highest value)	Numeric	0 Death certificate only; 1 Clinical; 4 Tumour marker (e.g., biochem/ immunol); 5 Cytology; 6 Histology (met); 7 Histology (prim); 8 Histology (? prim/met); 9 Not known
Diagnosis date	Date	DDMMYYYY
-AIHW diagnosis date accuracy estimator	Numeric	1 Estimated; 2 Not estimated; 9 Not known
ASSESSMENT AT DIAGNOSIS:		
Performance status (ECOG) (score highest value)	Numeric	0 Fully active; 1 Restricted; 2 Not able to work (up >50% waking hours); 3 Confined to bed/chair (>50% waking hours); 4 Totally confined to bed/chair; 8 Not known
Symptoms	Numeric	1 Erectile dysfunction; 2 Incontinence; 3 Urine leakage; 4 Other; 9 Not known (allow for multiples)
PSA (last PSA pre-biopsy):		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)
Imaging investigations	Numeric	1 US; 2 MRI; 3 CT; 4 PET; 5 Bone scan; 6 Other; 9 Not known (note: allow for multiples)
Biopsy type	Numeric	1 TRUS guided; 2 Transperineal; 3 Trans-urethral; 9 Not known (note: allow for multiples)
Biopsy core results		
Summary results (from all specimens)		
-Region of prostate with highest Gleason score	Numeric	1 RA; 2 RP; 3 LA; 4 LP; 8 Other; 9 Not known (note: allow for multiples)
-Presence of tumour	Numeric	1 No; 2 Yes; 9 Not known
-Histology type	Numeric	NNNNN (ICDO3 code)
-Number of core specimens:		
-Number examined	Numeric	NN
-Number positive for tumour	Numeric	NN
-Total length of tissue in cores:		
-Total linear length of cores examined (all cores) (mm)	Numeric	NN (see SPR)
-Total linear length of tumour (all cores) (mm)	Numeric	NN (see SPR)
-Percentage of tissue positive for tumour (derivable)	Numeric	NN (see SPR)
-Gleason grade:		
-Primary (dominant/most prevalent)	Numeric	NN (see SPR)
-Highest grade	Numeric	NN (see SPR)
-Specified grade (for unusual histology types)	Numeric	NN (see SPR)
-Gestalt pattern:		
-Dominant (most common)	String	Text
-2 nd most common	String	Text
-Higher tertiary	String	Text
-Other:		
-Perineural invasion	Numeric	N (1 Present; 2=Not identified; 9 Not known)
-Lymphatic/vascular invasion	Numeric	N (1 Present; 2=Not identified; 9 Not known)
-PIN (high grade)	Numeric	N (1 Present; 2=Not identified; 9 Not known)
Clinical TNM assessment		
-T	String	UICC/AJCC 2 digit
-N	String	UICC/AJCC 1 digit
-M	String	UICC/AJCC 1 digit
-TNM grouping	String	UICC/AJCC 1 digit
-TNM text	String	Text
-M sites	Numeric	1 Lung; 2 Liver; 3 Bowel; 4 Bone; 5 Brain; 6 Other; 7 Not Present; 9 Not known
-Staging scheme edition	String	UICC/AJCC Edition (e.g., 7 th)

CLINICAL MANAGEMENT (initial round)		
Intent (curative/non-curative)	Numeric	1 Curative; 2 Non-curative; 9 Not known
Treatment:		
-Surgery	Numeric	1 No; 2 Yes; 9 Don't know
-Radiotherapy	Numeric	1 No; 2 Yes; 9 Don't know
-ADT (Chemical)	Numeric	1 No; 2 Yes; 9 Don't know
-ADT (Surgical)	Numeric	1 No; 2 Yes; 9 Don't know
-Chemotherapy	Numeric	1 No; 2 Yes; 9 Don't know
-Other systemic therapy	Numeric	1 No; 2 Yes; 9 Don't know
-Other therapy	Numeric	1 No; 2 Yes; 9 Don't know
-Watchful waiting	Numeric	1 No; 2 Yes; 9 Don't know
-Active Surveillance	Numeric	1 No; 2 Yes; 9 Don't know
TRIAL:		
-Trial entry status	Numeric	1 Not offered; 2 Offered, accepted; 3 Offered, declined; 4 Offered, decision not known; 9 Not known if offered
-Experimental agent/protocol	String	Text (note: allow for multiples)
-Trial name/number	String	Text
-Entry date	Date	DDMMYYYY
-Completion date	Date	DDMMYYYY
SURGERY:		
-Date	Date	DDMMYYYY
-Type	Numeric	1 Open Rad Prostatect; 2 Robotically Assist Rad Prostatect; 3 Laproscopic Rad Prostatect; 4 Rad Retropub Prostatect; 5 TURP; 6 Other; 9 Not known
-Approach	Numeric	1 Open; 2 Laproscopic; 3 Robotic Assisted; 4 Open (converted from Laproscopic); 5 Open (converted from Robotic); 9 Not known
-Nerve sparing	Numeric	1 No; Yes: 2: Open; 3 Unilateral; 4 Bilateral; 9 Not known
-Pelvic lymph node dissection	Numeric	1 No; 2 Left; 3 Right; 4 Bilateral; 5 Yes (side unknown); 9 Not known
Surgical pathology:		
-Histology type	Numeric	NNNNN (ICDO3 code)
-Gleason grade:		
-Primary	Numeric	NN (see SPR)
-Secondary	Numeric	NN (see SPR)
-Tertiary (if applicable)	Numeric	NN (see SPR)
Other:		
-Multifocal	Numeric	1-Unifocal; 2 Multifocal; 9 Not known
-Prostate region (highest Gleason score)	Numeric	1 RA; 2 RP; 3 LA; 4 LP; 8 Other; 9 Not known (note: allow for multiples)
-Lymphatic/vascular invasion	Numeric	1 No; Yes: 2 Artery; 3 Vein; 4 Lymph; 5 Multiple vessel types; 6 Vessel not known; 9 Not known
-Extra-prostatic extension:		
-Status	Numeric	1 No; 2 Yes; 9 Not known
-Extent	Numeric	1 No; Yes: 2 Focal; 3 Extensive; 9 Not known
-Location1	Numeric	1 RA; 2 RP; 3 LA; 4 LP; 8 Other; 9 Not known (note: allow for multiples)
-Location2	Numeric	1 Base; 2 Mid; 3 Apex; 4 Other; 9 Not known (note: allow for multiples)
-Seminal vesicle invasion:		
-Occurrence	Numeric	1 No; 2 Yes; 9 Not known
-Region involved	Numeric	1 Left; 2 Right; 8 Other; 9 Not known (note: allow for multiples)
Regional nodes:		
-Number examined	Numeric	NN
-Number positive	Numeric	NN
Pathological TNM assessment		
-T	String	UICC/AJCC 2 digit
-N	String	UICC/AJCC 1 digit

-M	String	UICC/AJCC 1 digit
-TNM grouping	String	UICC/AJCC 1 digit
-TNM text	String	Text
-Staging scheme edition	String	UICC/AJCC Edition (e.g., 7 th)
Surgical outcome:		
-Margin involvement:		
-Clear/involved/equivocal	Numeric	1 Clear; 2 Involved; 3 Equivocal; 9 Not known
-Involvement (3+mm/<3mm)	Numeric	1 <3mm; 2 3+mm; 9 Not known
-Involvement (mm)	Numeric	NN
-Surgical complications:		
-Clavian grade	Numeric	NN Clavian grade code list
-Specific	Numeric	1 DVT; 2 Pulmonary Embolism; 3 Infection; 4 Impotence; 5 Incontinence; 6 Sexual dysfunction; 7 Other (note: allow for multiples)
-Text	String	Text field
-Medical complications:		
-Occurrence	Numeric	1 No; 2 Yes; 9 Not known
-Text	String	Text field
RADIOTHERAPY:		
-Radiotherapy type	Numeric	1 External beam; 2 Brachy; 3 Unsealed isotopes; 4 1+2; 5 1+3; 6 2+3; 7 1+2+3; 9 Not known
-External beam:		
--Occurrence	Numeric	1 No; 2 Yes; 9 Not known
--Start date	Date	DDMMYYYY
--Completion date	Date	DDMMYYYY
--Dose (Gy)	Numeric	NN.NN
--Fractions	Numeric	NN
--Delivery code	Numeric	1 Conformal; 2 IMRT; 3 GRT; 9 Not known
--Radiotherapy institution	String	Text
-Brachytherapy:		
--Occurrence	Numeric	1 No; 2 Yes; 9 Not known
--Start date (first implant)	Date	DDMMYYYY
--Completion (last implant)	Date	DDMMYYYY
--Dose (Gy)	Numeric	NN.NN
--Dose rate (HDR/LDR)	Numeric	1 LDR; 2 MDR; 3 HDR; 4 PDR; 9 Not known
--Fractions	Numeric	NN
ANDROGEN DEPRIVATION THERAPY:		
-Treatment phase (neoadjuvant/ adjuvant/palliative)	Numeric	1 Neoadjuvant; 2 Adjuvant; 3 Salvage; 4 Palliative; Not known
If neo-adjuvant/adjuvant:		
-Agent 1	String	Text
-Agent 2	String	Text
-Agent 3	String	Text
If palliative:		
-Agent 1	String	Text
-Agent 2	String	Text
-Agent 3	String	Text
-Surgical	Numeric	1 No; 2 Yes; 9 Not known
-Agent start date	Date	DDMMYYYY
-Delivery	Numeric	1 Continuous 2 Intermittent; Not known
-Agent stop date	Date	DDMMYYYY
-Surgical ADT date	Date	DDMMYYYY
CHEMOTHERAPY:		
-Agent/protocol 1	String	Text
-Agent/protocol 2	String	Text
-Agent/protocol 3	String	Text
-Agent/protocol 4	String	Text
-Agent/protocol 5	String	Text
-Start date	Date	DDMMYYYY
-End date	Date	DDMMYYYY
-Text field	String	Text
OTHER SYSTEMIC THERAPIES:		

-Agent/protocol 1	String	Text
-Agent/protocol 2	String	Text
-Agent/protocol 3	String	Text
-Agent/protocol 4	String	Text
-Agent/protocol 5	String	Text
-Start date	Date	DDMMYYYY
-End date	Date	DDMMYYYY
-Text field	String	Text
OTHER TREATMENTS:		
Text field	String	Text
RELAPSE/RECURRENCE		
-Clinical relapse:		
--Occurrence	Numeric	1 No; 2 Yes; 9 Not known
--Region	Numeric	1 Local; 2 Regional; 3 Distant; 4 1+2; 5 1+3; 5 2+3; 6 1+2+3; 9 Not known
--Distant recurrence site	Numeric	1 Lung; 2 Liver; 3 Bowel; 4 Bone; 5 Brain; 6 Other; 9 Not known (note: allow for multiples)
--Date of initial event	Date	DDMMYYYY
-Biochemical relapse:		
--Occurrence	Numeric	1 No; 2 Yes; 9 Not known
--Date of initial event	Date	DDMMYYYY
-Castrate resistance:		
--Occurrence	Numeric	1 No; 2 Yes; 9 Not known
--Date of initial event	Date	DDMMYYYY
Treatment of Relapse/Recurrence:		
-Treatment occurrence	Numeric	1 No; 2 Yes; 9 Not known
-Treatment type	Numeric	1 Surgery; 2 Radiotherapy; 3 Systemic; 4 1+2; 5 1+3; 6 2+3; 7 2+3; 8 1+2+3; Not known
-ADT treatment	Numeric	1 No; Yes: 2 Chemical; 3 Surgical; 9 Not known
-Text field	String	Text
FOLLOW-UP:		
-Last contact date	Date	DDMMYYYY
-Last known cancer status	Numeric	1 No evidence of cancer; 2 Evidence of cancer; 9 Not known
PSA LOG:		
During treatment:		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)
At end of treatment:		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)
Follow-up 1 (e.g., at 12 months)		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)
Follow-up 2 (e.g., at 24 months)		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)
Follow-up 3 (e.g., at 36 months)		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)
Follow-up 4 (e.g., at 48 months)		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)
Follow-up 5 (e.g., at 60 months)		
-Date	Date	DDMMYYYY
-Level (ug/L)	Numeric	NN.N (ug/L)

ANNEXURE 4

FINAL DRAFT: AUSTRALIAN PROSTATE CANCER CLINICAL REGISTRY PATIENT-REPORTED OUTCOMES TOOLS

CONTENT

Many of the Movember Health Outcomes Indicators will be addressed in a patient-reported questionnaire.
Some of the Movember Health Outcomes Indicators will be addressed in sub-studies.

MOVEMBER HEALTH OUTCOMES INDICATORS FOR PROSTATE CANCER

Result	No.	Statement	Covered in questionnaire Part A	Covered in questionnaire Part B	Covered in sub-studies
I am satisfied with the information, care and treatment I received	A1	I had access to well-coordinated advice and care		✓	
	A2	I made a well-informed treatment decision that I do not regret		✓	
	A3	I had access to the treatment of my choice	✓		
I am physically well	B1	I have fully recovered from any urinary dysfunction that I had	✓		
	B2	I am satisfied with the level of sexual function that I have	✓		
	B3	I have fully recovered from any bowel dysfunction that I had	✓		
	B4	I am effectively managing any pain, fatigue, nausea and other symptoms that I experience	✓	✓	
I am mentally well	C1	I know what to expect during and after treatment, including when and where to seek help if specific issues arise			✓
	C2	I am able to live a meaningful life in the community of my choice			✓
	C3	I have accepted and am prepared for the possible consequences and possible outcomes of my cancer and my treatment(s)			✓
	C4	I am not depressed or anxious	✓	✓	

QUESTIONNAIRE ITEMS

All registry participants answer a short questionnaire (Part A) and then are randomly assigned (with stratification) to different additional questionnaires (Part B) as well as some demographic questions (Part C).

PART A

- All registry participants to complete
- Will take 12-15 minutes to complete (38 items in total)
- EPIC 26
- K10
- Treatment choice questions

PART B

- A sample of participants answers ONE of B1, B2, B3 or B4
- Will take up to 10 minutes to complete
- B1 → Decision making (10 items). Davison Satisfaction Questionnaire + Decision Regret Scale
- B2 → Cancer-related distress (18 items). MAX PC
- B3 → Physical health and mental health (12 items). SF12
- B4 → Service satisfaction (16 items). SCA

PART C

- All registry participants to complete
- Will take 2-3 minutes to complete

PURPOSEFULLY EXCLUDED ITEMS THAT WILL BE INVESTIGATED VIA SUB-STUDIES

The following items / domains are excluded and will be investigated via sub-studies:

1. Result statement C1 – “I know what to expect during and after treatment, including when and where to seek help if specific issues arise”
2. Result statement C2 – “I am able to live a meaningful life in the community of my choice”
3. Result statement C3 – “I have accepted and am prepared for the possible consequences and possible outcomes of my cancer and my treatment(s)”
4. All results statements pertaining to partners and carers will be examined via separate sub-studies
5. Questions specifically relating to nocturia (the need to get up in the night to urinate). This can be investigated using IPSS or another measure via sub-studies
6. Broad questions about whether men are receiving support. This can be investigated via sub-studies

MODE OF ADMINISTRATION

The proposal is to have mixed mode of administration.

FIRST CONTACT

- Men are sent a letter of introduction, signed by their own Consultant or the Head of the Department in their respective institution
- Accompanying the letter will be an Explanatory Statement, outlining the purpose of the registry and providing important information to men about consent

-
- For men who are listed as requiring an interpreter in the patient's medical record, a copy of the Explanatory Statement is sent in other languages
 - Also included in the information pack would be another letter stating that someone would be in touch with the man by telephone to organise a convenient time to conduct the first questionnaire

FIRST QUESTIONNAIRE

- Administration of the first questionnaire would be via telephone
- At the end of the initial telephone call, the person administering the questionnaire would give participants the option of completing follow-up questionnaires via the web (e.g. smartphone, laptop, tablet, desktop). Participants could opt-in to using these web-based modes or could continue to complete the questionnaire by telephone
- Consider sending participants a "prompt sheet" prior to the telephone interview. (This has been used in the PCOS telephone survey). We could send out a sheet containing the response options for the relevant questions. The interviewer would still read out the question and the responses but would also identify for the respondent the appropriate box in the prompt sheet that contained possible responses
- Possibility of using existing networks of trained and qualified nurses to administer the telephone questionnaire.

ONGOING FOLLOW-UPS

- Some participants will receive and complete the questionnaire via the web
- The remaining participants will continue to receive and complete the questionnaire by telephone
- Participants will be able to change modes at any point in time after the initial contact

PILOT TESTING

- We will need to conduct some pilot testing of telephone-based and web-based administration for our selected instruments that have not already been tested for these modes
- Test telephone-based administration using a trained data collector for;
 - EPIC-26
- Test web-based administration using a custom-designed user interface for;
 - EPIC-26
- We will also need to conduct some pilot testing of using mixed modes of administration
 - Test telephone-based initial survey + telephone-based follow-up compared to telephone-based initial survey + web-based follow-up

TIMING OF INITIAL (BASELINE) QUESTIONNAIRE

ISSUES

In order to get a good baseline of a man's quality of life and function, it is preferable to obtain patient-reported outcomes data *after diagnosis* but *before treatment*.

In some states and territories, this is possible given the structure of the health system and the method of notifications of prostate cancer cases. In the smaller states where treatment is quite centralised, e.g. TAS, SA, NT and WA, it is a definite possibility. For example, in South Australia, SA-PCCOC is able to scan theatre lists and has a reasonable chance of getting access to most men prior to treatment in order to complete patient-reported outcomes questionnaires. In addition, the opportunity window is larger in South Australia because the median time from diagnosis to primary treatment is 4 months.

- Median time from diagnosis for radical prostatectomy patients (N=1350) is 4 months (IQ range 3-6months)
- Median time from diagnosis for external beam radiotherapy patients (N=931) is 4 months (IQ range 3-7months)

However, in other states and territories it is not possible to access men prior to treatment. It is particularly hard for the larger states with many regional treatment centres (Vic, NSW and Qld) to collect baseline data if they don't recruit on hospital/clinic presentation. For example, in Victoria notifications are received via the Victorian Cancer Registry. Processing times are often delayed and it can be many months before notifications are received by the Victorian PCR. In addition, the median time from diagnosis to primary treatment is less than 30 days

Note that there are trade-offs when gathering baseline data. It is possible that in states and territories where men are first approached *before treatment*, there may be a lower participation rate than in states and territories where men are first approached *12 months after treatment*.

PROPOSAL

Therefore, the proposal is *not* to have a one-size-fits-all approach. Instead, we propose that each state and territory makes initial contact with men either pre-treatment or post-treatment, depending on the conditions in that state or territory.

In order to still capture evidence of changes from pre-treatment to post-treatment, there are several options.

1. Rely on baseline data collected pre-treatment in a small number of states and territories
2. Conduct a sub-study using different recruitment methods (e.g. scan theatre lists in a certain number of hospitals in the more decentralised states) in order to access a sample of men pre-treatment and get a pre-treatment baseline
3. Conduct a sub-study at 3-6 months post-treatment and ask men to recall their experiences prior to treatment so that we get a pre-treatment baseline. Eg "In the month before diagnosis of your prostate cancer ...". In order to make sure the clinical records and the man are both on the same page with the date we should probably ask the man upfront "When were you first told by a Doctor that you had prostate cancer?"

If men are recruited at different time points (i.e. pre-treatment vs. post-treatment) then there may be unrecognised biases in the data. This is a trade-off that the working group is aware of. In all analysis and reporting the registry will need to clearly differentiate those men who answer the question pre-treatment vs. post-treatment. This will need to be clearly communicated to stakeholders.

The overall intention is to measure longer term outcomes. The registry will need to time the questionnaires and adequately adjust for "baseline" (whether truly pre-treatment or recalled pre-treatment) in order to achieve this aim.

A pilot test would be useful in order to compare patient responses pre-treatment with post-treatment recall 3-12 months later to identify any biases of reported baseline function, bother and psychological wellbeing.

DRAFT PRO QUESTIONNAIRE

CONFIRMATION OF INFORMATION

Please confirm that the information we have is correct for the following items;

1. Date of birth
2. Post code
3. Mobile phone number
4. Email address
5. Name and contact number of a person to contact if we can no longer reach you at this address or phone number

QUESTIONS ABOUT TREATMENT

1. What was the date you were first told you had prostate cancer (DD/MM/YYYY)
2. Have you had treatment for your prostate cancer? Yes / No
3. If yes,
 - a. What treatment(s) did you have? (may be yes to more than one)
 - Surgery (radical prostatectomy)
 - Active surveillance or “observation”
 - External beam radiotherapy
 - Brachytherapy with permanent seeds implanted
 - Brachytherapy with temporary needles or catheters (“high dose rate”)
 - Hormone therapy “injections or pills” or androgen deprivation therapy
 - Orchidectomy (“castration”)
 - High Intensity Focussed Ultrasound (HIFU)
 - Cryotherapy
 - Chemotherapy
 - Other
 - b. What was the name of the main doctor(s) who treated you?
 - c. What was the name of the main hospital(s) or clinic(s) where you were treated?
4. Has a doctor ever told you that you have: [all questions Yes / No. If yes, approx. MM/YYYY]
 - a. Arthritis, rheumatism, or another condition of the joints or bones?
 - b. High blood pressure or hypertension?
 - c. Heart disease, for example coronary artery disease, atherosclerosis, angina or heart attack?
 - d. Stroke or another neurological condition?
 - e. Diabetes
 - f. Lung disease, for example asthma or emphysema
 - g. Cancer (other than prostate cancer)
 - h. Kidney disease
 - i. Blood disease, for example anaemia or leukaemia
 - j. Stomach or intestinal disease, for example ulcers
 - k. Urinary condition
 - l. Any other conditions
 - Please specify _____

PART A (38 ITEMS) – TO BE ANSWERED BY ALL PARTICIPANTS

EPIC 26 (*Expanded Prostate Cancer Index Composite –short form*)

K10 (*Kessler-10*)

CHOICE QUESTIONS

1. I had access to the treatment(s) of my choice Yes No
2. If not, why not? _____

END PART A

PART B – A STRATIFIED SAMPLE OF PARTICIPANTS ANSWERS ONE OF B1, B2, B3 OR B4**PART B1 – DECISION MAKING (10 ITEMS)**

Satisfaction questionnaire – (TBC)

Decision Regret Scale (TBC)

END PART B1

PART B2 – MAX PC (18 ITEMS)

The Modified 18-item Memorial Anxiety Scale for Prostate Cancer

END PART B2

PART B3 – SF-12 (12 ITEMS)

SF-12 Health Survey

END PART B3

PART B4 – SCA (16 ITEMS)

Service Satisfaction Scale for Cancer Care (SCA)

END PART B4

PART C (DEMOGRAPHICS) – TO BE ANSWERED BY ALL PARTICIPANTS

1. Which of the following best describes your current relationship?
 - a. Living with a spouse or partner
 - b. In a significant relationship, but not living together
 - c. Not in a significant relationship
 - d. Widowed
2. If you are in a significant relationship, what is the gender of your spouse or partner?
 - a. Female
 - b. Male
3. Are you now working in a paying job?
 - a. Yes, full-time
 - b. Yes, part-time
 - c. No, but looking for a job
 - d. No, retired
 - e. No, disabled
4. Do you currently have private health insurance?
 - a. Yes
 - b. No

The following questions are also about you and your household. We are asking these questions this one time only.

5. How much school did you complete?
 - a. Primary school
 - b. Year 10 or equivalent
 - c. Year 12 or equivalent
 - d. University under-graduate degree
 - e. University post-graduate degree
6. What is the total of all wages/salaries, government benefits, pensions, allowances and other income your household usually receives? *[NB – below scales are used by ABS in the Census]*
 - a. \$2,000 or more per week (\$104,000 or more per year)
 - b. \$1,500 - \$1,999 per week (\$78,000 - \$103,999 per year)
 - c. \$1,250 - \$1,499 per week (\$65,000 - \$77,999 per year)
 - d. \$1,000 - \$1,249 per week (\$52,000 - \$64,999 per year)
 - e. \$800 - \$999 per week (\$41,600 - \$51,999 per year)
 - f. \$600 - \$799 per week (\$31,200 - \$41,599 per year)
 - g. \$400 - \$599 per week (\$20,800 - \$31,199 per year)
 - h. \$300 - \$399 per week (\$15,600 - \$20,799 per year)
 - i. \$200 - \$299 per week (\$10,400 - \$15,599 per year)
 - j. \$1 - \$199 per week (\$1 - \$10,399 per year)
 - k. Nil income
 - l. Negative income
7. Are you of Aboriginal or Torres Strait Islander origin?
 - a. No
 - b. Yes, Aboriginal
 - c. Yes, Torres Strait Islander
 - d. Yes, both
8. Do you speak a language other than English at home?
 - a. No, English only
 - b. Yes, Italian
 - c. Yes, Greek
 - d. Yes, Cantonese
 - e. Yes, Arabic
 - f. Yes, Mandarin
 - g. Yes, Vietnamese
 - h. Yes, other
 - Please specify _____

END PART C