



INFORMATION ABOUT PATIENT RECRUITMENT SERVICES OFFERED BY THE CANCER INSTITUTE NSW

This information package is designed to provide useful information to researchers interested in using the Patient Recruitment Service of The Cancer Institute NSW. The documents included in this package are intended to offer information regarding the procedures involved in initiating a new study and details of the patient recruitment process itself.

If you have any questions please contact:

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THE NSW CENTRAL CANCER REGISTRY

What is the Cancer Registry?

The NSW Central Cancer Registry (CCR) was established in 1971 and receives notifications of cancer in residents of New South Wales. The Registry is situated at the Cancer Institute NSW which acts as the manager of the NSW CCR and custodian of the cancer data on behalf of the Director General of NSW Health. The Cancer Institute NSW is the first publicly funded Cancer Control Agency in NSW.

All information sent to the Registry is kept confidential, is held under tight security and is protected by the Public Health Act 1991.

What information is on the Registry?

The CCR collects notifications of cancer incidence and mortality for all residents of NSW. Information is collected about patients with cancer and includes:

- Name and address, date of birth and sex
- Country of birth
- Clinical details about the cancer
- Information about the notifying institution and doctor

Personal details, such as name and address, are needed to ensure that accurate information is recorded for each person and that each new cancer is only counted once in the statistics. The data items recorded about each cancer case are listed in Appendix 1.

How does information get on to the Registry?

Notification of cancer is a statutory requirement under the Public Health Act 1991. All public and private hospitals, radiotherapy departments, aged care facilities, pathology departments and outpatient departments are required to notify the NSW Central Cancer Registry when they diagnose or treat someone with cancer.

What is information on the Registry used for?

The Cancer Registry keeps a record or 'registers' every cancer diagnosed in residents of NSW. The aims of the registry are to:

- Monitor and record the number of new cases of cancer and deaths from cancer in NSW
- Produce regular and ad hoc reports on cancer incidence and mortality patterns
- Utilise the data to support epidemiological and clinical research
- Evaluate the benefits of cancer screening programs to determine their effectiveness
- Assist in planning and monitoring services for the control of cancer and the care of cancer patients in NSW
- Make the data available for use by health providers, planners, educators and research scientists
- Contribute cancer data to national and international agencies to assist in cancer control.

Reports on incidence and mortality from cancer are published regularly. Occasional reports include analyses of trends in NSW, survival from cancer, variation according to geographical areas and reviews of specific cancers. Publications are available on the Cancer Institute NSW website at www.cancerinstitute.org.au.

Who has access to information on the Registry?

The Registry publishes yearly reports showing the numbers of cases and rates of different types of cancer in NSW. The report is available to the general public and is used by clinicians, health planners and researchers.

Researchers can apply to obtain information about cancer patient's names and addresses only when the following conditions are met:

- The research they propose is scientifically sound and likely to contribute to the control of cancer or improvement of the care of cancer patients.
- An Ethics Committee has reviewed the proposal and approves access to the information.
- Doctor and patient consent is obtained to provide the name and address as recorded on the registry to a researcher.
- The researchers sign a form committing them to use the information only for the purposes approved by the Ethics Committee and to protect the confidentiality and privacy of the information provided.

Identified information can be released back to the hospital or laboratory who originally provided a cancer notification on request from the notifier and to the Australian Institute of Health and Welfare for the purpose of removing people registered twice in different state registries to ensure that national cancer statistics are accurate.

For more information on the NSW Central Cancer Registry and the way it operates, please call us on (02) 8374 5749 or email at ccr@cancerinstitute.org.au.

1. If you would like a copy of the latest Cancer in NSW: Incidence and Mortality report you can obtain a copy through the website www.cancerinstitute.org.au.
2. To obtain more statistics on cancer in your area you can go to the cancer registry reporting module www.statistics.cancerinstitute.org.au

PATIENT RECRUITMENT OVERVIEW

The Cancer Institute NSW provides a service to researchers whereby patients who have been notified to the registry may be recruited to participate in a research study. Prior ethical approval of the study is required from the NSW Population and Health Services Research Ethics Committee. This Committee is accredited as a lead Human Research Ethics Committee for cancer related epidemiology research. All studies are monitored for adverse events by the ethics committee.

The Patient Recruitment (PR) team works closely with the NSW Central Cancer Registry to help researchers gain access to a sample of potential participants for their study.

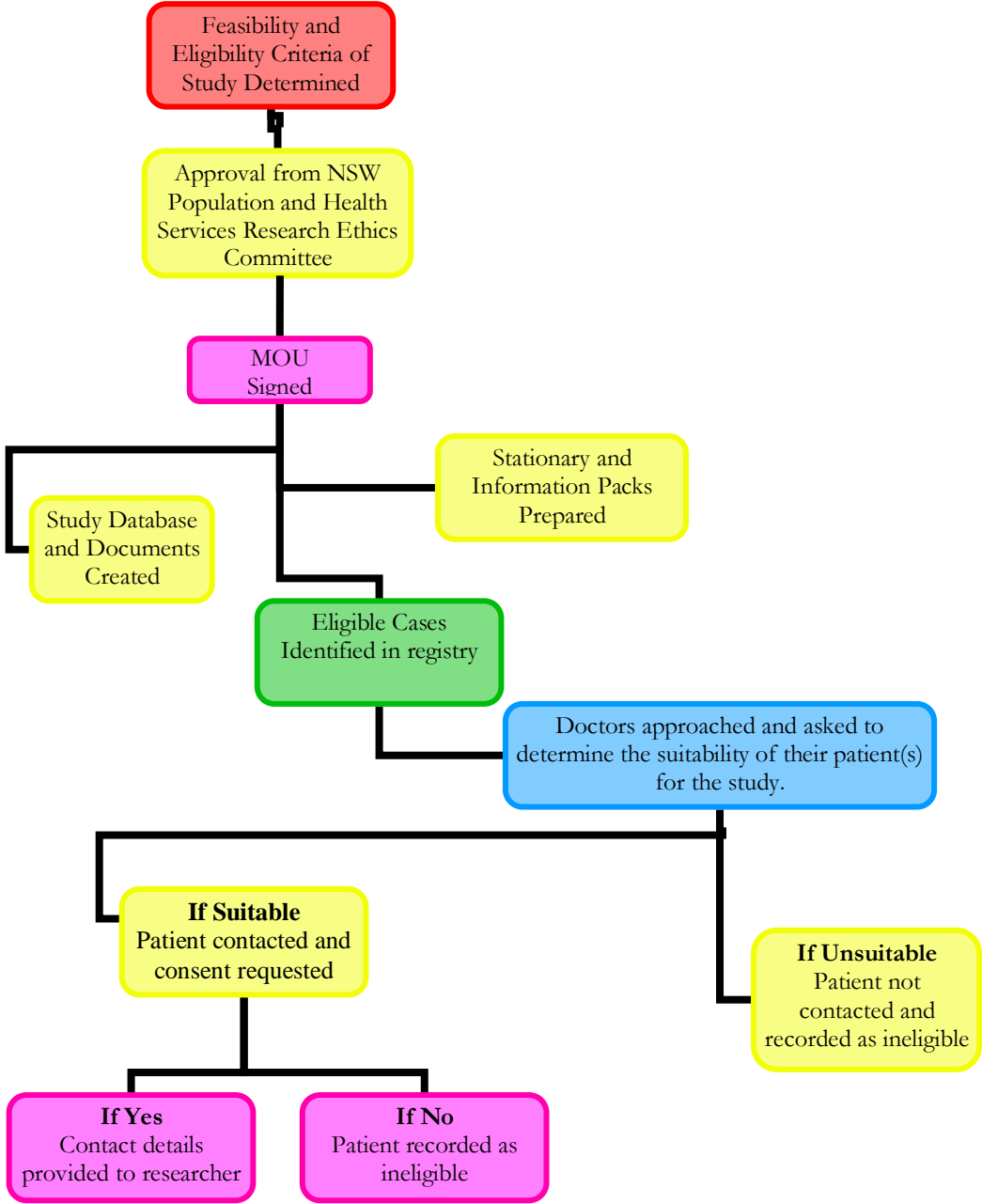
Initially, PR works with the researchers to establish the characteristics of the desired sample and the specific inclusion/exclusion criteria to apply to potential cases. When this picture of the sample has been generated and the feasibility of the study confirmed, PR will then assist researchers in compiling their application to the NSW Population and Health Services Research Ethics Committee.

Several template documents are provided. These include a description of the recruitment protocol to be included in the 'methodology' section (Appendix 2) and contact documents to be used by PR in writing to both doctors and patients to establish the suitability and the receptiveness of potential cases (Appendix 3).

Once the Ethics Committee have approved the project, the obligations of PR and the researchers are documented through the completion of a Memorandum of Understanding (MOU). The Cancer Institute NSW provides the patient recruitment service on a cost recovery basis. While an early Costing Estimate will be provided by PR, these figures will be revised and updated as the MOU is finalised. The Cancer Institute NSW will invoice the researchers for actual costs incurred on a quarterly basis.

After the MOU and Costing Estimate have been signed off, the PR team will begin ascertaining the sample. Initially, the PR team asks patients for their permission to have their contact details released to a research group. The names and contact details of patients who agree are sent to the research team, who may then approach them about study participation. For patients who consent to participating in the study the Cancer Institute NSW will release clinical cancer details. All details provided must be approved by the NSW Population and Health Services Research Ethics Committee. Information on patient's whose doctor did not consent to them being contacted for the study and on patients who did not consent to participate are also provided to the researchers to assist with examining selection bias. The information provided is aggregated data and is not potentially identifiable.

PATIENT RECRUITMENT FLOW CHART



Note
 Once recruitment is finalised researchers will be provided with:

- Clinical cancer details for patients who consent to participating in the study, and
- An aggregated de-identified summary of ineligible cases and the reasons for their ineligibility

USEFUL TO READ

It is useful to be familiar with the following documents before undertaking any research:

- Health Records and Information Privacy Act 2002
- Declaration of Helsinki
- Information about the NSW Population and Health Services Research Ethics Committee is available on the Cancer Institute NSW website at http://www.cancerinstitute.org.au/cancer_inst/research/ethicspopresearch.html
- 2007 National Statement on Ethical Conduct in Human Research by NHMRC available at: <http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

Furthermore, the Cancer Institute NSW has a variety of useful links for researchers at http://www.cancerinstitute.org.au/cancer_inst/research/links.html

APPENDIX 1

VARIABLES COLLECTED BY THE CCR AND POTENTIALLY AVAILABLE FOR RESEARCH (SUBJECT TO CHANGE/REVIEW)

Demographics

Name
Aliases
Date of Birth
Country of Birth
Address Information

Tumour Items

Date of Diagnosis of Primary Cancer
Cancer Site
Cancer Histology
Laterality of primary cancer
Tumour Size (may not always be available)
Admission Date
Best basis of diagnosis at this episode
Principal diagnosis
Additional diagnoses
Mode of separation
Degree of Spread at this episode

Death related items

Cause of death
Date of death

Clinician details (not available for all records)

Treating Doctors name
Treating Doctors address
Treating Doctors institution code
General Practitioners name
General practitioners address
Pathology accession no.
Pathology Laboratory
Registration no of attending medical officer

APPENDIX 2

DESCRIPTION OF THE PATIENT RECRUITMENT PROTOCOL FOR ETHICS APPLICATION

The Patient Recruitment (PR) team will provide to the research team the contact details for patients who have been confirmed as eligible for research participation and who have given consent for their contact details to be released.

The PR team will establish the eligibility of patients on the Registry according to the study selection criteria. The survival status of all eligible patients will be checked to ensure that patients who have died are not contacted. PR will then identify an appropriate clinician for the patient and send a letter to this Doctor to inform them about the study and confirm that the patient is suitable for participation in research. In this letter the Doctor will be asked the following:

- Is the patient able to read and understand English?
- Is the patient physically and mentally able to complete a self-administered survey?
- Has the patient been informed of their cancer diagnosis?

The above questions are generally always asked but additional questions will be asked where appropriate and according to study requirements (e.g. where nationality is concerned we would additionally ask doctors to confirm a patient's country of birth).

Clinicians who have not responded to this letter within two weeks of it being sent will be telephoned by the PR team at two weekly intervals, up to five times, to confirm the suitability of the identified patients. Once the clinician has indicated the patient is suitable to be contacted by the PR team about the study, potential participants will be sent a project information letter, a CCR information leaflet, a reply paid envelope and a consent to be contacted form, seeking written permission for the PR team to forward their contact details to the researchers. Where necessary, parents of potential participants will be asked for their consent for their child to participate.

All patients will be encouraged to discuss their possible involvement in the study with their primary treating clinician, the PR team or the study researchers if they wish. Potential participants who have not responded within two weeks will be sent a second letter by PR. After that, if there has been no response, no further contact will be made as it will be assumed that the patient is not interested in participating in the research. Follow up phone calls will generally not be made.

Upon receipt of a signed patient consent form, PR will provide the relevant contact details for that patient to the researchers. The researchers will then separately approach these patients about participating in the study and provide them with further information. For those participants who subsequently consent to participating in the study, PR will provide their cancer details to the researchers. A de-identified summary of cases where either the doctor or the patient does not consent will be provided to the researchers after the completion of recruitment.

APPENDIX 3

PATIENT RECRUITMENT RESOURCES

The following pages illustrate examples of the way doctors and patients are approached to participate in a study by PR. The examples shown can be adjusted to meet study purposes but the overall format of the letters should be kept the same. The letters refer specifically to the NSW CCR, but can be adjusted if the study involves another registry. The Patient Recruitment Coordinator shall assist and provide guidance for the development of these resources and other study related material pertinent to the recruitment process.

Additional resources that will need to be developed by the researchers in consultation with the Patient Recruitment Coordinator are:

- Clinician information sheet
- Participant information sheet
- Study invitation letter for participant (may include reminder letter if required)
- Consent form for Study Participation
- Protocols where necessary

EXAMPLE OF DOCTOR FIRST PATIENT LETTER

Date

Dr's Full Name

Dr's Address

Dear [insert Dr Title]

Study Title (formal name of study - no abbreviations)

Researchers at The [insert research group e.g. name of University or Institution conducting the study] are conducting a study to assess the [insert brief description of what the study is about – include aims of the study in description].

The NSW Central Cancer Registry receives notifications of all types of cancer diagnosed or treated in residents of NSW. Notification of cancer is a statutory requirement under the Public Health Act 1991.

The NSW Central Cancer Registry is assisting the [insert research group] by identifying patients who may be eligible for their study. According to our records, a patient who has been seen by you may be eligible.

Could you please indicate on the enclosed consent form (yellow) whether this patient is eligible to participate in this study and if they may be approached by the Registry? Please return the consent form to us by fax or in the reply-paid envelope provided. If you are not the current treating doctor for this patient, please provide the name and contact details of their treating physician (if known), or the physician to whom you referred this patient.

If you agree, the Registry will ask the patient if the research team may contact them about the study. If consent is obtained, the Registry will provide the patient's contact details to the research team who will contact the patient and ask them to participate. The research team will not be given the contact details from the patient's registry record without their consent.

Patient participation in this study is voluntary. The patient will be informed that neither their current nor future medical care will be affected in any way by their decision to participate. They will also be informed that if they do decide to participate in the study, they will be free to withdraw at any time and that they do not have to give a reason for doing so. It is not necessary for you to speak to this patient about this study however you may want to.

Patient participation in this study involves [provide explanation of what is being collected e.g. self-administered survey/questionnaire etc]. Enclosed is an information sheet with more details of the study and a copy of the information leaflet (blue) that will be sent to potential participants. This project has been approved by the NSW Population and Health Services Research Ethics Committee and the [insert details of other human research ethics committee).

If you have any queries about this request, or would prefer to call us with your response, please telephone Serina Faraji on freecall 1800 XXX XXX. Alternatively, you can write to us at: Patient Recruitment, NSW Central Cancer Registry, Locked Mail Bag 1, Kings Cross, 1340.

Thank you for your assistance.

Yours sincerely,

Manager, NSW Central Cancer Registry

EXAMPLE OF DOCTOR ADDITIONAL PATIENT LETTER

Date

Dr's Full Name
Dr's Address

Dear [insert Dr's Name]

Study Title (formal name of study – no abbreviations)

I recently wrote to you about a study being conducted by researchers at the [insert name of research group e.g. University or Institution) to assess the [insert brief description of what the study is about – include aims of the study in description]. I asked you to confirm the eligibility for this study of a patient seen by you and to provide approval for the Registry to contact them. According to our records, another patient who has been seen by you may also be eligible for the study.

Could you please indicate on the enclosed consent form (yellow) whether this patient is eligible to participate in this study and whether they may be approached by the Registry? Please return the consent form to us by fax or in the reply-paid envelope provided. If you are not the current treating doctor for this patient, please provide the name and contact details of their treating physician (if known), or the physician to whom you referred this patient.

If you agree, the Registry will ask the patient if the research team may contact them about the study. If consent is obtained, the Registry will provide the patient's contact details to the research team who will contact the patient and ask them to participate. The research team will not be given the contact details from the patient's registry record without their consent.

Patient participation in this study is voluntary. The patient will be informed that neither their current nor future medical care will be affected in any way by their decision to participate. They will also be informed that if they do decide to participate in the study, they will be free to withdraw at any time and that they do not have to give a reason for doing so. It is not necessary for you to speak to this patient about this study however you may want to.

Participation in this study involves the [provide explanation of what is being collected e.g. self-administered survey/questionnaire etc]. I have enclosed an information sheet with more details of the study and a copy of the information leaflet (blue) that will be sent to potential participants. This project has been approved by the NSW Population and Health Services Research Ethics Committee and the [insert details of other human research ethics committee].

If you have any queries about this request, or would prefer to call us with your response, please telephone Serina Faraji on freecall 1800 XXX XXX. Alternatively, you can write to us at: Patient Recruitment, NSW Central Cancer Registry, Locked Mail Bag 1, Kings Cross, 1340.

Thank you for your assistance.

Yours sincerely,

Manager, NSW Central Cancer Registry

EXAMPLE OF FIRST LETTER TO PATIENTS

Date

Patient's Full Name
Patient's Address

Dear [insert patient's Name]

Study Title [full name – no abbreviations]

Researchers from the [insert details of research group] are conducting a study [briefly describe objective and purpose of study].

The NSW Central Cancer Registry receives notifications about all people in NSW who have been diagnosed with cancer. This information is received under the authority of the Public Health Act 1991. One of its purposes is to assist research into the causes, prevention and treatment of cancer. I have enclosed a leaflet describing how the Registry operated.

One way that we assist with research is to ask people who have been notified to the Registry whether we can provide their contact details to researchers so that they can ask people to participate in their studies.

The researchers from the [insert name of group] would like to find out [insert brief description of what information will be collected and why]. Your contribution will assist in [insert brief description of the how their participation will benefit others with this cancer type]. I have enclosed a blue leaflet prepared by the researchers describing the study and what you would be asked to do if you take part.

Once you have read the information sheet, we would be grateful if you could:

- Complete and sign the enclosed response form (yellow) as soon as possible and indicate whether or not you consent to the Registry providing your contact details to the [insert name of research group].
- Complete some questions on this form to determine whether or not the study is suitable for you. If it is not suitable you will receive a letter advising you of this and you will not be asked to take part.

If you choose to take part, and the study is suitable for you, the researchers will contact you by mail or phone with more information about the study.

If we have not heard from you in two weeks we will send you another letter to find out whether you would like more information about the study from the researchers. A copy of the yellow response form is printed on the reverse side of this letter for you to keep for your reference.

To find out more details about this request please call the Patient Recruitment Officer on freecall 1800 XXX XXX. If you would like to speak with someone in your language, please call 1800 XXX XXX and leave a message. Your call will be returned as soon as possible. You can also write to us at Patient Recruitment, NSW Central Cancer Registry, Locked Mail Bag 1, Kings Cross, 1340.

If receiving this request has raised any questions or concerns about your cancer and you would like to speak to a professional counsellor please call the [insert details of specific Helpline if relevant] or the Cancer Council Helpline on 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.

Yours sincerely

Manager, NSW Central Cancer Registry

EXAMPLE OF SECOND LETTER TO PATIENTS

Date

Patient's Full Name
Patient's Address

Dear [insert patient's Name]

Study Title (full name – no abbreviations)

I recently wrote to you about a study being conducted by researchers at [insert name of group and brief description of the objectives and purpose of the study]. I asked if the NSW Central Cancer Registry could provide the researchers with your name and address so that they could contact you and find out if you would like more information about the study.

The NSW Central Cancer Registry receives notifications about all people in NSW who have been diagnosed with cancer. This information is received under the authority of the Public Health Act 1991. One of its purposes is to assist research into the causes, prevention and treatment of cancer. I have enclosed a leaflet describing how the Registry operates.

One way that we assist with research is to ask people who have been notified to the Registry whether we can provide their contact details to researchers so that they can ask people to participate in their studies.

The researchers from the University of Sydney are interested in finding out if [insert brief description of what information will be collected and why]. Your contribution will assist in [insert brief description of the how their participation will benefit others with this cancer type]. I have enclosed a blue leaflet prepared by the researchers describing the study and what you would be asked to do if you take part.

Once you have read the information sheet, we would be grateful if you could:

- Complete and sign the enclosed response form (yellow) as soon as possible and indicate whether or not you consent to the Registry providing your contact details to the [insert name of research group].
- Complete some questions on this form to determine whether or not the study is suitable for you. If it is not suitable you will receive a letter advising you of this and you will not be asked to take part.

To find out more details about this request please call the Patient Recruitment Officer on freecall 1800 XXX XXX. Your call will be returned as soon as possible. You can also write to us at Patient Recruitment, NSW Central Cancer Registry, Locked Mail Bag 1, Kings Cross, 1340.

If receiving this request has raised any questions or concerns about cancer and you would like to speak to a professional counsellor please call [insert details of specific hotline if relevant] or the Cancer Council Helpline on 13 11 20.

Thank you for considering this request. We look forward to hearing from you soon.

Yours sincerely

Manager, NSW Central Cancer Registry