

## **INFORMATION FOR PARTICIPANTS IN THE NORTHERN TERRITORY HEALTHCONNECT TRIAL**

### **Instructions for use**

*The Trial Project must use this document in accordance with the Privacy Protocol for using information about Trial Participants in the Northern Territory HealthConnect Trial. The information contained in this document must be provided to prospective Trial Participants to enable them to make decisions about whether or not to participate in the Trial Project and to allow the release of information about them.*

*All information required by consumers to ensure they are fully informed before consenting to participate is documented here. However, in recognition that many Indigenous Australians in the Katherine region may not use English as their first language, the Trial team will ensure all this information is communicated verbally in a culturally-appropriate manner. The Trial team will also use a number of educational aids (such as posters).*

### **Information for Participants in the Trial**

The Northern Territory trial is testing a proposed electronic health records network known as HealthConnect. The two-year research and development phase of HealthConnect is being undertaken by the Commonwealth, in partnership with State and Territory Governments. The Northern Territory trial is being developed with input from doctors, Aboriginal health workers, and other clinical staff, Aboriginal community organisations and other consumers, as well as health and hospital administrators.

The proposed model involves the collection of summary health information when a consumer receives a health care service, the safe transfer of that summary information to a secure storage site, and the subsequent retrieval of that information or parts of it, by health providers - with the consent of the consumer.

The principal aim of the Northern Territory HealthConnect Trial is to improve the quality of health care in the host region by providing for more complete, appropriate and timely sharing of information among those involved in delivering and managing health care services.

This brochure provides information about the Northern Territory HealthConnect Trial, and in particular, how the Trial will access, store and use your health information if you agree to take part in the Trial.

### **Consent**

Under the law, governments must make sure that you have all the information you need to make an informed decision about taking part in a Trial. In addition they must provide details about the arrangements for allowing access to the information collected during the Trial about you and your care.

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If you are willing to take part after receiving this information, you will be asked to sign a consent form. The consent obtained from you will also cover the release of certain information about you for the purposes of the Trial, including details about the health services you use - for each occasion on which you consent to such information being included on your HealthConnect record. The consent form identifies the service providers (for example, doctors, hospital and pathology group) who will release details about the services used by you within the Trial Project. It is a good idea to keep a copy of your signed consent form.

### **Who can sign a consent form on behalf of Trial Participants?**

A guardian or person holding a power of attorney that extends to the right to make decisions about an individual's health care, can sign the consent form on behalf of that individual. The Northern Territory HealthConnect Trial Office will need information to verify that the authorised person holds the required authority, so a photocopy of the authority must be attached to this form.

Where a person informally provides care for a prospective Trial participant but does not hold a power of attorney extending to health matters (eg a spouse caring for a mentally or physically incapacitated partner), consent can be given on behalf of the prospective Trial participant, provided the following two statements are attached to the consent form:

- a letter from the prospective Trial participant's usual medical practitioner advising that the individual concerned does not have the mental or physical capacity to consent on his or her own behalf and that participation in the Trial is not contrary to the individual's best interests; and
- a statement from the person's carer attesting to the fact that the carer ordinarily makes health decisions on the person's behalf.

### **Who can sign a withdrawal form on behalf of a Participant?**

If the Trial participant is unable to sign a withdrawal form, an authorised person can act on their behalf in a similar manner to the consent procedure described above. If documentation of a person's inability to sign the form was already provided during the consent procedure, then it does not need to be provided again during the withdrawal procedure. However, if the authorised person began acting on behalf of the Trial participant after the person entered the Trial, documentation (as described above) will need to be provided during the withdrawal process.

### **Alternative forms of signature**

Where the Trial participant or authorised representative is unable to sign due to illiteracy or physical impairment, the signature on the consent form may be in the form of the written name or mark of the Trial participant or authorised representative. The mark on the consent form must be witnessed by someone who knows the participant or

their representative and who can attest to that person's inability to sign on their own behalf.

### **Effect of intellectual disability or mental illness**

Where someone has an intellectual disability or mental illness, the Trial Trainer/Educator must be satisfied that the condition does not prevent the person concerned (whether it is the Trial participant or person authorised to act on behalf of the Trial participant) from understanding the nature of the consent process. The Trial Trainer/Educator must also be satisfied that any person authorised to act on behalf of the Trial participant is able to understand and to provide informed consent.

A person with an intellectual or mental impairment can refuse to participate in research. Refusal by a person with an intellectual or mental impairment to participate in research must be respected and acted upon by the Trial Trainer/Educator.

### **Who is responsible for the Trial?**

The Commonwealth and State/Territory governments have jointly agreed to fund the Northern Territory HealthConnect Trial and will closely monitor the progress of the Trial.

The Northern Territory HealthConnect Trial is supported through a partnership between the Commonwealth Department of Health and Ageing and NT Department of Health and Community Services. Participating health providers include Katherine District Hospital, Wurlli-Wurlinjang Health Service, Katherine West Health Board (Yarralin and Timber Creek clinics) and a NT Department of Health and Community Services clinics (Barunga clinic).

### **Is participation voluntary?**

Participation in the Trial is completely voluntary. It is up to you whether you want to be involved, and you can change your mind at any time.

### **When will the Trial start?**

The Trial is expected to begin in September 2002.

### **When will my participation in the Trial commence?**

If you agree to participate in the Trial, you will be regarded as a Trial participant from the date you sign your consent form.

### **When will the Trial finish?**

The Trial is expected to finish on 30 June 2003.

### **What happens if the Trial is extended?**

If the Trial period is extended beyond 30 June 2003, the Northern Territory HealthConnect Trial Office will contact all Trial participants, informing them of the extension, and offering the opportunity to withdraw. This will occur prior to the date on which the Trial will end.

If the HealthConnect Trial Office is unable to contact you, your participation in the Trial will cease at the date specified on your consent form.

### **What happens if you leave the Trial?**

You might agree to participate in the Trial but change your mind later.

You have the right to withdraw your consent to participate in the Trial at any time. Any data collected about you by HealthConnect up until that time will still be used for trial evaluation purposes. However, your HealthConnect record will no longer be able to be accessed by providers.

You can withdraw from the Trial by:

- completing the withdrawal form provided by the Trial and forwarding it to local Trial Office personnel at any of the participating health services.

**OR**

- telephoning the Northern Territory HealthConnect Trial Office on 0413 014178 and then completing a withdrawal form provided and returning it to the Trial Office or a Trial Office worker at any of the participating health services.

If you do not have a withdrawal form, the Trial Office will send you one by mail upon request.

The date your withdrawal becomes effective will be the date on which Northern Territory HealthConnect Trial Office receives your signed withdrawal form.

### **INFORMATION COLLECTED ABOUT YOU**

The Trial is a form of research. Information about the effectiveness of the Trial will be valuable in helping us to develop a model for how HealthConnect can work on a national basis.

#### **What information will be collected and how will it be collected?**

A small amount of information will be collected when you enrol in the Trial. This will include some information provided by you about your family medical history, basic contact details and demographic information.

Some additional background information may be obtained from your nominated general practitioner, the Katherine Hospital and pathology services, including information about:

- allergies, adverse events, or intolerances (e.g. lactose) or that may affect your healthcare;
- religious beliefs and practices that may affect your health care;
- diagnoses;
- diabetes risk factors and monitoring information;
- chronic disease risk factors; and
- current medications;

If there is anything you do not want included on your *HealthConnect* record, you can tell the Trial Trainer/Educator what information should not be included. The Trainer/Educator will then ensure that this information is not included in the background information on your *HealthConnect* record.

This information which is included on your *HealthConnect* record will be available to all those who you have agreed can access your records.

If you agree to participate in the Trial, you will be asked each time you have a service provided whether you want an event summary about that service to be placed on your *HealthConnect* record. If you give your verbal consent, the following kinds of information will be included on your *HealthConnect* record by your general practitioners, the hospital, the clinic or pathology service:

- new allergies;
- new diagnoses;
- presenting problem;
- general observations;
- medication changes;
- treatments or procedures;
- diabetes specific risk factors and monitoring information;
- chronic disease risk factors;
- pathology results;
- Allergies, adverse events, or intolerances which may affect care;
- Religious beliefs and practices which may affect your care and treatment; and
- Current medications.

Generally, a service provider will show you what will go onto your *HealthConnect* record, but sometimes, this may be practically difficult. In these cases, the provider will tell you the kind of information they will be including and you can contact the *HealthConnect* office to obtain a copy of the information on your record. If there are any mistakes on the record, you can ask for them to be corrected.

In the case of pathology tests ordered by a participating organisation (including hospital pathology), the test results will only be placed on your *HealthConnect* record if you give your consent for this to occur.

### **When will collection of information start?**

Information will start to be collected from the date the Trial commences or the date you sign the consent form, whichever occurs first.

### **How will this information be used?**

Your *HealthConnect* record should allow you and your provider(s) to have better access to information about your health care. This can allow you to be more actively involved in the management of your health care and treatment.

It is also intended that the information that is gathered will be used to help work out whether an electronic health network helps to improve the quality care provided to consumers. The Trial will pass on data for analysis to an Evaluator and to the Commonwealth and State Governments. The data used for this analysis will not identify you in any way.

### **How will I know if someone has looked at the information on my *HealthConnect* record?**

*HealthConnect* includes an audit trail which will allow you to identify who has accessed your *HealthConnect* record and when. You can ask *HealthConnect* to provide you with a copy of your “audit trail”.

Information can be downloaded by a participating organisation from the *HealthConnect* record onto a local computer system or it can be printed out. Where this occurs, the audit trail of *HealthConnect* cannot record where the information has gone. In this situation, your confidentiality is protected by the usual practices and policies of the service providers, who are required to keep any personal health information in an appropriate manner. *HealthConnect* requires service provider participants to have such policies and procedures in place as one of the conditions of Trial participation.

### **How can I access the information collected on me?**

You have the right to see your complete *HealthConnect* record at any time. To ask for a copy of your complete record, you can contact a local Trial Office worker at any of the participating health care services (or contact the Trial Office on 0413 014178).

### **Will information be used for research purposes?**

The information collected about you will only be used to evaluate the *HealthConnect* trial itself.

All information that could be used to identify you, such as your name, address, phone number, date of birth or your postcode, will be removed prior to publication of any evaluation data.

The evaluation team will not be permitted to use the information for any other purpose, such as to identify individuals, to make a profit from the data, or to limit any individual’s access to health care services.

Data that is published by HealthConnect will be presented in such a way so as to ensure that it does not identify any particular person or allow a person's identity to be reasonably ascertained from the data.

After the evaluation of the Trial Projects, a 'confidentialised' data set will be available. The data set will not allow the identity of any person to be apparent or to be reasonably able to be ascertained.

Detailed procedures will be developed to bind the Northern Territory HealthConnect Trial Office, the Evaluator and researchers in relation to the publication and release of this data set from the evaluation.

### **What happens to your information if you leave the Trial?**

It is impossible to take back data once it has been collected by the Trial, so when you leave the Trial, data which has been collected about you will remain in the database for the purpose of evaluating the Trial.

The information collected before the date that you have withdrawn from the trial will remain available to the Trial and the Evaluator for the purpose of evaluating HealthConnect. Information will remain in the data collection in a form that does not identify you in any way.

### **Will information collected about you be kept private?**

The Northern Territory Trial Office will have access to information that will identify you personally. The Trial Office will collect, store, use and disclose information about you in a way that respects the privacy of your information.

Information about you that has been provided to the Trial Trainer/Educator will be kept secure and will only be used for the purposes of providing health services and for evaluating the Trial and for no other purpose. If the Trial ceases, the information will then be destroyed in a way that protects your privacy. [You can be given a copy of your HealthConnect record prior to the information being destroyed.]

### **Complaints process**

The Trial has an obligation, through its funding agreement with the Department to ensure that information about Trial participants is protected against loss and unauthorised access, use, modification or disclosure. If you think your information has been mishandled during the course of the Trial, you can make a formal complaint to the Trial Office (contact 0413 014 178).

The Menzies School of Health Research Ethics Committee can also be contacted regarding any aspects of the Trial (contact Gabriella Falls on (08) 8922 8624).

If you think that the Northern Territory Trial Office or the Commonwealth has mishandled your information during the course of the Trial, you can make a formal complaint to the Federal Privacy Commissioner. If you do have a complaint, it is

suggested that you contact the Trial Office in the first instance. (A Trial Complaints Policy document is also available for further information).

If you agree to participate in the Trial you will have:

- access to someone from the Northern Territory HealthConnect Trial Office to talk to if you have a complaint or concern about the handling of your information during the Trial. The name of the person to contact is provided on the consent form;
- access to the Northern Territory Health Complaints Commission if you have any complaints about your health care. The contact details for the Health Complaints Commission will be listed on the consent form;
- the right to lodge a formal complaint to the HealthConnect Trial Office, the Health Complaints Commission or the Federal Privacy Commissioner;
- a guarantee that the information about you will be collected in a fair, lawful and non-intrusive way and also that the purpose for which information is collected will be explained to you;
- a guarantee that any information about you will be stored by the HealthConnect Trial Office in a safe and secure way to prevent unauthorised people having access to it;
- access to information about you which is kept by the HealthConnect Trial Office, and the right to amend this information if it is incorrect; and
- a guarantee that information collected by the HealthConnect Trial Office will be used only for the purposes of the Trial.

**For more information about the Trial please contact:**

The Trial Manager  
(Wurli Wurlinjang Health Service, Katherine)

Phone: 0419 817 275

Email: [healthconnect@wurli.org.au](mailto:healthconnect@wurli.org.au)

For more information regarding ethical consideration of the Trial processes, please contact:

Gabriella Falls  
Menzies School of Health Research, Darwin.  
Phone: (08) 8922 8624