

# Attachment 6: » » » » » » » »

## Integrate Ethics Review Document

### *Consolidated Ethics Review Submission*

**Version 2.1**  
**September 27, 2000**

Prepared by: *Natalie Kishchuk*  
*Jocelyne Picot*  
*Infotelmed Communications Inc.*

### **1. Title of project**

First Nations Telehealth Research Project

### **2. Name and organizational affiliation of principal investigator.**

Alexa Brewer  
Medical Services Branch  
Health Canada  
Jeanne Mance Building, Tunney's Pasture  
Ottawa K1A 0L3

### **3. Names and organizational affiliations of all co-investigators**

Project Manager  
Ernie Dal Grande  
Medical Services Branch  
Health Canada  
Jeanne Mance Building, Tunney's Pasture  
Ottawa K1A 0L3

#### *Contractors responsible for carrying out the evaluation:*

Natalie Kishchuk, PhD  
Jocelyne Picot, PhD  
Infotelmed Communications Inc.  
38 Place du Commerce  
Verdun, Québec H3E 1T8

# Final Results Report

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A Peer Review Committee, consisting of expert representatives from a number of institutions and associations, oversees the project. Its members are:

Dr. Joe Kaufert  
University of Manitoba

Dr. Penny Jennet  
University of Calgary

Dr. James Irvine  
University of Saskatchewan

Dr. Alain Cloutier  
Université Laval

Ms. Maria MacNaughton  
Health Canada

Ms. Lisa Dutcher  
Aboriginal Nurses Association

Ms. Margaret Neylan  
British Columbia Institute of technology (retired)

## 4. Signatures of all investigators

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## 5. Apparent conflicts of interest

No investigator in this study has any interest in any of the telehealth supplier firms.

## 6. Participating institutions

This project involves the delivery of health services via telehealth linkages through the health centers managed by the Band administrations five First Nations communities, listed below. The personnel involved with these centers are either employees of the Band or, in a minority of cases, Health Canada. The five First Nations communities will be linked with specialized medical staff in the secondary and tertiary institutions, also listed below.

Anahim Lake, B.C. linked with:	Cariboo General Hospital, Williams Lake
Fort Chipewyan, Alberta:	Northern Lights Hospital at Fort McMurray
Southend, Saskatchewan:	La Ronge Hospital, La Ronge; Prince Albert Hospital, Prince Albert; Royal University Hospital, Saskatoon
Berens Rivers, Manitoba:	Health Sciences Centre, Winnipeg
La Romaine, Québec:	Centre de santé Sept-Iles, Centre hospitalier universitaire du Québec, Québec City.

## 7. Dates of project start and expected completion

March 2000 - March 2001

## **8. Previous history of the project at this institution**

This is a new project at all the participating institutions.

## **9. Summary of proposed research**

*Objective and hypotheses, with evidence that justifies this research with human beings at this time*

Telehealth is the delivery of health information, resources and services through information and communications technology. As one of several telehealth demonstration and evaluation projects funded through the Health Transition Fund, the First Nations' Telehealth Project will deploy and evaluate applications of telehealth in five remote First Nations communities. The research objectives are: to assess the extent to which telehealth: 1) improves patient and community access to care, including timeliness of access; 2) renders service delivery in remote communities more cost-effective; and 3) improves linkages between to remote health care centres and secondary, tertiary and educational facilities in each province.

Overall, the research literature in telehealth suggests that it has the potential to improve health services delivery while maintaining patient health outcomes, but that its cost-effectiveness and implementability have yet to be clearly demonstrated. Research to date has tended to concentrate on the accuracy and reliability of information and diagnoses provided through telehealth applications. In general, these studies provide relatively strong evidence that quality of information provided is comparable to that provided through usual channels. However, other aspects of quality of care, including continuity and comprehensiveness, have not been addressed. The organizational implications of implementing telehealth are not well documented, although some studies mention changes in workloads and work organization for health personnel.

It is also not clear as yet whether telehealth represents an overall improvement in the quality and accessibility of care, versus a shifting of the same care to less costly methods of delivery. While many studies have demonstrated the cost-effectiveness of various telehealth applications, they have tended to limit their assessment of costs to the time involved from the specialty physicians. More comprehensive studies including equipment, telecommunications, and organizational costs suggest that cost-effectiveness is not guaranteed, and at the very least must be assessed over a relatively long amortization period. Moreover, usage levels of telehealth systems, a major factor in cost-effectiveness, are often less than expected. No studies have systematically examined the proportion of eligible patients in a given practice population who use telehealth. Studies of cost reductions due to decreased patient travel and wait time show that use of telehealth may diminish patient transfers, but not in all cases. The extent to which telehealth defers rather than replaces in-person consultations has not been addressed

There is evidence, however, that telehealth may have benefits for both patients and providers. Reactions among local providers (in most studies, general practitioners) are generally positive, and there is some evidence that can improve the quality of their services. Patient satisfaction with telehealth is high, and in studies where it has been assessed, patients report that their quality of life is improved by using telehealth. Moreover, in some types of applications, patients report that they feel more empowered or in control of their interactions with health professionals when using telehealth.

## *Study design, with scientific justification*

Due to the exploratory nature of the hypotheses and impossibility of conducting a controlled trial in these small communities, the evaluation design is essentially descriptive and longitudinal. The evaluation methods to be used will provide information about both the entire project and each specific community.

1. **Monitoring of telehealth system usage:** Continuously throughout the study period, nursing station staff and remote health staff will complete logs of patient encounters for all patients eligible to use the telehealth applications, regardless of whether it is used. These logs contain information on the health condition prompting the consultation, the actions undertaken by the local and remote providers using telehealth during the encounter, and follow-up actions required.
2. **Patient satisfaction:** In each community, patients will be asked to complete brief questionnaires or interviews assessing their satisfaction with several facets of the encounter and their preferences for using telehealth.
3. **Qualitative interviews with key informants:** At two points during the study period, qualitative interviews will be conducted with four types of key stakeholders: nursing station personnel (managers, nurses, CHR, social services providers, translators); remote centre and education telehealth partners (physicians, nurses and technical teams in the nursing stations linked to the participating communities); staff in educational institutions linked to the communities; community leaders (elders, council members and health committee members); federal and provincial agency representatives. The stakeholders will be asked to respond as key informants giving their views on the evaluation questions from their perspectives within the project and the communities. They will be identified in collaboration with project leaders, nursing station staff and other relevant sources such as the Peer review Committee. Approximately ten semi-structured interviews will be conducted in each site at each time point, and will be one half hour to one hour in length. They may also be conducted as group consultations if this is more appropriate in the community.
4. **Cost assessment:** Nursing station management will provide cost data on patient transfers for eligible patients during the study period.  
  
Because 1) many of telehealth application being evaluated target chronic conditions such as diabetes, and 2) of the need to examine the extent to which telehealth defers rather than replaces in-person consultations, individual patients will be followed longitudinally throughout the study period, using blinding procedures described in the section on confidentiality.

Information from these four sources will be aggregated into case studies of each participating community.

## **10. Research participants in each site and in overall study**

The study will enroll a continuous series of volunteer adult and child patients from the beginning of telehealth deployment until at least January 31 2001, with the condition that at least 30 patients in each site will participate, for an overall minimum sample size of 120 patients (see description below: one community will not use the telehealth systems in direct patient encounters). This sample size will permit reliable point estimates at the level of each community as well as reliable aggregate data across the entire study.

The combination of telehealth applications to be implemented in each of the five communities varies, having been selected on the basis of an in-depth needs assessment involving consultations with key community leaders, health staff and other professionals, as well as available health status data. (The specific health conditions are described below). Patients considered eligible for enrollment in the research study (the research population) are thus those:

- who present to the community nursing station with a complaint related to the health conditions targeted by the telehealth applications available in the community
- who consent to use the telehealth system (or, for children under 16 years, whose parent or guardian consent to its use).
- who consent to participate in the evaluation (or, for children under 16 years, whose parent or guardian consent to participation.)

Use of the telehealth application will require consent from each patient (or each patient's parent or guardian) at each health center visit; that is, patients are free to decline telehealth use at any visit. Moreover, based on their clinical judgment, nursing station staff may decide in certain circumstances to not propose use of the telehealth system to eligible patients. Nursing station staff will maintain a record of the number of patients who do not use the telehealth application for which they are eligible, either because they decline to participate or because the nursing station staff do not offer it, but no other information will be collected about these patients.

***The eligibility criteria for patients in each community are:***

**1. La Romaine**

- (1) Diabetes monitoring: consenting patients who have been diagnosed as diabetic.
- (2) Cardiovascular monitoring: any consenting patient who may require an electrocardiogram, or vital sign monitoring, for routine, follow-up, or emergency reasons, as identified by the CHC nurse.
- (3) ENT - any consenting patient who has been identified by the CHC nurse as requiring diagnosis or treatment from an ENT specialist.

**2. Berens River**

- (1) Patient Care: - consenting patients who have been identified by the local CHC personnel as requiring access to specialist care.
- (2) Diabetic Education: consenting patients who have been diagnosed as diabetic and who may benefit from patient education.
- (1) Continuing Medical Education - consenting local health care personnel.

**3. Southend**

- (3) Access to specialists - consenting patients who have been identified by the local CHC personnel as requiring access to specialist care.
- (4) Diabetic education - consenting patients who have been diagnosed as diabetic and who may benefit from patient education.
- (5) Mental Health - local health and other personnel participating in community capacity building for mental health.

#### 4. **Fort Chipewyan**

Rehabilitation: consenting patients receiving rehabilitation treatments from an assistant under supervision for physiotherapy, speech therapy or occupational therapy.

#### 5. **Anahim Lake**

Urgent/Emergent cases - comprising of cardiac, diabetic, respiratory ailments as well as major cuts, fractures and burns. The urgent/emergent telehealth will assist the Cariboo Memorial Hospital's emergency services in Williams Lake so that they may be better prepared when the patient arrives from Anahim Lake.

Because some of the technology involved (notably interactive video) is flexible, it is anticipated that it may be used for patients with other health conditions. To the extent possible, the evaluation will monitor this additional usage.

### 11. Exclusions

Only those patients who do not consent to participate, or for whom no telehealth application has been implemented in the community, are excluded from this study.

### 12. Step-by-step description of what will be done with research participants at each stage of the research operations

In general, the health care for any eligible, consenting patients involved in the telehealth study will follow standard care practice for each medical condition for which the telehealth system is used. This standard will not be altered whether or not the telehealth system is used. The ways in which the means of service delivery will be modified through the use of telehealth are described below, as are the data collection procedures to be used for patients. Because the targeted health conditions, the telehealth technologies deployed and therefore the health care delivery operations vary by community, they are described in detail for each.

#### ***La Romaine***

##### *Telehealth care*

- (1) Diabetes - Medical Consultations - In addition to the standard care which is given to diabetic patients, the patients involved in this study will be monitored for glucose levels from their homes.
- (2) Cardiovascular monitoring - Patients with suspected or established cardiovascular disease will receive the same standard of care provided at the Community Health Centre (CHC) in La Romaine. In emergencies, the telehealth network will permit patients with emergency cardiac problems to have an electrocardiogram (ECGs) and vital signs recorded by a nurse at the CHC and sent immediately to a physician at the Sept-Iles Regional Hospital (SIRH) for immediate diagnosis, which will be provided by computer-mediated video and audio interaction between the physician and the CHC. The subject will then be cared for in the standard manner, that is, stabilized and medically evacuated if deemed necessary by the physician. On a non-emergency basis, patients with cardiovascular problems may have ECGs done at the CHC and sent to the physician at the Sept-Iles Regional Hospital.

- (3) ENT (Ear, nose, throat) - After it has been established by the nurse at the CHC that the patient should see an ENT specialist, the standard procedure would be for the subject to obtain an appointment with the ENT specialist at the Sept Iles Regional Hospital (SIRH). With the telehealth network, the nurse will send ENT images of eligible, consenting patients to the specialist first. On the basis of the information and images received, the physician will provide advice regarding treatment.

*Study procedures*

1. Nursing station personnel will determine the eligibility of patients presenting to the nursing station for participation in the evaluation study based on their presenting health problem. They will obtain consent from those patients who are willing to participate in the research study:
  - a. If they staff determine that a telehealth consultation could be beneficial to the patient AND
  - b. If the patient consents to telehealth use.
2. Nursing station personnel will proceed to collect the information necessary, transmit it to the remote health personnel, and arrange for communicating the results (most likely, but not necessarily, in the context of a regularly scheduled consultation, which could happen in real-time or be scheduled for a future communication).
3. Following the consultations:
  - nursing station personnel will complete the encounter log AND
  - remote personnel will complete the encounter log AND
  - patients will complete a satisfaction questionnaire or interview.

***Berens River***

*Telehealth care*

- (1) Patient Care - The standard care provided to patients in need of access to specialists in the Health Sciences Centre is for the nursing station staff to identify the need for a consultation with a general practitioner, who will refer the patients to the specialist clinics as required. The telehealth system will allow consenting patients to consult with a specialist by interactive video. Local nurses will participate in the session as well, ensuring that the patient understands instructions regarding any treatment required.
- (2) Patient Education - (Diabetes care, prevention activities and clinical care). In addition to the standard care and information given to diabetic patients and patients at risk, the telehealth network will permit consenting patients and staff at the nursing station to link to diabetes health educators for information and education regarding prevention. The telehealth link will also be used to help monitor foot care. The standard care provided to patients in need of counselling is to refer the subject to a counsellor at the Health Sciences Centre (HSC). The telehealth network will permit initial assessments and some counselling to take place by interactive video.
- (3) Continuing Medical Education - Nurses and other members of the local healthcare community will participate in CME sessions.

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## *Study procedures*

1. Nursing station personnel will determine the eligibility of patients presenting to the nursing station for participation in the evaluation study based on their presenting health problem. They will obtain consent from those patients who are willing to participate in the research study:
  - a. If they determine that a telehealth consultation could be beneficial to the patient AND
  - b. If the patient consents to telehealth use.
2. An appointment will be scheduled for consultation with the professional at the remote site, perhaps in a regularly scheduled telehealth clinic. The telehealth consultation will then take place with the nursing station staff and translators present, as required, under the clinical guidance of the remote health personnel according to usual standards of practice.
3. Following the consultations:
  - Nursing station staff will complete the encounter log AND
  - remote personnel will complete the encounter log AND
  - patients will complete a satisfaction questionnaire or interview.

## ***Southend***

### *Telehealth care*

- (1) Access to specialists in LaRonge via interactive video - The standard care provided to patients in need of access to specialists in the LaRonge Health Centre (LRHC), Prince Albert Hospital, and Royal University Hospital (particularly adult and child psychiatry, dermatology, and TB follow up) is for the nursing station staff to identify the need for a consultation with a general practitioner, who will refer the patients to the specialist clinics as required. The telehealth system will allow consenting patients to consult with a specialist by interactive video. Local nurses will participate in the session as well, ensuring that the patient understands instructions regarding any treatment required.
- (2) Diabetic education - In addition to the standard care and information given to diabetic patients and patients at risk, the telehealth network will permit consenting patients and staff at the nursing station to link to a nutritionist/dietician and diabetes educator in the LRHC and the Prince Albert Grand Council Diabetic team for information and education regarding prevention.
- (1) Staff/Community Education - Nurses and other members of the local healthcare community will participate in CME sessions. Nursing station and other band staff will be linked as required to psychologists at the University of Saskatchewan, to develop community capacity in mental health.

## *Study procedures*

1. Nursing station personnel will determine the eligibility of patients presenting to the nursing station for participation in the evaluation study based on their presenting health problem. They will obtain consent from those patients who are willing to participate in the research study:
  - a. If they determine that a telehealth consultation could be beneficial to the patient AND
  - b. If the patient consents to telehealth use.



2. An appointment will be scheduled for consultation with the professional at the remote site, perhaps in a regularly scheduled telehealth clinic. The telehealth consultation will then take place with the nursing station staff and translators present, as required, under the clinical guidance of the remote health personnel according to usual standards of practice.
3. Following the consultations:
  - nursing station personnel will complete the encounter log AND
  - patients will complete a satisfaction questionnaire or interview.

### ***Fort Chipewyan***

#### *Telehealth care*

- (1) Supervision of a rehabilitation assistant - The standard care provided to patients in need of rehabilitation services - including physical, occupational and speech therapy - is to refer them to providers of these services at the Northern Lights Regional Health Centre (NLRHC) in Fort McMurray. The telehealth network will permit eligible, consenting patients to receive these services from an assistant, under supervision from a qualified senior rehabilitation professional located in NLRHC.
- (2) Televisitation/telespirituality - Visits between friends and family members in Fort Chipewyan of patients hospitalized at NLRHC will be arranged through the Aboriginal Liaison Office at NLHRC.

#### *Study procedures*

##### Rehabilitation

Initial assessment of patients will take place at NHLRC by the appropriate rehabilitation specialist, with observation by the rehabilitation assistant. The specialist will develop a treatment plan, which will then be implemented by the rehabilitation assistant under the clinical guidance of the rehabilitation specialist according to usual standards of practice. Every fifth treatment session will be observed by the rehabilitation specialist, and the treatment plan adjusted as necessary.

Consent for participation in the telehealth program and research study will be obtained from patients or their guardians before their first telehealth session.

Following each session, including those that are not supervised using telehealth, the rehabilitation assistant will complete a session log form and patients will complete a satisfaction questionnaire. Following each session which uses telehealth, the rehabilitation specialist will complete a session log form and will compile a monthly report. Patients will complete a satisfaction questionnaire

Near the end of the project, a cross-sectional study of patient outcomes will be conducted. A random sample of 30 active rehabilitation patients will be selected. For each of these patients, the following will be asked to complete a brief questionnaire assessing overall progress in rehabilitations and the contribution of the telehealth system to that progress (instruments to be developed) 1) patient him or herself; 2) rehabilitation assistant 3) rehabilitation specialist.

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## Televisitation

The televisitation sessions will be scheduled during regular hours when rehabilitation sessions are not going on. With the assistance of the televisitation liaison (the NLRHC Aboriginal Liaison), hospitalized patients will visit with friends or family in Fort Chipewyan.

Following the session, the televisitation coordinator will complete a session log form and patients will complete a satisfaction questionnaire which includes items on the therapeutic value of visitation.

## **Anahim Lake**

### *Telehealth care*

Urgent/ Emergent Telehealth - The standard care for trauma is to stabilize the patient and medically evacuate traumatic conditions, which cannot be treated locally. The telehealth application will facilitate the process of triage and subsequent medical evacuations, if needed, by providing the professionals at the Cariboo General Hospital in Williams Lake with advance information about the patient's condition - for example, vital signs, video images of injuries, or other relevant data.

- 1) The telehealth network may permit consenting trauma patients to receive immediate specialist treatment at the Cariboo General Hospital in Williams Lake. Urgent/Emergent cases would comprise of cardiac, diabetic and respiratory ailments as well as major cuts, fractures and burns.

### *Study procedures*

1. Nursing station personnel will determine the eligibility of patients presenting to the nursing station for participation in the evaluation study based on their presenting health problem. They will obtain consent from those patients who are willing to participate in the research study:
  - a. If they determine that a telehealth consultation could be beneficial to the patient AND
  - b. If the patient consents to telehealth use.
2. Emergency trauma consultations will take place as the need arises, with the telehealth system being available 24 hours, seven days a week. The telehealth consultation will then take place with the nursing station staff and translators present, as required, under the clinical guidance of the remote health personnel according to usual standards of practice.
3. Following the consultations:
  - local personnel will complete the encounter log AND
  - remote personnel will complete the encounter log AND
  - patients will complete a satisfaction questionnaire or interview.

### **13. Measures**

The appendices contain copies of all the measures to used:

1. **Patient encounter forms:** checklist-type forms, specific to each community, developed specifically for this research, including: date, time and length of usage, as a proportion of total encounter; health problem prompting the consultation; who was present, at the local and remote sites; manoeuvres during the telehealth encounter; results of the visits in terms of subsequent actions; any technical problems experienced; the implications of using telehealth in terms of costs incurred or avoided. The section of the forms recording what was done during the visit provide proxy indicators of quality of care, in that for those telehealth applications which address conditions for which guidelines for appropriate primary clinical practice have been established (diabetes, mental health, and cardiology), the forms include check points for the recommended components of appropriate care.
2. **Patient satisfaction questionnaire:** a 12-item questionnaire based on Loane, Bloomer & Corbett, 1998 and adapted for use as either an interview or self-completed questionnaire
3. **Key informant interviews;** Developed for this study and following the format used successfully for the interviews conducted during the needs assessment phase of the project.

### **14. Description of all possible risk and harms and discomforts, of all procedures, services, tests or measures for the purpose of this study, which are not part of ordinarily accepted care of the subject.**

The services to be provided through telehealth will be delivered by the same providers in the same practice parameters as ordinarily accepted care, but using information and communications technologies. The possible risks to the patient include loss of sensitivity or accuracy in transmission of information either from the patient or from the remote health personnel, with a risk that important information may be missed and quality of care compromised. There may also be a risk that physicians increase testing and diagnostic procedures, exposing patients to the greater risks through these, in order to reduce uncertainty associated with telehealth usage.

Harms or discomforts to patients may include psychological unease in participation in health encounters with remote personnel, or in the case of store-and-forward technology, discomfort with the electronic transmission of private information.

### **15. Identification of ways in which management or treatment of the subject's condition will be prolonged or delayed because of the research, and if any standard therapies or diagnostic procedures will be withheld for the purpose of the study.**

No treatments will be prolonged, delayed or withheld as purpose of this study.

### 16. Procedures for removing patients from the study

Patients are free to decline participation at any point in the study. Declining to participate will in no way affect care or services.

Removal of patients from the study and/or not making the study available to patients — in other words, delivering their care through conventional rather than telehealth channels - will be at the complete discretion of the patients' usual providers (local health center staff) in conjunction with patients themselves, according to their joint judgment about the suitability of patients to receive care through telehealth.

### 17. Direct and Indirect Benefits

#### *General benefits for communities*

The research study will test the effectiveness of telehealth to provide health care delivery. The results of this study will permit the communities involved and other similar communities to determine the cost-effectiveness and benefits of adopting and implementing telehealth technology. For communities, the main benefits are therefore expected to be 1) and the realization of savings by reducing the number of patient transfers. 2) greater access for local healthcare personnel to specialists and continuing education, enabling them to keep their medical and health care knowledge current.

#### *General benefits for individual patients*

During the study, eligible consenting patients may be able to avoid traveling out of their community to obtain a specialist medical consultation. The study may permit participants to receive specialized health care more quickly than previously.

#### *Specific benefits according to communities*

##### *La Romaine*

- (1) Diabetes - Medical Consultations - The benefit of the research project for the eligible, consenting patients is access to continuous, rather than periodic monitoring of their diabetic condition, and this monitoring will be possible from their homes. They will also have the benefit of immediate medical assistance and advice should their glucose levels change.
- (2) Cardiovascular monitoring - The benefit for eligible, consenting patients and local health care staff is that, in any emergency, local health care staff may obtain information and immediate advice from a physician specialist and possibly not have to medically evacuate or transfer the patient for treatment. Patients will not have to travel out of their community for a routine electrocardiogram.
- (3) ENT - Eligible, consenting patients can possibly obtain a diagnosis almost immediately and instructions regarding treatment given to local health care staff, avoiding patient travel out of the community.
- (4) Dermatology - Eligible, consenting patients can possibly obtain a diagnosis regarding skin lesions and other dermatological problems. Instructions would be provided by the dermatologist remotely located, regarding treatment.

*Berens River*

- (1) Patient Care - The benefits to consenting patients is that they will have access to a specialist without having to travel out of their community. The benefits to specialists who participate in the study is that they will be able to treat patients remotely more promptly. As a result of the study, the community may be able to realize savings from travel avoidance.
- (2) Patient Education (Diabetes care, prevention activities and clinical care) - The benefit to participating consenting patients is that they will receive information and education which could help them avoid complications arising from various health problems
- (3) Continuing Medical Education - The benefit to local healthcare staff is that they can participate in CME sessions and upgrade their knowledge without having to travel outside the community. These benefits will be passed on to the patients, which they see in the Nursing station.

*Southend*

- (1) Access to specialists - The benefits to consenting patients are that they may be able to see a specialist more quickly and they will not need to travel outside the community. The benefits to specialists who participate in the study is that they will be able to treat patients remotely more promptly. As a result of the study, the community may be able to realize savings from travel avoidance.
- (2) Diabetic education - The benefit to participating consenting patients is that they will receive information from a nutritionist regarding their diet, and other information, which could help them avoid complications of diabetes.
- (3) Staff/Community Education - The community will benefit receiving expertise in the prevention and management of mental health problems.

*Fort Chipewyan*

With the use of a telehealth network, rehabilitation services will be provided closer to the patient's home and community. It will be possible to assess the usefulness of telehealth in providing supervision for rehabilitation assistants.

*Anahim Lake*

Urgent/ Emergent Telehealth - With the use of a telehealth network, it will be possible to triage trauma earlier and make more effective decisions regarding medical evacuations.

## **18. Costs and compensation**

The total amount of funding for this research project has been made available through Health Canada's Health Transition Fund. The funds are being administered by the Medical Services Branch of Health Canada, through Memoranda of Understanding with each of the five provinces and communities involved.

Patients or health care professionals involved in this research study will not be remunerated or compensated financially for participating in the study.

## 19. Description of the procedures for obtaining informed consent

### *Patients*

All eligible patients will be given the opportunity to provide their informed consent (1) to receive health care through telehealth and (2) to participate in the telehealth research study. In the case of patients under 16 years, informed consent will be obtained from the child's parent or legal guardian. The consent process has been designed to respect the elements of capacity, comprehension and voluntariness. A verbal and written explanation will be given to each prospective subject in the language of his or her choice. Potential research participants will be given sufficient time to ask questions and opportunity to consider the information provided. A copy of the signed consent form will be given to the subject, and a copy kept on file by the Community Health Centre until the end of the study.

If the patient is unable to sign, or if circumstances make it impossible for the subject to provide written consent, the consent of the subject will be obtained (1) orally or (2) tape-recorded. Where consent is oral, a record of it will be made in an appropriate log or book dated and signed by the researcher, the project officer or the nurse at the health care center.

If the consent is tape-recorded, the recording will clearly identify the subject, the researcher and the date.

In certain cases involving medical emergencies, consent to use telehealth may be waived if the subject is placed at risk due to the delay which will be occasioned if a full explanation is given, or if the subject is not competent or not conscious. If the subject becomes conscious he or she must be promptly afforded the opportunity to give free and informed consent concerning continued use of telehealth or participation in the telehealth study.

### **The following information will be provided verbally to each participant;**

(\* Indicates items which are included on the adult consent form. A parallel version for parents whose children are eligible patients is also provided.)

#### 1. **\*Purpose:**

We are asking you to participate in a telehealth research project. The basic purpose of this project is to obtain information about the use of telehealth technology in your Community Health Center. It is part of a study that is being done in four other First Nations Communities in northern Canada.

#### 2. **\*Description**

The telehealth system uses television or the telephone to let you talk to a doctor, a specialist or a counselor. This may mean that you will not have to travel to \_\_\_\_\_ to see the doctor or specialist. If you agree, you would see the doctor, specialist or counselor on the television set without having to travel to \_\_\_\_\_.

We are also asking you to participate in a study to see if this system suits your health care needs. If you agree to participate, you would be asked complete a short questionnaire (or answer short questions briefly) to tell us about your preferences for using telehealth (this will take about 10-15 minutes).

If you agree to participate, the nurse in your health center will fill out a form about what happened in your visit here today: who was here, what was done and what will be done next. If you speak to a doctor, specialist or counselor using the telehealth system today, that person will also fill out a form. These forms will help us keep track of how the telehealth system is being used. If you come into the health center another time, the nurse

will fill out another form and give them both a number or a code so that she can keep track of how the telehealth system is used over time. You will not have to do anything for these forms.

All of the forms will be sent to the researchers at McGill University who will put all the information from this community and the four other First Nations' communities together. **YOUR NAME WILL NOT BE PUT ON ANY OF THE FORMS: NO ONE OUTSIDE THE HEALTH CENTER WILL KNOW ANYTHING ABOUT YOUR VISITS THERE.**

3. **\*Benefits**

There are a few benefits to participating in this project. First, it is possible that you would see the specialist sooner than if you had to travel to \_\_\_\_\_ to see him/her. Secondly you may not have to travel to \_\_\_\_\_ to see the specialist: you could see the specialist from the Health Center. Thirdly, you may get the results of your visit sooner than before, and obtain the treatment earlier.

There are some potential benefits to your community as well. If the telehealth equipment is found to be useful, it will stay in the community at the end of the project. The \_\_\_\_\_ community may also save money because there will be fewer trips out of \_\_\_\_\_.

4. **\*Risks and discomfort**

There are a few risks or discomforts involved in using telehealth technology. There is a risk that the doctor, specialist or counselor will not be able to see or hear you or your test results as well as usual. This might make him or her miss something about your health problem or it might make him or her want you to take more tests so he or she can be more sure.

It is possible that the tests or treatment that you need will require you to travel to the hospital in \_\_\_\_\_ anyway.

You may feel that it is not as private as seeing the doctor in person, and you may prefer to speak to the doctor in person rather than on a TV set.

5. **\*Consequences of non-participation**

If you decide not to participate in this study, you will receive the same care and attention that you would have received if we did not have a telehealth system in place.

6. **\*Alternatives**

If telehealth is not used, the alternative is to refer you for a consultation or an appointment with the doctor or specialist.

7. **\*Privacy and Confidentiality**

If you decide to participate in this study, your privacy will be protected in the following ways:

- a. Your name will not appear on any of the recorded information.
- b. Only information grouped together will be reported in any publication or report.
- c. The final report will be released only when the community has approved the final report and consented to its publication.

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- d. While using telehealth equipment, any transmissions of images or recordings will remain part of your confidential medical files and will not be used for anything else.

### 8. \*Voluntariness

You are free to participate in this study or not, and if you do, you have the right to stop being in it at any time.

### 9. \*Contact persons

A list of contact persons in your community who are knowledgeable about the study has been provided to you. You can contact any of them at any time if you have questions about the study.

### *Key informants*

As mentioned above, at two points during the study, qualitative interviews will be conducted with project stakeholders. Because they will be responding in the public roles, they will not be asked to provide written consent. However, they will be formally asked for consent to participate, and they will be told that they are free to decline participation without consequence. They will also be informed that:

- a. All of their responses will be held confidential to the research team
- b. No individual will be identifiable in any report; only aggregate information will be reported
- c. The final report will be released only when the community has approved the final report and consented to its publication.

With participants' permission, the interviews will be tape-recorded.

## 20. Confidentiality

**Encounter Logs:** the logs recording telehealth usage to be filled in by local and remote health care personnel will be identified by a numbered code, and will not contain any patient identifiers. The list of codes will be accessible to health care staff only, and will remain in a locked filing cabinet at the CHC. The completed logs will be kept in a locked filing cabinet apart from the master list of codes designated for this purpose at the CHC. On a weekly basis, these logs will be sent, by fax, to the project evaluation office at McGill University, where they will be kept in a locked filing cabinet for the duration of the data collection period. The receiving fax is in a secure location accessible only to project staff and the departmental secretariat.

**Patient satisfaction:** the completed questionnaires will be collected and stored at the CHC and sent by Canada Post, once a month, to the project evaluation office at McGill University where they will be kept in a locked filing cabinet for the duration of the data collection period.

**Key informant interviews.** The tape recording will be transcribed verbatim without identifying information and the tapes destroyed within one year of the interview.

**Cost information:** Data related to costs will be kept in a locked filing cabinet in the project evaluation office for the duration of the project.

No individual patient or key informant will be identified by name in any report, and care will be taken to ensure that individual respondents are not identifiable.



Finally, because this evaluation will occur in the work settings of nursing station staff, particular care will be taken to preserve the confidentiality of information related to work organization, work performance and staff relations, in order to protect the interests of all participants in the project.

## **21. Special provisions for research involving aboriginals**

The conduct of this project respects the code of ethics, which was developed and documented at the beginning of the project, a copy of which is appended.

### **Appendices:**

1. Instruments
2. Consent forms
3. Code of ethics

