UNIVERSITY OF CALGARY

APPROACH

Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease

CONSENT FORM

TITLE: APPROACH - Alberta Provincial Program for Outcome Assessment in Coronary Heart disease
SPONSOR: Alberta Health Services and Alberta Health and Wellness
PRINCIPAL INVESTIGATOR: Merril Knudtson MD
Clinical Steering Committee members: Ross Tsuyuki PharmD (Chair), Michael Curtis MD, Neil Brass MD, Arvind Koshal MD, Wayne Tymchak MD, Michelle Graham MD, Andrew Maitland MD, Brent Mitchell MD, Dean Traboulsi MD, William Ghali MD.

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research project is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

BACKGROUND/PURPOSE

Your physician has determined that you require a coronary angiogram. This project is a surveillance project. This project follows patients who undergo angiography to determine short- and long-term outcome and cost. The APPROACH initiative has assembled a multi-disciplinary team of investigators (cardiologists, surgeons, nurses, epidemiologists and biostatisticians) who are using this database as a tool to study issues surrounding the delivery of cardiac care (eg. quality of care, resource utilization and clinical outcomes). OUR GOAL IS TO IMPROVE HEALTHCARE. This research involves information gathering ONLY. Results from many patients will be combined into a summary - your individual identifying information will not be disclosed.

Data collection began in 1995. Currently patients like yourself (who are undergoing angiography) are being registered throughout Alberta as well as BC, SK, Toronto, Windsor, London, NS and NL.

WHAT WOULD YOU HAVE TO DO?

If you agree to participate in this research you will be contacted by mail at one week, one year and then biannually and asked to complete a questionnaire. For example, you will be asked to list your hospitalizations and medications and also answer questions relating to your health. There will be **no costs** to you by participating in this research.

PRIVACY

All of the information gathered in this research will remain confidential. The information collected will only be available to those investigators participating in the research for the purpose of analyzing the results. The data collected will be pooled - you will not be personally identified. Your cardiologist is aware of your participation in this research and is aware of the findings from this project.

Please visit our web site at www.approach.org to see our current team, research and publications.

BENEFITS

If you agree to participate in this study there may or may not be a direct medical benefit to you. The information we gain from this study may help us to provide better treatments in the future for patients like yourself.

SIGNATURES

Your signature on this form indicates that you understand to your satisfaction the information regarding your participation in this research project and agree to participate as a subject.

In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from this research at any time without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have any further questions concerning matters related to this research, please contact Dr. M. Knudtson (Principal Investigator) at 403-210-7385.

If you have any questions concerning your rights as a possible participant in this research, please contact the Ethics Resource Officer, Research Services, University of Calgary, at 220-3782.

We ask that if you relocate, you contact our central Research Office in Edmonton (toll free 1-800-390-2248) and leave a message so that we can keep your file current.

_____	_____
PARTICIPANT'S NAME	SIGNATURE and DATE
_____	_____
INVESTIGATOR/DESIGNATE NAME	SIGNATURE and DATE
_____	_____
WITNESS' NAME	SIGNATURE and DATE

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A copy of this consent form has been given to you to keep for your records and reference.

Revised: Oct 2009