



**AOA RESEARCH FOUNDATION LTD**  
**APPLICATION FOR RESEARCH GRANT**

Applicants should read the Instructions to Applicants before completing this form

A  
2003

**Project Title: The Absolute cost to the Individual and the Community of Post-Operative Infections in Total Joint Replacement**

**Details of Chief Investigator:**

Title, Initials and Surname: A/Pr P.N.Smith

Appointment: Associate Professor in Orthopaedic surgery  
Medical School  
Australian National University

Contact Address: c/- Orthopaedic and Trauma Research Unit  
The Canberra Hospital  
P.O.Box 11  
Woden, ACT 2606

Telephone: 02 62325566

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**Academic Qualifications (Indicate conferring institutions and dates):**

1986 Flinders University of South Australia BMBS

1995 Royal Australasian College of Surgeons FRACS

Hours/week devoted to this project: 1 day

Hours/Week devoted to other projects: 3 hours

**Details of Associate Investigators:**

(1) Title, Initials and Surname: Ms J Cahill

Appointment: Research Officer

Contact Address: /- Orthopaedic and Trauma Research Unit  
The Canberra Hospital  
P.O.Box 11  
Woden, ACT 2606

Telephone: 02 62442122

Fax: 02 62442334

Email: jenny.cahill@act.gov.au

**Academic Qualifications (Indicate conferring institutions and dates):**

1986 University of Sydney B(App) Sc

Hours/week devoted to this project: 25 hours/week  
projects: 0

Hours/Week devoted to other projects: 0

**Institution at which research will be conducted:**

The Canberra hospital  
Dept of Surgery  
Orthopaedic and Trauma Research Unit

**Institution which will administer the grant:**  
**Trauma and Orthopaedic Research Unit**  
**Department of surgery**  
**The Canberra Hospital**

**EXPERIMENTS ON HUMAN SUBJECTS OR ANIMALS**

(Delete inappropriate option)

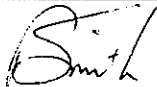
Does the project involve experiments on human subjects? YES

If Yes, has the Ethics Committee of the Institution concerned approved the project and certified that it conforms to the general principles set out in the NH&MRC Statement on Human Experimentation? YES

Does the project involve experiments on animal subjects? NO

If Yes, has the Ethics Committee of the Institution concerned approved the project and certified that it conforms to the general principles set out in the NH&MRC Statement on Animal Experimentation? YES/NOT YET

Signature of Chief Investigator:



Date:

**CERTIFICATION OF HEAD OF DEPARTMENT**

I certify that this project is appropriate to the general facilities in my Department and that I am prepared to have the project carried out in my Department.

Title and Name: **Kimberley Pierce**

Department: **EXECUTIVE DIRECTOR, SURGICAL SERVICES.**

Signature:



Date: **24.2.03**

Note: A confidential statement may be forwarded direct to the RACS if thought advisable.

**CERTIFICATION OF HEAD OF INSTITUTION OR NOMINEE**

I certify that this request satisfies all the requirements of the institution and that the classifications quoted for personnel are in accordance with practice at this institution.

Title and Name: **K.A. Pierce**

Appointment: **ED SS**

Signature:



Date: **24.2.03**

**BUDGET**

Detailed Budget Items	Priority	Amount Requested (\$)	Office Use Only
Part-time research officer - (NHMRC level PSP2- junior graduate research assistant)	1	\$20,000	
Data collection, archiving and processing	2	\$1,500	
Consumables-stationery, printing	3	\$500	
Australian Institute of Health and Welfare Data search costs	4	\$ 1,000	
Please include GST			
<b>TOTAL</b>		<b>\$22,500</b>	

**OTHER RESEARCH SUPPORT**

<p><b>Currently Held Funding: Nil</b>          The Orthopaedic and Trauma Research Unit at The Canberra Hospital will provide technical support in the form of computing resources and office space and any additional data collection costs necessary.          An application has been made to the NHMRC for a project grant for 2004. If successful this will be used to complete stage 3 of the research .</p>
<p><b>Requested Funding for Coming Year Nil</b></p>

### **AIMS OF THE PROJECT:**

List the specific aims and potential significance of the project. If hypotheses are to be tested, they should be clearly stated.

### **AIMS**

This study has the specific primary aim of determining the overall cost of infection in total joint replacement to both the individual and the health system for the first time. The total economic costs of treatment of infection will be collated, including inpatient and outpatient costs of medical care. The costs to the patient in terms of quality of life, general health and disease specific outcomes and economic loss or burden will also be determined. The cost to the individual expressed in terms of cost per quality adjusted life year will be derived. Combining these, an overall cost for the entire episode of infection complicating total joint arthroplasty will be obtained.

These variables will be analysed comparing across two population groups.

- 1) Patients who have undergone uncomplicated primary total joint replacement
- 2) Patients who have undergone total joint replacement complicated with infection

### **HYPOTHESES**

The study has the following hypotheses:

- 1) Quality of life, general health and disease specific outcomes will be significantly reduced when comparing the two above patient groups
- 2) The inpatient cost of management of infection after total joint replacement represents a part only of the overall cost burden.

This study will enable for the first time a rigorous analysis of the consequences of infection in joint replacement surgery. Studies to now have not gone beyond consideration of the cost of the in-hospital episode of care and have not been comprehensive in capturing all cost inputs.

### **SIGNIFICANCE**

Our pilot study data has demonstrated the existing underestimation of treatment costs for infection in total joint arthroplasty based purely on the thorough analysis of all inpatient inputs alone. However, is clear that in order to ascribe a cost to an event, all aspects of cost must be considered, including personal health, quality of life and loss of joint function as well as short and long-term financial costs. This study will for the first time bring all these elements together and establish a new standard for cost modeling.

In establishing an overall cost for the complication of infection following total joint replacement, we will be able to perform a meaningful evaluation of cost-benefit in relation to measures of prophylaxis to prevent infection. This will enable both treating Orthopaedic Surgeons and Health Administration to allocate resources in an informed fashion and direct standards of care and practice to minimize the occurrence of infection, leading to better patient outcomes and thereby reduce the financial burden currently borne.

### **ETHICAL IMPLICATIONS OF THE PROJECT: EXPERIMENTS ON HUMANS AND ANIMALS**

This Study aims to determine the economic and health outcome consequences of infection following hip and knee replacement surgery. The study involves analysis of inpatient care records to establish costs of the hospital stay episodes. Individual patients are also interviewed with a view to obtaining details of economic cost, general health and joint specific outcomes.

#### **Consent**

All participants will be fully informed as to the aims and process of the study prior to consent being obtained.

All participants will sign a consent form. This consent will authorise the Health Insurance Commission to release Medicare and Pharmaceutical Benefits Scheme data that relates to the participants total joint replacement.

Involvement in the research is voluntary and participants can withdraw from it at any time.

#### **Confidentiality**

Subject confidentiality will not be at risk. Raw data will be stored in a locked filing cabinet in the Trauma and Orthopaedic Research Unit. All data for clients participating in the study will then be de-identified and held on a secure password protected computer in the Trauma and Orthopaedic research Unit.

## Risks

No risk to the participants is envisaged

The ACT Health and Community Care Human Ethics Committee has approved the study

### **BACKGROUND, RESEARCH PLAN, JUSTIFICATION OF BUDGET AND RELEVANT PUBLICATIONS**

Only published papers and papers accepted for publication in refereed journals are to be listed. Abstracts should not be included. Ensure that sufficient detail is provided in the Research Plan for assessors to understand the proposal. Up to 5 additional A4 pages may be attached for this section.

#### BACKGROUND

With an ageing population and the development of surgical techniques, the incidence of total joint replacement is increasing. Data from the National Joint Replacement Registry shows there were over 45,000 hip and knee joint replacements performed 2000-2001 with an increase of 9% during 2001-2002<sup>1</sup>. This trend is expected to continue as the percentage of the population over 65 increases over the next 25 years.

The most widely reported outcome of total joint replacement is an increase of quality of life for the patient<sup>2</sup>. To date the quality of life studies have focused on the pre versus post quality of life after a primary joint replacement with no complications. These have shown that quality of life is significantly improved post surgery in the areas of function, pain and mobility. Some studies show greater gains being made with hip arthroplasty<sup>3,4</sup>, but similar trends are seen with both procedures with some studies showing gains approaching the norms for the normal population<sup>5</sup>. Quality of life studies have also been performed following groups of patients who have undergone revision surgery for aseptic prosthetic failure. There is however a paucity of research performed to study the general health and joint specific outcomes after treatment of infection after joint replacement.

No studies have been published comparing outcomes of uncomplicated versus infected total hip replacement. There is only a single paper comparing the outcomes of septic versus aseptic revision in total knee arthroplasty<sup>6</sup>. This study reported on the short term outcomes using a disease specific function scale and the SF-36. The results showed a significantly higher percentage of patients with septic revision stating that they were unable to return to normal activities of daily living.

One of the most serious complications of total joint replacement is infection post surgery. Infection following joint replacement surgery is both devastating for the patient and enormously costly for the health system. Most patients who suffer infection after total joint replacement will undergo multiple surgical procedures and a significant proportion will not achieve a cure of the infection despite aggressive surgical and antibiotic treatment.

Periprosthetic infection, once established is difficult to eradicate and the focus is very much on prevention of infection. Measures such as laminar air-flow systems, body exhaust suits and the use of prophylactic antibiotics are currently used to minimise infection risk<sup>7</sup>. These methods have been shown to reduce the risks of infection significantly from the original 9% seen in Charnley's initial experience of joint replacement performed in standard operating theatres without prophylactic antibiotics. Importantly, these measures to prevent infection have been demonstrated to be individually effective and also synergistic<sup>8-10</sup>. The cost effectiveness of these measures has been studied in a limited fashion using estimates of inpatient cost of infection as the denominator<sup>11</sup>. These analyses have unfortunately not been comprehensive in capturing all inpatient costs and the wider costs following hospitalisation and to the community have not been included in the equation. Therefore, no satisfactory information currently exists enabling a rigorous cost-benefit analysis of infection prophylaxis to be performed.

The infection rate after primary arthroplasty is now widely reported to be 1% or less with the risk in revision surgery at least double this figure. Therefore it is likely that at least 450 new cases of infection after joint replacement occur annually in Australia. Although relatively rare, we have demonstrated that the in-hospital cost of treatment of these infections is extremely high. Revisions due to infection are considered complex, costly operations with extended lengths of stay in hospital and greater risks of

complications post surgery. Research has examined the costs of infection in relation to the increase in the length of hospital stay and the costs of revision procedures<sup>12-14</sup>.

Our research group has performed a pilot study examining the in-hospital cost of treatment of infection occurring following total joint replacement in a group of 54 patients treated in the period from 1996 to 2001<sup>15</sup>. 37 of these patients were diagnosed with a deep periprosthetic infection and 17 with a superficial wound infection. This study was unique in Australia and comprehensively captured all identifiable inpatient care inputs including medical costs, operative theatre costs, prostheses, nursing and allied care costs, costs of all investigations and all intravenous therapy and related drug treatment costs.

This study revealed that The Canberra Hospital spent over two million dollars over the period 1996 to 2001 treating infected total joint arthroplasties. Average length of patient stay for these complex cases was 38 days (up to 4 months in some instances) compared to the current average length of stay for an uncomplicated operation of just over 6 days. The average cost of treatment of infection after joint replacement in this study was approximately \$50,000 per patient. The average cost at The Canberra Hospital of treating a deep infection of the hip joint was \$53,239 per patient and \$40,444 for a deep infection of the knee. The costs were considerably higher when two stage revision procedures were considered in isolation. A two stage revision hip replacement cost over \$60,000 per patient and a two stage revision knee replacement cost over \$90,000.

When considered as a national issue, with approximately 450 new cases of periprosthetic infection on the basis of known probability occurring annually, the burden to the Australian Health System is at least 22 million dollars per year.

This cost, although considerable, forms only part of the total picture. In addition to these there are the medical costs post the hospital episode to account for. Some patients suffer personal or family economic costs, which remain hidden but are often considerable. The quality of life of the individual is seriously adversely affected for an extended period of time. The performance of the affected joint is likely to be inferior in the long term compared with that of an uncomplicated operation and the patient is exposed to later risk of further revision surgery. These issues are all-important and must be accounted for accurately in order to fully assess the impact of infection as a complication. There has been no study which analyses the total cost of infection following total joint arthroplasty. There is no research that combines the total economic, personal and social costs and examines them over time.

## REFERENCES

1. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. Adelaide: AOA, 2002.
2. Laupacis A, Bourne R, Rorabeck C, Feeny D, Wong C, Tugwell P, Leslie K, Bullas R. The effect of elective total hip replacement on health-related quality of life. *Journal of Bone & Joint Surgery*. 1993;75-11:1619-26.
3. March LM, Cross MJ, Lapsley H, Brnabic AJ, Tribe KL, Bachmeier CJ, Courtenay BG, Brooks PM. Outcomes after hip or knee replacement surgery for osteoarthritis. A prospective cohort study comparing patients' quality of life before and after surgery with age-related population norms. *Medical Journal of Australia*. 1999;171-5:235-8.
4. Salmon P, Hall GM, Peerbhoy D, Shenkin A, Parker C. Recovery from hip and knee arthroplasty: Patients' perspective on pain, function, quality of life, and well-being up to 6 months postoperatively. *Archives of Physical Medicine & Rehabilitation*. 2001;82-3:360-6.
5. Wiklund I, Romanus B. A comparison of quality of life before and after arthroplasty in patients who had arthrosis of the hip joint. *Journal of Bone & Joint Surgery*. 1991;73-5:765-9.
6. Barrack RL, Engh G, Rorabeck C, Sawhney J, Woolfrey M. Patient satisfaction and outcome after septic versus aseptic revision total knee arthroplasty. *Journal of Arthroplasty*. 2000;15-8:990-3.
7. Josefsson G, Lindberg L, Wiklander B. Systemic antibiotics and gentamicin-containing bone cement in the prophylaxis of postoperative infections in total hip arthroplasty. *Clinical Orthopaedics & Related Research*. 1981-159:194-200.
8. Wilde AH, Ruth JT. Two-stage reimplantation in infected total knee arthroplasty. *Clinical Orthopaedics & Related Research*. 1988-236:23-35.

- 9. Berg M, Bergman BR, Hoborn J.** Ultraviolet radiation compared to an ultra-clean air enclosure. Comparison of air bacteria counts in operating rooms. *Journal of Bone & Joint Surgery - British Volume.* 1991;73-5:811-5.
- 10: Blomgren G, Hoborn J, Nystrom B.** Reduction of contamination at total hip replacement by special working clothes. *Journal of Bone & Joint Surgery - British Volume.* 1990;72-6:985-7.
- 11. Kreibich DN, Vaz M, Bourne RB, Rorabeck CH, Kim P, Hardie R, Kramer J, Kirkley A.** What is the best way of assessing outcome after total knee replacement? *Clinical Orthopaedics & Related Research.* 1996-331:221-5.
- 12. Antti-Poika I, Santavirta S, Kontinen YT, Honkanen V.** Outcome of the infected hip arthroplasty. A retrospective study of 36 patients. *Acta Orthopaedica Scandinavica.* 1989;60-6:670-5.
- 13. Barrack RL, Sawhney J, Hsu J, Cofield RH.** Cost analysis of revision total hip arthroplasty. A 5-year followup study. *Clinical Orthopaedics & Related Research.* 1999-369:175-8.
- 14. Iorio R, Healy WL, Richards JA.** Comparison of the hospital cost of primary and revision total hip arthroplasty after cost containment. *Orthopedics.* 1999;22-2:185-9.
- 15. Terwiel EL.** A cost analysis of infection in total joint replacement. *School of Medicine. Tasmania: University of Tasmania, 2001.*

### RESEARCH PLAN

This research project will involve collection of information in two separate groups of patients concerning

1. General Health Status
2. Disease Specific Status
3. Financial Cost of Treatment and
4. Health Related Quality of Life

These groups are:

Group 1: Patients who have undergone uncomplicated primary total joint replacement

Group 2: Patients who have undergone total joint replacement complicated with infection

**Funding from the AOA research Foundation would support the data collection and research involving Group 2. The overall design is detailed below.**

Patients from both these groups will be approached for willingness to participate in this study. The purpose, methods and time commitments involved in the project will be explained to the participants prior to obtaining witnessed written consent. Ethics approval to conduct this project has been obtained from the ACT Health and Community Care Human Ethics Committee.

Group 1 (uncomplicated primary total joint replacement) will comprise 100 patients who underwent a total joint arthroplasty during 1995-1996 and were part of the Care Continuum and Health Outcomes Project. All available participants of this project will be included in the current research. These patients were seen pre-operatively and then followed one week, three weeks, six weeks and six months post-operatively.

The data collected during this period includes financial costs incurred for treatment, resources utilized in the community and the SF 36 to assess general health status.

Our pilot costing study involved the retrospective analysis of the medical records of 54 patients treated for infection at The Canberra Hospital following total knee and hip arthroplasty between 1996-2001.

Thirty-seven of these patients were diagnosed with a deep periprosthetic infection and seventeen with a superficial infection. These patients will form the basis of the second group.

Participants from both groups will be interviewed to obtain the following information:

1. General Health Status information.

The SF-36 will be administered to assess current general health status and outcome after surgery. The results will also be compared to the known population norms.

2. Disease specific information.

The Harris Hip Score and the Knee Society Clinical Rating System will be used to assess joint specific status and outcomes.

### 3. Financial Costing of Treatment

A comprehensive in-hospital cost of service delivery analysis was performed for the patients of group 2. The in hospital costs of surgery for the patients in Group 1 were collated as part of the Care Continuum and Health Outcomes Project. These costs will be built upon with analysis of further pharmaceutical, medical and rehabilitation costs beyond the acute hospital stay.

The Financial costs will be obtained from several sources:

- hospital medical records which will have detailed information about the ongoing outpatient costs and tests required, utilization of allied health services and pharmaceutical costs
- community medical and pharmaceutical costs obtained through the Health Insurance Commission (via consent of patients to use their medicare numbers).

An interview will be conducted with the subjects to obtain qualitative data on other economic considerations.

Total direct economic costs of the infection complication will be collated, incorporating inpatient and outpatient medical costs, loss of income to the patient and cost per quality adjusted life year.

### 4. Health Related Quality of Life

The QWB, a multi-attribute health status classification system with preference scores will be utilized to assess health-related quality of life. Quality-adjusted life years (QALYs) will then be calculated and with the costs associated with the intervention a cost utility derived.

### Statistical Validation - Number of Subjects

A review of the current literature was conducted to obtain data necessary for power calculations. Analyses were conducted for the disease specific measures, costings and general health measure. The results are outlined below.

#### SF 36 data:

Means and standard deviations from Van Essen et al (1998) used to perform calculations.

	Type I error=0.05	Type I error=0.01	Type I error=0.001
Power=80%	20	30	45
Power=90%	27	38	55
Power=95%	33	45	61

A sample size of n= 20 is required to give a power of 0.8 at 95% confidence interval.

Therefore this design with n= 37 in Group 2 and n= 100 in Group 1 is adequate.

#### Costings data:

Costings data from the pilot study ( Terweil 2001 ) used to perform analysis.

Comparison of mean costs for infected total joint replacement made with mean costs of uncomplicated total joint arthroplasty.

	Type I error=0.05	Type I error=0.01	Type I error=0.001
Power=80%	2	4	7
Power=90%	4	5	7
Power=95%	4	5	8

Therefore this design with n= 37 in Group 2 and n= 100 in Group 1 is adequate.

#### Disease specific data:

##### 1. Knee Society Clinical Score

Data from Barrack et al (2000), Bullens et al (2001) and Van Essen et al (1998) used to perform analysis.

	Type I error=0.05	Type I error=0.01	Type I error=0.001
Power=80%	7	11	16
Power=90%	9	13	19
Power=95%	11	16	21

Therefore this design with n= 37 in Group 2 and n= 100 in Group 1 is adequate.

##### 2. Harris Hip Score:

Data from Lieberman et al (2001) used to perform analysis.

	Type I error=0.05	Type I error=0.01	Type I error=0.001
Power=80%	12	17	26
Power=90%	15	22	32
Power=95%	19	26	35

Therefore this design with n= 37 in Group 2 and n= 100 in Group 1 is adequate.

#### Handling and Analysis of Data

All data obtained will be maintained on a dedicated, non-networked, secure password protected computer located in the Trauma and Orthopaedic Research Unit at The Canberra Hospital.

The total costs incurred for each group will be collated. Descriptive statistics will be employed for this data. The general health outcomes data, disease specific data, economic data and incremental cost per QALY for the two groups will be compared using a paired t test.

The SF-36 scores will also be compared to the known population norms using ANOVA if the population is normally distributed. A modified ANOVA will be used if the data is not normally distributed.

Dr Bruce Shadbolt, co-investigator epidemiologist, and the Statistical Consulting Unit at the ANU will provide statistical support for this project.

#### JUSTIFICATION OF BUDGET

This research has three stages. The first stage, the collection of pilot in-hospital costings data for the group of total joint replacement complicated with infection has been completed. The second stage is the collection of quality of life, general health, disease specific and additional economic data for this group. It is for this stage of the research that funding is sought. The third stage, collecting the above information for the uncomplicated total joint replacement group will be conducted after the second stage has been completed.

The budget requested comprises part of the estimated data collection and running costs for this part of the project. An experienced research officer is required to liaise with different groups, conduct interviews and perform data collection and analysis.

#### RELEVANT PUBLICATIONS

The data derived from the pilot study concerning in-hospital costings for the treatment of infection after joint replacement is in the process of being submitted as a paper to the Journal of Arthroplasty.

A list of recent publications for Dr Smith is below.

#### Dr Paul N Smith - Publications

1. Ehrendorfer S., LeQuesne G., Penta M., **Smith P.N.**, Cundy P.J. Bilateral Synovitis in Symptomatic Unilateral Transient Synovitis of the Hip. Acta Orthop Scand 67:149-152, 1996

2. **Smith P.N.**, Rampersaud R., Rorabeck C.H. Incipient Compartment Syndrome of the Thigh Following Total Knee Arthroplasty. The Journal of Arthroplasty 12: 835-838, 1997

3. **Smith P.N.**, Rorabeck C.H. Results of Revision Total Knee Arthroplasty in The Face of Significant Bone Deficiency. Orthopaedic Clinics of North America , 361-371, April 1998

4. **Smith P.N.**, Gie G.A. Avulsion Fracture of the Ischial Tuberosity Following Complex Total Hip Arthroplasty - an unusual cause of hip pain. Journal of Arthroplasty, 13: 603- 606, 1998

5. Barrack R.L., **Smith P.N.**, Munn B, Engh G, Rorabeck C.H. The Ranawat Award. Comparison of surgical approaches in total knee arthroplasty. Clinical Orthopaedics and Related Research, 356: 16-21, 1998

6. **Smith P.N.**, Gie G.A, **Revision Total Hip Arthroplasty Using Impacted Allograft - The Femoral Side. Invited article: Orthopaedic Product News, July- Sept1998**

7. **Smith P.N.**, Eyres K.S. Safe removal of Massive Intrapelvic Cement using Ultrasonic Instruments. Journal of Arthroplasty, 14: 235-238, 1999

8. **Smith P.N.**, Taylor R., Ling R.S.M. The Influence of Weight Bearing on the Measurement of Polyethylene Wear in Total Hip Arthroplasty. Journal of Bone and Joint Surgery, 81B: 259-265, March 1999

9. **Smith PN**, Gelinas J, Kennedy K, Thain L, Rorabeck CH, Bourne RB. Kinematics of the knee - an in vivo MRI study. Journal of Bone and Joint Surgery 81B(suppl 1):19

10. Kaper BP, **Smith PN**, Bourne RB, Rorabeck CH, Robertson D. Medium term results of a mobile bearing total knee replacement. Clinical Orthopaedics and Related Research. 367: 201-209, 1999

11. **Smith PN**, Gelinas J, Kennedy K, Thain L, Rorabeck CH, Bourne RB. Popliteal vessels in knee surgery. A magnetic resonance imaging study. Clinical Orthopaedics and Related Research. 367: 158-164, 1999

12. Scarvell J, **Smith PN**, Refshauge KM  
MRI Kinematics of the Normal and ACL Deficient Knee  
Accepted for Publication,  
Journal of Biomechanics, 2003

13. Scarvell J, **Smith PN**, Refshauge KM  
Development of Concepts in Knee Kinematics  
Accepted for publication Jan 2003, Archives of Physical Medicine and Rehabilitation



***HUMAN RESEARCH ETHICS COMMITTEE***

File No:

Dr Paul Smith  
Orthopaedic Surgeon  
Trauma and Orthopaedic Research unit  
The Canberra Hospital

- 6 JAN 2003

Dear Dr Smith

The ACT Health and Community Care Human Research Ethics Committee considered the proposed study 'The Overall Cost to the Individual and the Community of Post-Operative Infections in Total Joint Replacement', at the meeting held on 9 December 2002. Ethics Committee Submission No ETH.11/02.417 refers.

The Committee approved the study, including the Patient Information Sheet (Version: 27.11.02), Consent Form (Version: 27.11.02) and Questionnaire.

I attach for your records an Outcome of Consideration of Protocol form.

You may recall that the ACT Health and Community Care Guidelines for Submission of Application require you to complete payment of the levy when approved by the Ethics Committee.

Please forward \$27.50 levy fee to the Secretariat, ACT Health and Community Care Human Research Ethics Committee, GPO Box 825, Canberra ACT 2601 as soon as possible. An invoice is attached for your attention.

I confirm that the ACT Health and Community Care Human Research Ethics Committee is constituted according to the National Health and Medical Research Council Guidelines and operates in compliance with applicable regulatory requirements and the International Conference on Harmonization Guidelines on Good Clinical Practice.

Yours sincerely

Elizabeth Grant AM  
Chair  
Ethics Committee  
18 December 2002

**ACT HEALTH AND COMMUNITY CARE**  
**HUMAN RESEARCH ETHICS COMMITTEE**

**Outcome of Consideration of Protocol**

**Submission No:** ETH.11/02.417

**Date of Approval:** 9 December 2002

**Project Title:**

The Overall cost to the Individual and the Community of Post-Operative Infections in total joint Replacement

**Submitted by:**

Dr Paul Smith

Your project was considered by the ACT Health and Community Care Human Research Ethics Committee and Not approved more information required. Chair may approve study out of session for a period of two years.

Further Action required:

**Review due:** December 2003

**The Ethics Committee require as part of the review process that:**

- At regular periods, and not less frequently than annually, Principal Investigators are to provide reports on matters including:
  - security of records
  - compliance with approved consent procedures and documentation
  - compliance with other approved procedures.
  - as a condition of approval of the protocol, that Investigators report immediately:
    - adverse affects on subjects
    - proposed changes in the protocol
    - unforeseen events that might affect continued ethical acceptability of the project.
- All published reports to carry an acknowledgement stating:
  - approved on 9 December 2002 by the ACT Health and Community Care Human Research Ethics Committee.



MS ELIZABETH GRANT AM, CHAIR

Date: 9 December 2002