APPLICANT'S CHECKLIST

All studies except clinical trials of investigational medicinal products

REC Ref:	
Short Title of Study:	Spiritual Assessment Tools of children in an Paediatric Setting
CI Name:	Rev. Alister Bull
Sponsor:	NHS Greater Glasgow and Clyde Spiritual Care

Please complete this checklist and send it with your application

- Send ONE copy of each document (except where stated)
- ALL accompanying documents must bear version numbers and dates (except where stated)
- When collating please do NOT staple documents as they will need to be photocopied.

Document	Enclosed?	Date	Version	Office use
Covering letter on headed paper	○ Yes ○ No			
NHS REC Application Form, Parts A&B	Mandatory			
NHS REC Application Form, Part C (SSA)	○ Yes ○ No			
Research protocol or project proposal (6 copies)	Mandatory			
Summary C.V. for Chief Investigator (CI)	Mandatory			
Summary C.V. for supervisor (student research)	○ Yes ○ No			
Research participant information sheet (PIS)	○ Yes ○ No			
Research participant consent form	○ Yes ○ No			
Letters of invitation to participants	○ Yes ○ No			
GP/Consultant information sheets or letters	○ Yes ○ No			
Statement of indemnity arrangements	○ Yes ○ No			
Letter from sponsor	○ Yes ○ No			
Letter from statistician	○ Yes ○ No			
Letter from funder	○ Yes ○ No			
Referees' or other scientific critique report	○ Yes ○ No			
Summary, synopsis or diagram (flowchart) of protocol in non–technical language	○ Yes ○ No			
Interview schedules or topic guides for participants	○ Yes ○ No			
Validated questionnaire	○ Yes ○ No			
Non–validated questionnaire	○ Yes ○ No			
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.	○ Yes ○ No			

WELCOME TO THE NHS RESEARCH ETHICS COMMITTEE APPLICATION FORM

An application form specific to your project will be created from the answers you give to the following questions. Please read this guidance carefully before selecting your answers.

1. Is your project an audit or service evaluation?

○ Yes ◉ No

2. Select one research category from the list below:

- ○ Clinical trials of investigational medicinal products (including phase 1 drug development)
- ○ Clinical investigations or other studies of medical devices
- ○ Other clinical trial or clinical investigation
- ◉ Research administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- ○ Research involving qualitative methods only
- ○ Research limited to working with human tissue samples and/or data

If your work does not fit any of these categories, select the option below:

- ○ Other research

2a . Please answer the following questions:

a) Does the study involve the use of any ionising radiation?	○ Yes	◉ No
b) Will you be taking new human tissue samples?	○ Yes	◉ No
c) Will you be using existing human tissue samples?	○ Yes	◉ No

3. Is your research confined to one site?

◉ Yes ○ No

4. Does your research involve work with prisoners?

○ Yes ◉ No

5. Does your research involve adults unable to consent for themselves through physical or mental incapacity?

○ Yes ◉ No

6. Is the study, or any part of the study, being undertaken as an educational project?

◉ Yes ○ No

NHS Research Ethics Committee NHS
Application form for research administering questionnaires/interviews for quantitative analysis or mixed methodology study

This form should be completed by the Chief Investigator, after reading the guidance notes. See glossary for clarification of different terms in the application form.

Short title and version number: (maximum 70 characters – this will be inserted as header on all forms)
Spiritual Assessment Tools of children in an Paediatric Setting

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Yorkhill, Women and Children's Directorate, Glasgow and Clyde

Project reference number from above REC:

Submission date: 24/08/2006

PART A: Introduction

A1. Title of the research

Full title: The use of Spiritual Assessment Tools in the delivery of Spirutal Care by a chaplain with hospitalised school–aged children

Key words: Spiritual, assessment, children, spiritual care, chaplain, hospitalised

A2. Chief Investigator

Title:	Rev.
Forename/Initials:	Alister
Surname:	Bull
Post:	Head of Chaplaincy Services
Qualifications:	Bachelor of Divinity (Hons.), Masters in Theology (Taught)
Organisation:	Women and Children's Directorate
Address:	Yorkhill Site
	Dalnair Streeet
	Glasgow
Post Code:	G3 8SJ
E–mail:	alister.bull@yorkhill.scot.nhs.uk
Telephone:	0141 201 0595
Fax:	

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application

A3. Proposed study dates and duration

Start date: 01/11/2006
End date: 01/11/2011
Duration: Years: 5 ; Months:

A4. Primary purpose of the research: *(Tick as appropriate)*

- ☐ Commercial product development and/or licensing
- ☐ Publicly funded trial or scientific investigation
- ☑ Educational qualification
- ☐ Establishing a database/data storage facility
- ☑ Other

If Other, give details:
The purpose of this research project is to ascertain from qualitative data, how helpful age−appropriate spiritual assessment tools are in the pastoral encounter between a chaplain and the child. There are no spiritual assessment tools used in paediatrics. Therefore, this qualitative research is aimed to provide a spiritual assessment tool that can be used by healthcare chaplains working in an acute paediatric setting.

A6. Does this research require site−specific assessment (SSA)? (Advice can be found in the guidance notes on this topic.)

◉ Yes ○ No

If No, please justify:

If Yes, Part C of the form will need to be completed for each research site and submitted for SSA to the relevant Local Research Ethics Committee. Do not submit Part Cs for other sites until the application has been booked for review and validated by the main Research Ethics Committee.

Management approval to proceed with the research will be required from the R&D Department for each NHS care organisation in which research procedures are undertaken. This applies whether or not the research is exempt from SSA.

PART A: Section 1

A7. What is the principal research question/objective? *(Must be in language comprehensible to a lay person.)*

In what way does a spiritual assessment tool facilitate the chaplain in delivering spiritual care to hospitalised school−aged children?

A8. What are the secondary research questions/objectives? *(If applicable, must be in language comprehensible to a lay person.)*

Does the spiritual assessment tool reveal accurately the spiritual needs of children?
Does the child require more than one spiritual assessment?
Does the spiritual assessment require different formats?
What measures would be needed to be in place for the effective delivery of a spiritual assessment tool?
Who should deliver a spiritual assessment tool?

A9. What is the scientific justification for the research? What is the background? Why is this an area of importance?*(Must be in language comprehensible to a lay person.)*

The justification of this research is threefold. First of all, the effective and accurate use of this tool requres gathered evidence for it to be used correctly by other healthcare chaplains. Secondly, this research enables the rights of the child to be upheld as their views and participation contributes to the spiritual care service offered to children throughout NHS Scotland. Thirdly, there is no research developed on the use of spiritual assessment tools for hospitalised children in the United Kingdom.

This research builds upon research already conducted at Yorkhill entitled, "The spiritual needs of hospitalised children with complex healthcare needs." In this previous research the spiritual needs of children were identified but still left research questions unanswered concerning how these needs can be best met by the chaplain.

The importance of this project is underlined by the fact that no research of this nature has been developed in the United Kingdom. The vulnerability of hospitalised children whose healthcare could be detrimental or beneficial to their future development, their spiritual resolve and purpose in life. This is accentuated by the lack of research work in this crucial area in Child health. Therefore, if spiritual care is to be offered in a relevant way to such children, research into this area will inform how spiritual care can serve and protect the needs of such children.

A10. Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, patient groups or communities in the design of the research.

This section must be completed in language comprehensible to the lay person. It must also be self−standing as it will be replicated in any applications for site−specific assessment on Part C. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

Purpose
The Purpose of this research is to discover directly from children if a spiritual assessment tool provides insight to the spiritual needs of children.

Design
The research would adopt a qualitative research method, using a portfolio of spiritual assessment tools comprising of specially designed story boards and card games. This enables themes to emerge in a non−directive way from the child's participation. The reason why this qualititative research method has been proposed is based on the success of a previous research project conducted at Yorkhill.

Methodology
First of all, the researcher would pilot a simple parental questionnaire that would verify key characteristics of their child's experience of culture and belief to insure the language used with them is inclusive. Secondly, a pilot approach would be used for five cases assessing the effectiveness of the tool to answer the research question and the selection process of the children.

Consent and Research Environment
The procedure surrounding the interview would involve a researcher making an initial visit to a clinical area within the hospital to select a school aged hospitalised child. First of all, reassurances are offered to parents and ward staff that indicate that the interview would not interfere with medical or nursing procedures; nor interrupt social life of the patient, e.g... visiting, education & leisure; nor be held if the child was in acute distress, nor continue if the child became physically or emotionally upset. Secondly, due time would be given to the consent process and an information leaflet would be issued at the point of request for consent providing reassures to the family. Thirdly, the researcher will gain parental and child consent. Fourthly, the researcher would either decide to visit later and interview in a room in the ward or by mutual agreement at the bedside.

Theoretical framework
This qualitative research, based on the grounded theory. Grounded theory "is grounded in reality and provides explanations of events as they occur" and was chosen because it enabled themes to emerge by constant comparison of the data from a difficult subject material (Clamp 1999; Sheldon 1998). This enables the children to share their experience through story pictures and card games, pictures with which they could hopefully relate.

What happens to the research participant?
First of all, the researcher would establish parental insight into their child's belief and cultural understanding through answering a simple parental questionnaire. Secondly, the researcher would explain to the child that their help was needed to tell a story and play a card game. The visual nature of this data would require it to be filmed and an audio record kept. Thirdly, the story board enables the child to participate, using character cards developing the plot with the researcher. Fourthly, the researcher would ask open ended questions that would develop from story material to personal reflection, such as, Who do you think the child will meet in hospital? Who did you meet here and what has been happening to you? Lastly, when the interview was finished and the child returned to the parent, the researcher would transcribe the interview.

A13. Give details of any non–clinical research–related intervention(s) or procedure(s). *(These include interviews, non–clinical observations and use of questionnaires.)*

Additional Intervention	Average number per participant	Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.
Face to Face Interview	1	45	The face to face interview is concurrent with the video recording. The interview is conducted by the researcher in the ward. The researcher is an experienced visitor with children. The interview would be at the bedside or a room on the ward. The level of privacy will be determined by the research participant.
Video Recording	1	45	The video recording is concurrent with the face to face interview
Other Questionnaire	1	15	The questionnaire is to ascertain the parent's view of their child's cultural practices and beliefs prior to research visit. This will be in the ward.

A14. Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews/group discussions, or use of screening tests for drugs)?

(●) Yes ( ) No

If Yes, give details of procedures in place to deal with these issues
It is unlikely that there will be any disadvantages. However, there is the slight possibility that a child might become distressed when telling their story. If this was to happen to a child, the interview would be stopped and the parent or a member of staff would be called immediately to comfort the child.

The Information Sheet should make it clear under what circumstances action may be taken

A18. What is the potential for benefit to research participants?

The potential benefit to the research participant is two−fold. First of all, the views of children are being taken into consideration concerning what is the best way to understand the spiritual needs of children in order to facilitate spiritual care in an acute setting in NHS Scotland. Secondly, the chaplain will be equipped with an age appropriate pastoral tool that enables the healthcare chaplain to support the child. The net result of this is that vulnerable children will receive increased support that will help their healthcare journey.

A19. What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to the researchers themselves? *(if any)*

None

A20. How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited?
Give details for cases and controls separately if appropriate:

(i) Identified
The procedure surrounding the interview would involve a researcher making an initial visit to a clinical area within the hospital to find out if there are any possible research participants that meet the research criteria.

(ii) Approached
Consent would be gained from the patient's consultant prior to the nurse approaching a patient who met the research subject criteria.

(iii) Recruited
First of all, reassurances are offered to parents and ward staff that indicate that the interview would not interfere with medical or nursing procedures; nor interrupt the social life of the patient, e.g. visiting, education & leisure; nor be held if the child was in acute distress, nor continue if the child became physically or emotionally upset. Secondly, due time would be given to the consent process and an information leaflet would be issued at the point of request for consent providing reassures to the family. Thirdly, the researcher will gain parental and child consent. Fourthly, the researcher would either decide to visit later and interview in a room in the ward or by mutual agreement at the bedside.

A21. Where research participants will be recruited via advertisement, give specific details.

☐ Not Applicable

Recruited during patient's stay at Yorkhill site or information displayed in Yorkhill

If applicable, enclose a copy of the advertisement/radio script/website/video for television (with a version number and date).

A22. What are the principal inclusion criteria? *(Please justify)*

The subjects would be hospitalised school−aged children, ideally between ages 6 – 13, who may either have chronic conditions, for example, cardiac problems, cancer, bone−disorders, or long−term difficulties as a result of physical trauma. The size of the sample would be twenty, selected in a convenient manner from the above conditions. They would be at an age level that would work well with the technique. They would be able to see and speak English. The sample would be inclusive of patients of all faiths or none.

A23. What are the principal exclusion criteria? *(Please justify)*

The exclusion criteria are:−
1. children outside of the age range of 6 – 13.
2. Children visually impaired
3. Children who do not have English as their first language.

This pilot project is being developed in English and will be developed later for other languages.

All these are based on the age appropriateness of the spiritual assessment tool, the visual nature of the assessment tool and a clear understanding to express themselves

A24. Will the participants be from any of the following groups? *(Tick as appropriate)*

- [x] Children under 16
- [ ] Adults with learning disabilities
- [ ] Adults who are unconscious or very severely ill
- [ ] Adults who have a terminal illness
- [ ] Adults in emergency situations
- [ ] Adults with mental illness (particularly if detained under Mental Health Legislation)
- [ ] Adults with dementia
- [ ] Prisoners
- [ ] Young Offenders
- [ ] Adults in Scotland who are unable to consent for themselves
- [ ] Healthy Volunteers
- [ ] Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students
- [ ] Other vulnerable groups

Justify their inclusion.

Children – This is the age range of the patients that Chaplaincy offer spiritual care and for which the spiritual assessment toll would be used.

A26. Will informed consent be obtained from the research participants?

(•) Yes ( ) No

If Yes, give details of who will take consent and how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos, interactive material.

If participants are to be recruited from any of the potentially vulnerable groups listed in A24, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

If consent is not to be obtained, please explain why not.

First of all, reassurances are offered to parents and ward staff that indicate that the interview would not interfere with medical or nursing procedures; nor interrupt social life of the patient, e.g. visiting, education & leisure; nor be held if the child was in acute distress, nor continue if the child became physically or emotionally upset. Secondly, a minimum of 24 hours would be given to the consent process and an information leaflet would be issued at the point of request for consent providing reassures to the family. The consent process would involve the parent seeing the spiritual assessment tools used by the researcher to determine whether or not the child can see them. (Samples of the Spiritual assessment tools are enclosed) Thirdly, the researcher will gain parental and child consent. Fourthly, the researcher would either decide to visit later and interview in a room in the ward or by mutual agreement at the bedside. Fifthly, if the parent or child would appreciate advice from someone, i.e. a religious leader, from their own faith, the Chaplaincy department will facilitate the contact.

Copies of the written information and all other explanatory material should accompany this application.

A27. Will a signed record of consent be obtained?

◉ Yes ○ No

If Yes, attach a copy of the information sheet to be used, with a version number and date.

A28. How long will the participant have to decide whether to take part in the research?

A minimum of 24 hours would be given to the consent process and an information leaflet would be issued at the point of request for consent providing reassures to the family and patient.

A29. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)*

There are no arrangements for participants who might not adequately understand verbal explanations or written information in English or who have special communication needs. The spiritual assessment tool is initially being developed in English with the future possibility of being used in other languages.

A33. Will individual research participants receive any payments for taking part in this research?

○ Yes ◉ No

A34. Will individual research participants receive *reimbursement of expenses* or any other *incentives or benefits* for taking part in this research?

○ Yes ◉ No

A35. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for *negligent* harm?

Insurance is provided by the NHS CNORIS Insurance scheme

Please forward copies of the relevant documents.

A36. What arrangements have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, participants for *non–negligent* harm?

No arrangements are made

Please forward copies of the relevant documents.

A37. How is it intended the results of the study will be reported and disseminated?*(Tick as appropriate)*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☑ Other publication
- ☑ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

- [x] Written feedback to research participants
- [ ] Presentation to participants or relevant community groups
- [ ] Other/none e.g. Cochrane Review, University Library

A38. How will the results of research be made available to research participants and communities from which they are drawn?

1. Written results will be sent to the participants
2. A report will be submitted to forums through Public Involvement and Patient Focus forums , e.g Family Council

A39. Will the research involve any of the following activities at any stage (including identification of potential research participants)? *(Tick as appropriate)*

- [ ] Examination of medical records by those outside the NHS, or within the NHS by those who would not normally have access
- [ ] Electronic transfer by magnetic or optical media, e−mail or computer networks
- [x] Sharing of data with other organisations
- [ ] Export of data outside the European Union
- [x] Use of personal addresses, postcodes, faxes, e−mails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [x] Manual files including X−rays
  - [ ] NHS computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [x] Private company computers
  - [x] Laptop computers

Further details:
1. The laptop computer will be purchased from project funds for the sole purpose to store data independently.
2. Manual files will be stored in a lockable file cabinet in the chaplaincy office at Yorkhill.
3. Personal details of the patient such as address and postcode will be stored in order to pass on results.
4. Information will be shared with academic supervisor, employed by the University of Glasgow.

A40. What measures have been put in place to ensure confidentiality of personal data? Give details of whether any encryption or other anonymisation procedures have been used and at what stage:

The study would work in compliance with the Data Protection Act 1998, in regards to secure storage and identification of the subject through a study number. The data would be anonomized and a study number would refer to the child at the point of transcription.

A41. Where will the analysis of the data from the study take place and by whom will it be undertaken?

The analysis of the data will take place in the work place office and only anonymised data will be worked on from the home of Rev. Alister Bull on a laptop purchased specifcally for this research project.

A42. Who will have control of and act as the custodian for the data generated by the study?

Rev. Alister Bull

A43. Who will have access to the data generated by the study?

1. Researcher – Rev. Alister Bull
2. Supervisor – Dr. Heather Walton

A44. For how long will data from the study be stored?

10 Years Months

Give details of where they will be stored, who will have access and the custodial arrangements for the data:

A45–1. How has the scientific quality of the research been assessed?*(Tick as appropriate)*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi–centre research group
- ☑ Internal review (e.g. involving colleagues, academic supervisor)
- ☐ None external to the investigator
- ☐ Other, e.g. methodological guidelines *(give details below)*

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

If you are in possession of any referees' comments or other scientific critique reports relevant to the proposed research, these must be enclosed with the application.

A45–2. Has the protocol submitted with this application been the subject of review by a statistician independent of the research team?*(Select one of the following)*

- ○ Yes – copy of review enclosed
- ○ Yes – details of review available from the following individual or organisation (give contact details below)
- ◉ No – justify below

This project is a qualitative study working with small numbers.

A48. What is the primary outcome measure for the study?

Does a spiritual assessment tool provide the insights of the spiritual needs of children to facilitate the spiritual care offered by a healthcare chaplain?

A49. What are the secondary outcome measures?*(if any)*

What does the spiritual care assessment tool tell us about the child?

A50. How many participants will be recruited?
If there is more than one group, state how many participants will be recruited in each group. For international studies, say how many participants will be recruited in the UK and in total.

20

A51. How was the number of participants decided upon?

The decision for the number is pragamatic due to the nature of the conditions of participants who are recruited from. The number would allow for emerging themes to arise for the researcher to code and develop.

If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

A52. Will participants be allocated to groups at random?

◉ Yes ○ No

If yes, give details of the intended method of randomisation:
The participants will recruited in a convenient manner

A53. Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

First of all, there would be analysis of the material by the researcher through a qualitative software package, e.g. Nvivo. This would entail identifying in code the spiritual needs of children identified through the spiritual assessment tool used with the child. Secondly, the analysis will use three factors in collating the recurring themes: How the spiritual assessment tool aided the child in sharing their spiritual needs such as their feelings, views, ideas and behaviour; how did the chaplain respond and used the spiritual assessment tool during the pastoral encounter. Thirdly, the paper would be written by myself with consultation with my supervisors and steering group.

A54. Where will the research take place?*(Tick as appropriate)*

☑ UK
☐ Other states in European Union
☐ Other countries in European Economic Area
☐ Other

If Other, give details:

A55. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK, the European Union or the European Economic Area?

○ Yes ◉ No

A56. In how many and what type of host organisations (NHS or other) in the UK is it intended the proposed study will take place?

Indicate the type of organisation by ticking the box and give approximate numbers if known:

	Number of organisations
☑ Acute teaching NHS Trusts	1
☐ Acute NHS Trusts	
☐ NHS Primary Care Trusts or Local Health Boards in Wales	
☐ NHS Trusts providing mental healthcare	
☐ NHS Health Boards in Scotland	
☐ HPSS Trusts in Northern Ireland	
☐ GP Practices	
☐ NHS Care Trusts	
☐ Social care organisations	
☐ Prisons	
☐ Independent hospitals	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	

Other:

A57. What arrangements are in place for monitoring and auditing the conduct of the research?

The research will be monitored and audited by my Phd. supervisor, Dr. Heather Walton from the University of Glasgow, on a regualr basis.

Will a data monitoring committee be convened?

○ Yes ◉ No

If Yes, details of membership of the data monitoring committee (DMC), its standard operating procedures and summaries of reports of interim analyses to the DMC must be forwarded to the NHS Research Ethics Committee which gives a favourable opinion of the study.

What are the criteria for electively stopping the trial or other research prematurely?

A58. Has external funding for the research been secured?

○ Yes ◉ No

If No, what arrangements are being made to cover any costs of the research? If no external funding is being sought, please say so:

External Funding is being sought from several sources:
1. Greater Glasgow NHS Spiritual Care Department endowment funds
2. College of Healthcare Chaplains – funding avaialble to research projects that have recieved ethics approval
3. University of Glasgow

A59. Has the funder of the research agreed to act as sponsor as set out in the Research Governance Framework?

○ Yes ◉ No

Has the employer of the Chief Investigator agreed to act as sponsor of the research?

◉ Yes ○ No

Sponsor*(must be completed in all cases)*

Name of organisation which will act as sponsor for the research:

NHS Greater Glasgow and Clyde Spiritual Care

Status:

◉ NHS or HPSS care organisation ○ Academic ○ Pharmaceutical industry ○ Medical device industry ○ Other

If Other, please specify:

Address:	Dr. Alison Wood R & D Office Yorkhill Site, Dalnair St., Glasgow	
Post Code:	G3 8SJ	
Telephone:	0141 201 0005	Fax:
E–mail:	alison.wood@yorkhill.scot.nhs.uk	

The responsibilities of the sponsor may be shared between co–sponsors. If this applies, name the lead sponsor for the REC application in this box and enclose a letter giving further details of co–sponsors and their responsibilities.

Sponsor's UK contact point for correspondence with the main REC

Title: Forename/Initials: Surname:

Address:

Post Code:

Telephone: Fax:

E–mail:

A60. Has any responsibility for the research been delegated to a subcontractor?

○ Yes ◉ No

A61. Will individual *researchers* receive any personal payment over and above normal salary for undertaking this research?

○ Yes ◉ No

A62. Will individual *researchers* receive any other benefits or incentives for taking part in this research?

(•) Yes ( ) No

If Yes, indicate how much and on what basis this has been decided:
The researcher will receive the benefit of using the data for studying towards a Phd.

A63. Will the host organisation or the researcher's department(s) or institution(s) receive any payment or benefits in excess of the costs of undertaking the research?

( ) Yes (•) No

A64. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share−holding, personal relationship etc.) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

(•) Yes ( ) No

If Yes, give details:
I am employed by NHS Greater Glasgow and Clyde

A65. Other relevant reference numbers if known*(give details and version numbers as appropriate):*

Applicant's/organisation's own reference number, e.g. R&D (if available):
Sponsor's/protocol number:
Funder's reference number:
International Standard Randomised Controlled Trial Number (ISRCTN):
European Clinical Trials Database (EudraCT) number:
Project website:

A66. Other key investigators/collaborators*(all grant co−applicants should be listed)*

Title:
Forename/Initials:
Surname:
Post:
Qualifications:
Organisation:
Address:
Telephone:
Fax:
Postcode:
E−mail:

PART A: Summary of Ethical Issues

A68. What do you consider to be the main ethical issues which may arise with the proposed study and what steps will be taken to address these?

The main ethical issues in this research project is to ensure that the children feel safe at all times during the interview.

PART A: Student Page

A70. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/degree:
M.Phil leading to a Phd thesis

Name of educational establishment:
Department of Theology and Religious Studies, the Arts Faculty, the University of Glasgow

Name and contact details of educational supervisor:
Dr. Heather Walton
Department of Theology and Religious Studies
No. 4 The Square
University of Glasgow
G12 8QQ
hew@arts.gla.ac.uk
0141 330 5272

A71. Declaration of supervisor

I have read and approved both the research proposal and this application for the ethical review. I undertake to fulfil the responsibilities of a supervisor as set out in the Research Governance Framework for Health and Social Care.

Signature: .....

Print Name: Dr. Heather Walton

Date: 24/08/2006 (dd/mm/yyyy)

A one–page summary of the supervisor's CV should be submitted with the application

PART B: Section 1 – List of proposed research sites

List below all research sites you plan to include in this study. The name of the site is normally the name of the acute NHS Trust, GP practice or other organisation responsible for the care of research participants. In some cases it may be an individual unit, private practice or a consortium – see the guidance notes.

Principal Investigators at other sites should apply to the relevant local Research Ethics Committee for site–specific assessment (SSA) using Part C of the application form. Applications for SSA may be made in parallel with the main application for ethical review (once the main REC has validated the application), or following issue of a favourable ethical opinion. Approval for each site will be issued to you by the main REC following SSA.

1. Name of the research site:

Royal Hospital for Sick Children, Yorkhill, Women and Children's Directorate, Dalnair Street, Glasgow, G3 8SJ

Principal Investigator for the study at this site:

Title: Rev. Forename/Initials: Alister Surname: Bull

Post: Head of Chaplaincy Services
Address: Chaplaincy Centre Office,
1st Flr., Queen Mother's Hospital Dalnair St.
Glasgow
Postcode: G3 8SJ

PART B: Section 7 – Declaration

– The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

– I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

– If the research is approved I undertake to adhere to the study protocol, the terms of the full application of which the main REC has given a favourable opinion and any conditions set out by the main REC in giving its favourable opinion.

– I undertake to seek an ethical opinion from the main REC before implementing substantial amendments to the protocol or to the terms of the full application of which the main REC has given a favourable opinion.

– I undertake to submit annual progress reports setting out the progress of the research.

– I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer.

– I understand that research records/data may be subject to inspection for audit purposes if required in future.

– I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.

– I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application, will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature:	.....
Date:	24/08/2006 (dd/mm/yyyy)
Print Name:	Rev. Alister Bull

PART C: Site–Specific Assessment (SSA)

This form should be completed by the Principal Investigator for each site (see glossary)

Part C should be completed and sent with the relevant enclosures to each NHS Research Ethics Committee, which needs to consider site–specific issues. See guidance notes at the COREC website for further information about the application procedure.

The data in this box is populated from Part A.

Short title and version number:
Spiritual Assessment Tools of children in an Paediatric Setting

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Yorkhill, Women and Children's Directorate, Glasgow and Clyde

Project reference number from above REC:

Name of NHS REC responsible for SSA:
Yorkhill Ethic Committee

SSA reference (for REC office use only):

Questions C1, C4, C5, C6, C7, C8 and C13a correspond to questions A1, A2, A65, A10, A12, A13 and A29 on main application form respectively and will populate automatically:

C1. Title of the research *(Populated from A1)*

Full title:	The use of Spiritual Assessment Tools in the delivery of Spirutal Care by a chaplain with hospitalised school–aged children
Key words:	Spiritual, assessment, children, spiritual care, chaplain, hospitalised

C2. Who is the Principal Investigator for this study at this site?

Title: Rev. Forename/Initials: Alister Surname: Bull

Post:	Head of Chaplaincy Services, Yorkhill
Qualifications:	Bachelor of Divinity (Hons.), Masters in Theology (Taught)
Organisation:	Yorkhill
Address:	1st Floor, Queen Mother's Hospital
	Yorkhill
	Dalnair Street, Galsgow
Post Code:	G3 8SJ
E–mail:	alister.bull@yorkhill.scot.nhs.uk
Telephone:	0141 201 0595
Fax:	

A copy of a current CV (maximum 2 pages of A4) for the Principal Investigator(s) must be submitted with the application

C2–1. Give the names and posts of other investigators or members of the research team responsible to the local Principal Investigator for this site.
Include all staff with a significant research role. If the site is a network or consortium, list all participating investigators below.

Title:
Forename/Initials:
Surname:
Position:
Qualifications:
Role in the research team:

C3. Indicate the number of trials/projects within the organisation that the local Principal Investigator has been involved with in the previous 12 months:

1

How many are still current (active or recruiting)?

C4. Chief Investigator *(Populated from A2)*

Title:	Rev.	Forename/Initials:	Alister	Surname:	Bull
Post:	Head of Chaplaincy Services				
Qualifications:	Bachelor of Divinity (Hons.), Masters in Theology (Taught)				
Organisation:	Women and Children's Directorate				
Address:	Yorkhill Site				
	Dalnair Streeet				
	Glasgow				
Post Code:	G3 8SJ				
E–mail:	alister.bull@yorkhill.scot.nhs.uk				
Telephone:	0141 201 0595				
Fax:					

C5. Other relevant reference numbers if known *(Populated from A65)*

Applicants/organisation's own reference number, e.g. R&D (if available):
Sponsor's/protocol number:
Funder's reference number:
International Standard Randomized Controlled Trial Number (ISRCTN):
European Clinical Trials Database (EudraCT) Number:
Project website:

C6. Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order. Describe any involvement of research participants, patient groups or communities in the design of the research.
(Populated from A10)

Purpose
The Purpose of this research is to discover directly from children if a spiritual assessment tool provides insight to the spiritual needs of children.

Design
The research would adopt a qualitative research method, using a portfolio of spiritual assessment tools comprising of specially designed story boards and card games. This enables themes to emerge in a non−directive way from the child's participation. The reason why this qualititative research method has been proposed is based on the success of a previous research project conducted at Yorkhill.

Methodology
First of all, the researcher would pilot a simple parental questionnaire that would verify key characteristics of their child's experience of culture and belief to insure the language used with them is inclusive. Secondly, a pilot approach would be used for five cases assessing the effectiveness of the tool to answer the research question and the selection process of the children.

Consent and Research Environment
The procedure surrounding the interview would involve a researcher making an initial visit to a clinical area within the hospital to select a school aged hospitalised child. First of all, reassurances are offered to parents and ward staff that indicate that the interview would not interfere with medical or nursing procedures; nor interrupt social life of the patient, e.g... visiting, education & leisure; nor be held if the child was in acute distress, nor continue if the child became physically or emotionally upset. Secondly, due time would be given to the consent process and an information leaflet would be issued at the point of request for consent providing reassures to the family. Thirdly, the researcher will gain parental and child consent. Fourthly, the researcher would either decide to visit later and interview in a room in the ward or by mutual agreement at the bedside.

Theoretical framework
This qualitative research, based on the grounded theory. Grounded theory "is grounded in reality and provides explanations of events as they occur" and was chosen because it enabled themes to emerge by constant comparison of the data from a difficult subject material (Clamp 1999; Sheldon 1998). This enables the children to share their experience through story pictures and card games, pictures with which they could hopefully relate.

What happens to the research participant?
First of all, the researcher would establish parental insight into their child's belief and cultural understanding through answering a simple parental questionnaire. Secondly, the researcher would explain to the child that their help was needed to tell a story and play a card game. The visual nature of this data would require it to be filmed and an audio record kept. Thirdly, the story board enables the child to participate, using character cards developing the plot with the researcher. Fourthly, the researcher would ask open ended questions that would develop from story material to personal reflection, such as, Who do you think the child will meet in hospital? Who did you meet here and what has been happening to you? Lastly, when the interview was finished and the child returned to the parent, the researcher would transcribe the interview.

C8. Give details of any non−clinical research−related intervention(s) or procedure(s).*(These include interviews, non−clinical observations and use of questionnaires.)*
(Populated from A13)

Additional Intervention	**Average number per participant**	**Average time taken** (mins/hours/days)	**Details of additional intervention or procedure, who will undertake it, and what training they have received.**
Face to Face Interview	1	45	The face to face interview is concurrent with the video recording. The interview is conducted by the researcher in the ward. The researcher is an experienced visitor with children. The interview would be at the bedside or a room on the ward. The level of privacy will be determined by the research participant.
Video Recording	1	45	The video recording is concurrent with the face to face interview
Other Questionnaire	1	15	The questionnaire is to ascertain the parent's view of their child's cultural practices and beliefs prior to research visit. This will be in the ward.

C9a. Give the name of the research site for which the PI is responsible: *(Please give the name only. Further details of locations should be given in C10. The name of the site is normally the name of the acute NHS Trust, GP practice or other organisation responsible for the care of research participants. In some cases it may be an individual unit, private practice or consortium – see the guidance notes. Each GP practice is a separate site unless a formal consortium/network is in place.)*

Royal Hospital for Sick Children, Yorkhill

If you wish to add further information about the definition of the site, please do so below:

Acute Paediatrics

C9b. Give the name of the NHS or other organisation with which the PI holds the necessary contract (substantive or honorary) to undertake the research at this site:

Greater Glasgow and Clyde

C9c. For NHS sites, give the name and contact details of the Research Governance contact for the research site at the care organisation or consortium:

Title:	Dr	
Forename/Initials:	Alison	
Surname:	Wood	
Address:	R& D Office	
	RHSC, Dalnair St., Glassgow	Telephone: 0141 201 0005
		Fax:
Postcode:	G3 8SJ	
E–mail:	alison.wood@yorkhill.scot.nhs.uk	

C9d. For non–NHS sites, give details of the arrangements for the management and monitoring of the research at this site:

C10. Specify all locations or departments at which research procedures will be conducted at this site.
Include details of any centres at other NHS care organisations where potential participants may be seen and referred for inclusion in the research at this site. Give details of any research procedures to be carried out off site, for example in participants' homes.

In the wards of the individual patients

C11. How many research participants/samples is it anticipated will be recruited/obtained from this organisation in total?

Twenty

C12a. Give details of who will be responsible for obtaining informed consent locally, their qualifications and relevant expertise and training in obtaining consent for research purposes:

The named Chief Investigator – Rev. Alister Bull

C13a. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.) (Populated from A29)*

There are no arrangements for participants who might not adequately understand verbal explanations or written information in English or who have special communication needs. The spiritual assessment tool is initially being developed in English with the future possibility of being used in other languages.

C13b. What local arrangements have been made to meet these requirements (where applicable)?

☑ Not Applicable

C14. In addition to informing the GP (if required), what arrangements have been made to inform those responsible for the care of the research participants in the host care organisation of their involvement in the research?

The consent from consultants will be obtained first prior to approaching a potential participant. Therefore, before there was any contact with a family the researcher would speak to the patient's own clinician to seek with their agreement before any participation and liaison with the consultant or a member of nursing staff. This can be formalised by a written letter to the consultant.

C15. Are the facilities and staffing available locally adequate to perform any necessary procedures or interventions required for the study, and to deal with any unforeseen consequences of these?*(This should include consideration of procedures and interventions in both control and intervention arms of a study.)*

◉ Yes ○ No

If Yes, give the information necessary to justify your answer. If No, indicate what arrangements are being made to deal with the situation:

C16a. Give brief details of a contact point where participants may obtain further information about the study.

Rev. Alister Bull
Head of Chaplaincy Services
Yorkhill Site
Women and Children's Directorate
Greater Glasgow Health Board
Page No. 2064
Internal Ext. No. 80595
0141 201 0595
Fax: 0141 201 9276
alister.bull@yorkhill.scot.nhs.uk
Postal Address:
Chaplaincy Centre
1st Floor Queen Mother's Hospital,
Dalnair Street
Glasgow
G3 8SJ

C16b. What is the contact point for potential complaints by research participants?

Kate Colquhoun
Complaints Officer
0141 201 1000

Postal Address:
Chaplaincy Centre
1st Floor Queen Mother's Hospital,
Dalnair Street

Glasgow
G3 8SJ

C16c. Is there a local source where potential participants can obtain independent information about being involved in a research study? *See guidance notes.*

Family Support and Information Centre R&D Office and ward noticeboards

C16d. Please specify the headed paper to be used for the participant information sheet.

NHS Greater Glasgow and Clyde

C17. If any extra support might be required by research participants as a result of their participation, what local arrangements are being made to provide this?

The nature of this research project would not require further local arrangements for support. However, if issues were raised that reqired extra support the researcher would seek counselling support for the research participant when requested.

PART C: Declaration

– The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

– I undertake to abide by the ethical principles underpinning the Declaration of Helsinki and good practice guidelines on proper conduct of research.

– If the research is approved I undertake to adhere to the study protocol, the terms of the full application of which the main REC has given a favourable opinion and any conditions set out by the main REC in giving its favourable opinion.

– I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Controller.

– I understand that research records/data may be subject to inspection for audit purposes if required in future.

– I understand that personal data about me as a researcher in this application will be held by the relevant RECs and their operational managers and that this will be managed according to the principles established in the Data Protection Act.

– I understand that the information contained in this application, any supporting documentation and all correspondence with Research Ethics Committees relating to the application will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to a request under the Acts except where statutory exemptions apply.

Signature of the local Principal Investigator *	.....
Date:	24/08/2006 (dd/mm/yyyy)
Print Name:	Rev. Alister Bull

** The Chief Investigator should sign where s/he is also the local Principal Investigator for this research site.*

***PART C IS NOW COMPLETE AND SHOULD BE SUBMITTED** to the NHS Research Ethics Committee responsible for the site–specific assessment.*