

### APPLICANT'S CHECKLIST

#### All studies except clinical trials of investigational medicinal products

REC Ref:	05/Q0411/113
Short Title of Study:	Family Therapy Outcome and Service Evaluation Questionnaire 01
CI Name:	Dr Julia Bland
Sponsor:	Association of Family therapy

**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	<input type="radio"/> Yes <input type="radio"/> No			
NHS REC Application Form, Parts A&B	Mandatory			
Site-Specific Information Form (for SSA)	<input type="radio"/> Yes <input type="radio"/> No			
Research protocol or project proposal (6 copies)	Mandatory			
Summary C.V. for Chief Investigator (CI)	Mandatory			
Summary C.V. for supervisor (student research)	<input type="radio"/> Yes <input type="radio"/> No			
Research participant information sheet (PIS)	<input type="radio"/> Yes <input type="radio"/> No			
Research participant consent form	<input type="radio"/> Yes <input type="radio"/> No			
Letters of invitation to participants	<input type="radio"/> Yes <input type="radio"/> No			
GP/Consultant information sheets or letters	<input type="radio"/> Yes <input type="radio"/> No			
Statement of indemnity arrangements	<input type="radio"/> Yes <input type="radio"/> No			
Letter from sponsor	<input type="radio"/> Yes <input type="radio"/> No			
Letter from statistician	<input type="radio"/> Yes <input type="radio"/> No			
Letter from funder	<input type="radio"/> Yes <input type="radio"/> No			
Referees' or other scientific critique report	<input type="radio"/> Yes <input type="radio"/> No			
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	<input type="radio"/> Yes <input type="radio"/> No			
Interview schedules or topic guides for participants	<input type="radio"/> Yes <input type="radio"/> No			
Validated questionnaire	<input type="radio"/> Yes <input type="radio"/> No			
Non-validated questionnaire	<input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> Yes <input type="radio"/> 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.

**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  
 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  
 Research tissue bank

**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. Do you plan to include in this research 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** **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)

Family Therapy Outcome and Service Evaluation Questionnaire 01

**Name of NHS Research Ethics Committee to which application for ethical review is being made:**

Charing Cross

**Project reference number from above REC:** 05/Q0411/113

**Submission date:** 02/11/2005

**PART A: Introduction****A1. Title of the research**

**Full title:** Pilot study of the SCORE(Systemic Core Outcome and Routine Evaluation)self-report questionnaire as a measure of outcome and service evaluation in family therapy

**Key words:** Family therapy outcome research, self-report measures of family function, practice research networks.

**A2. Chief Investigator**

**Title:** Dr  
**Forename/Initials:** Julia  
**Surname:** Bland  
**Post:** Consultant Psychiatrist in Psychotherapy  
**Qualifications:** MA, MBBS, MRCPsych  
**Organisation:** South London and Maudsley Trust  
**Work Address:** Department of Psychotherapy  
 Maudsley Hospital  
 Denmark Hill  
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**Telephone:** 0207919238415  
**Fax:** 02079192514  
**Mobile:**

*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:** 01/02/2006  
**End date:** 01/02/2008  
**Duration:** Years: 2 ; 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

Question(s) 5 disabled.

**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, an application for SSA should be made for each research site on the Site-Specific Information Form and submitted to the relevant local Research Ethics Committee. Do not apply for SSA at sites other than the lead site until the main 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 office for each NHS care organisation in which research procedures are undertaken. This applies whether or not the research is exempt from SSA. R&D applications in England, Wales and Scotland should be made using the Site-Specific Information Form.*

**PART A: Section 1****A7. What is the principal research question/objective?** *(Must be in language comprehensible to a lay person.)*

Ethical approval is being sought to enable our group to initiate a pilot study of a questionnaire that is designed to measure family functioning and change following a course of family therapy. The questionnaire specifically asks family members to comment on whether they found family therapy useful as a way of helping them deal with their problems. It therefore provides a subjective measure of service evaluation as well as clinical change.

We are hoping to pilot the measure within other family therapy clinics throughout the UK. To date, we have 15 other family therapy clinics who have expressed an interest in piloting the questionnaire. We have been liaising closely with our colleagues in other sites and have ensured that the pilot has full endorsement from clinical teams and management.

The pilot will involve issuing the questionnaire to all family members (above the age of twelve) who are referred to services for family therapy. Forms will be issued at the beginning and end of therapy. We are aiming to obtain data from a total of 200 families from the various participating centres.

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

As a group, we are responding to the call for more information on the day to day outcomes of family interventions, and have produced a measure that we hope will provide a sensitive and reliable indicator of clinically significant change in family therapy settings, as well as providing valuable feedback from service users on their perceptions of the usefulness or otherwise of their therapy.

The measure is in the form of a brief, pragmatic and clinically based questionnaire that is designed to be completed by family members from 12 years of age upwards, to capture indicators of family functioning that may be sensitive to change over treatment. We are interested to know whether our measure will be sufficiently sensitive to be able to discriminate between families who are dysfunctional and those who are not. The ability of the questionnaire to identify problem areas within families is important not only in the context of beginning a piece of therapeutic work with them, but will be of interest to managers and policy makers who make important decisions regarding the future funding of family therapy services.

We know from clinical experience that many families find benefit from engaging in family therapy and are grateful for the service and we are hoping that the measure will enable clinicians and managers to examine and improve the quality of the care that they provide.

The importance of measuring routine outcomes has been enshrined in the recent government document 'Organising and Delivering Psychological Therapies' (Department of Health, 2004), and forms one of the three key components of practice based evidence (Margison et al, 2000 Barkham, M, 2003). The collection and analysis of such data from everyday practice is commensurate with clinical governance goals to develop and maintain standards of practice (Department of Health 1997).

Measures designed to provide information on family relationships and functioning are not in routine clinical use within the context of family therapy clinics in the UK. This is perhaps due to various problems with applicability in service settings (e.g. excessively lengthy or over-priced questionnaires), or possibly due to a lack of knowledge or general consensus on the most appropriate tools to use. Most of the existing questionnaires that were reviewed were developed in the 1970s and 80s in America. They reflect the dominant theoretical discourse of that time and are culturally biased and therefore not appropriate or practical for use in the UK. In addition, few of the existing measures focus on service evaluation and user-feedback. We hope to produce a measure that will be free for others to photocopy and use within diverse family therapy settings throughout the UK.

This is the context within which our questionnaire was developed. The initiative is supported by the

Association of Family Therapy which is the major training and accreditation organisation for family therapists.

**A10-1. 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.**

*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 the Site-Specific Information Form. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The questionnaire has been developed in the context of a Practice research network (PRN). Essentially, PRNs are composed of a number of collaborating clinicians (usually linked with one or more academic departments) who collect and share data from their every day practice, with the potential to generate large, clinically representative datasets. Our group is composed of: Professor Peter Stratton, Leeds University, Dr Emma Janes, SpR Psychotherapy Maudsley Hospital, London, Dr Julia Bland, Cons. Psychotherapist, Maudsley Hospital, Dr Anne Ward, Cons. Psychotherapist, Maudsley Hospital & Ms Judith Lask, former chair of the Association of Family therapy (AFT), Institute of Psychiatry, London.

A Literature search of the main databases was conducted. The main area of enquiry was of self-report measures (SRMs) of family function. The literature was then hand searched to enable us to obtain as representative a sample as possible. Ten measures were scrutinised by our group and the literature review is attached with this application.

Attention was paid to developments in family therapy theory and practice since the publication of the above-mentioned measures (such as the emergence of reflecting teams, goal-setting, narrative therapies and feminist approaches). A very obvious gap in the reviewed measures was a paucity of items relating to family member's appraisals of change and levels of satisfaction/dissatisfaction with their service. The group then generated questions that were felt to address these particular issues.

In selecting and eliminating questionnaire items, consideration was given to whether they appeared to fulfil any or all of our objectives of measuring: (1) Quality of life in the family, (2) Functionality of relationships in the family, (3) Change from beginning to end of therapy, (4) Need for more family therapy. Such objectives were felt to be necessary to hold in mind in order for the measure to have acceptable face validity to therapists and managers.

#### Consultation stage

The opinions of users of family therapy services have been sought, and initial feedback has been encouraging.

The group compiled a list of colleagues with expertise in family therapy whose professional opinions on the measure were deemed to be essential for it's development. Each colleague was asked to complete the questionnaire with their own family in mind, and to indicate what thoughts came to mind as they read the question as well as what made them answer the way that they did. We also asked them to consider the whole set of questions and to make any further comments that they wished.

It was considered to be important to seek the opinion of non-clinical friends and relatives, and so each member of our group approached three non-clinical friends and asked them to go through the same exercise. In addition, we thought it would be useful at this stage to issue the questionnaire to a friend of a different ethnic background to our own as we hope to produce a measure which is as culturally unbiased as possible.

#### Overview of questionnaire development

Phase 1 (Initial development) Literature review and production of first drafts of SCORE, according to hypothesised domains of family functioning. Consultation with experts, service users and managers. (Done)

Phase 2 (First Pilot phase) Expansion of Questionnaire to 59 items to enable piloting on 200 clinical cases. Piloting will be carried out over several sites to enable the rapid accumulation of the large dataset that is required for factor analysis and to examine the internal consistency of the scale. Data collection at multiple sites is intended to commence by early 2006. Data will be drawn from families who are consecutively referred to participating FT clinics at the beginning and end of their therapy. Data collection ends when 200 cases have been sampled. For the purposes of the first phase statistical analysis, only the responses from

the female head of the household will be examined in the first instance.

Phase 3 (Analysis of results) Statistical analysis of dataset using multivariate factor analysis to determine whether the measure has an underlying factor structure, and the calculation of Cronbach's alpha to determine the internal consistency of the scale. It is envisaged that a greatly refined and shorter (and therefore more clinically pragmatic) measure will emerge as a result of statistical analysis of the data. A qualitative analysis will be carried out on the subset of items that invite a free response from family members. The results of the qualitative analysis will be used to inform further development of the questionnaire.

Phase 4 (Second Pilot Stage) Widespread piloting of the refined measure at multiple family therapy sites throughout the UK, including concurrent administration of other outcome measures. In parallel to data collection on clinical populations, a large dataset in the region of 1000 responses will be generated from a non-clinical population. This will be achieved via telephone interviews conducted on our behalf by a market research firm. This phase is expected to commence in early 2007.

Phase 5 (Further psychometric evaluation). This stage of statistical analysis will examine the instrument's concurrent and divergent validity with other measures, as well as whether 'cut-off' points can be derived that enable discrimination between clinical and non-clinical populations. A smaller pilot to determine test-retest reliability could be performed at this stage.

**Study Participants: recruitment and inclusion/exclusion criteria**

The measure is intended to be piloted on consecutive referrals to the family therapy services that have agreed to become involved in piloting. The questionnaire will be administered to all family members aged 12 years and over who have agreed to take part in the study. The cut off point of twelve was chosen because the language and format of the questionnaire would have to be significantly adjusted for younger children. Versions of the questionnaire will be developed for younger children if the pilot results show that the questionnaire is a valid means of assessing outcome following family therapy.

The pilot is intended to be as inclusive as possible, and this is commensurate with our objective of producing a measure that can be used routinely and applied universally in the myriad settings where family work is being practised.

Following referral, an information sheet will be sent to the family explaining that we are conducting a piece of research into the effectiveness of family therapy which involves family members filling in a short questionnaire at the beginning and end of their therapy. The sheet will be sent to families along with their letter of invitation for a first appointment and will have a 'Frequently Asked Question' format. The sheet will explain that the questionnaire will ask family members to comment on what they feel their particular difficulties are, and what they would most like to change. It will also state that family members will be asked for their consent to participate when they arrive at the clinic, that participation is entirely voluntary and that they can withdraw from participation at any time. It will also state that the information given will be treated as confidential. The information sheet will also explain that because the data being collected will be anonymised, it will not be possible for members of the research team to act on the clinical information. Therefore if filling the questionnaire raises any particular concerns for them, we would advise them to discuss this with their therapist at the start of therapy.

When the family arrives for their first appointment, the aims of the study will be explained by their therapist. It will be explained that participation is voluntary, and that we will require them to sign a consent form if they wish to be included in the study. It will be explained that all information will be treated as confidential, and that coding will ensure there is no way for the families to be identified by any third party. The consent form will contain the above information and will explain that participation in the study is not designed to bestow any direct therapeutic benefit.

#### **A10-2. In which parts of the research have patients, members of the public or service users been involved?**

- As user-researchers
- As members of a research project group
- As advisor to a project
- As members of a departmental or other wider research strategy group
- None of the above

*Please provide brief details if applicable:*

**A10-3. Could the research lead to the development of a new product/process or the generation of intellectual property?**

Yes  No  Not sure

*Question(s) 11-12 disabled.*

**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.
Other Questionnaire			

**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*

The possibility that the questionnaire will raise difficult issues for family members will be raised at the outset, in the information sheet. It will be explained to participants that the researchers are different from their therapists, and that the information that they give will not be easily traced back to them, due to the process of anonymisation of data. Participants are advised that if they find any particular aspect of the questionnaire troubling, that they should raise this with the treating therapist who has given them the questionnaire to fill out. This should ensure that any difficult thoughts or feelings that arise in the context of completing the questionnaire will have a chance to be explored in a sensitive and caring manner by the treating therapist.

The possibility exists that the disclosure of a criminal offence (such as alleged and previously undisclosed sexual, physical or emotional abuse of a family member) could take place. In the first instance, this would be explored in a sensitive and empathic manner by the therapist. The family would be made aware of our duty to pass on this information to social services for a full investigation, if it is considered that the family member or other members of society could remain at risk of harm (this obligation is also clearly stated on the information sheet). The treating therapist would endeavour to seek the families consent to disclose this information to the relevant authorities. The therapist in question should seek the advice of their professional colleagues and supervisors before acting on such information, and should do so in accordance with local protocol and professional guidelines. If necessary the local Caldicott Guardian could be consulted for advice in cases where family members do not wish to co-operate with such disclosure.

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

**A15. What is the expected total duration of participation in the study for each participant?**

The questionnaires are designed to be administered to each family member at the beginning and end of their family therapy. Different families require different lengths of time in family therapy clinics. For example, in the Maudsley family therapy clinic, the majority of families complete their therapy within a six month time frame. Appointment are spaced at three-weekly to monthly intervals during this time, with sessions titrated according to clinical need.

*Question(s) 16-17 disabled.*

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

It is not the primary intention for the questionnaire to provide direct benefit, however it is envisaged that the answers that are given may be explored further as part of the therapeutic process. Incorporating the questionnaire into the therapy in this way could be potentially beneficial for the respondents.

*Question(s) 19 disabled.*

**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:*

The measure is intended to be piloted on consecutive referrals to the family therapy services that are involved.

(1) Following referral, a letter will be sent to the family explaining that we are conducting a piece of research into the effectiveness of family therapy which involves family members filling in a short questionnaire at the beginning and end of their therapy. The letter will explain that questions will ask family members to comment on what they feel their particular difficulties are, and what they would most like to change. The letter will state that family members will be asked for their consent to participate when they arrive at the clinic, that participation is entirely voluntary and that they can withdraw from participation at any time without this affecting their treatment. It will also state that the information given will be treated as confidential.

(2) When the family arrives for their first appointment, the aims of the study will be explained by their therapist. It will be explained that participation is voluntary, and that we will require them to sign a consent form if they wish to be included in the study. It will be explained that all information will be treated as confidential, and that coding will ensure there is no way for the families to be identified by any third party.

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

Not Applicable

*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)**

All family members attending for family therapy aged 12 and above. The cut off point of twelve has been chosen because the language and format of the questionnaire would have to be adjusted for younger children. It is envisaged that versions of the questionnaire will be devised for younger children if the pilot results show that the questionnaire is useful.

The pilot is intended to be as inclusive as possible, and this is commensurate with our objective of producing a measure that can be used routinely and applied universally in the myriad settings where family work is being practised.

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

As outlined above, we are excluding children under the age of twelve. The language and structure of the questionnaire would need to be significantly altered to sample the views of younger children. If the pilot is successful in showing the measure to be effective then we will begin work to address the issue of younger child respondents.

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

- 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.*

The measure is designed to provide us with family member's perspectives on their particular problems and it is therefore essential to include the views of children. Families who attend family therapy clinics within child and adolescent and adult mental health services have a wide range of difficulties and generally have complex and highly individual needs. It is quite possible, for example that a family with a member who has a terminal illness could be referred for treatment. This member may or may not attend with other members of the family, and their illness may or may not become a substantial focus in therapy.

It would be conceivable for persons from many of the groups mentioned above to be represented in the pilot (with the exception of unconscious or severely physically ill patients), but this would be a reflection of the diversity of patients that are referred for family work and our questionnaire is not intended to be used exclusively with any particular group of people or problem.

- No participants from any of the above groups

*Question(s) 24 1–5–25 disabled.*

**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.*

When the referral letter is received by the department, a letter will be sent to the family explaining the aims and purpose of the pilot study. It will be explained in the letter that participation is entirely voluntary and requires written consent, which will be asked for by the Therapist when they arrive for their first appointment.

When the family arrive for their first appointment, the therapist will explain the purpose of the study and ask family members to take a minute to study the consent form. It will be explained that participation is entirely voluntary and can be withdrawn at any time. Families will also be reassured that non-participation will not jeopardise their therapy, and that participation is not designed to bestow any direct therapeutic benefit.

*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?**

At least one week (this is likely to be the minimum time frame between receipt and processing of referral and the first appointment).

**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.)**

Family therapy clinics routinely use interpreters when and where necessary, if requested by families to aid communication. The language of the questionnaire has been designed to be as simple as possible, and questions could be directly asked by the therapist (or interpreter) in cases where people have reading difficulties for whatever reason.

*Question(s) 30 disabled.*

**A30–1. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.**

- The participant would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained. Any identifiable data or tissue would be anonymised or disposed of.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.

*Further details:*

*Question(s) 31–32b disabled.*

**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. Insurance/indemnity to meet potential legal liabilities**

*Note: References in this question to NHS indemnity schemes include equivalent schemes provided by Health and Personal Social Services (HPSS) in Northern Ireland.*

**A35-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?**

*Note: Where a NHS organisation has agreed to act as the sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, describe the arrangements and provide evidence.*

- NHS indemnity scheme will apply
- Other insurance or indemnity arrangements will apply (give details below)

The pilot will be carried out in family therapy clinics within NHS trusts and therefore covered by professional and trust indemnity.

Please enclose a copy of relevant documents.

**A35-2. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?**

*Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), describe the arrangements and provide evidence.*

- NHS indemnity scheme will apply to all protocol authors
- Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

**A35-3. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators and, where applicable, Site Management Organisations, arising from harm to participants in the conduct of the research?**

*Note: Where the participants are NHS patients, indemnity is provided through NHS schemes or through professional indemnity. Indicate if this applies to the whole of the study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, describe the arrangements which will be made at these sites and provide evidence.*

- All participants will be recruited at NHS sites and NHS indemnity scheme or professional indemnity will apply
- Research includes non-NHS sites (give details of insurance/indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

Question(s) 36 disabled.

**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
- 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?**

Participants will be invited to examine the results of the study by visiting the web site of the Association of Family therapy, where a lay readable-version of our results will be published.

**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
- Sharing of data with other organisations
- Export of data outside the European Union
- Use of personal addresses, postcodes, faxes, e-mails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
  - Manual files including X-rays
  - NHS computers
  - Home or other personal computers
  - University computers
  - Private company computers
  - Laptop computers

*Further details:*

Direct quotations from respondents are likely to be used in the qualitative analysis of the questionnaire (ie. what different thoughts, meanings and associations were stimulated by particular questions). However, these comments would be completely anonymised if published.

No personal data will be stored on an NHS computer because the data will be anonymised using codes before entry (see below).

**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 University of Leeds has a sophisticated system for data storage and Professor Peter Stratton has volunteered to be the custodian of the data.

Each participating clinic will have a codebook which will be used to assign identification codes to each family member. The identification codes will bear no resemblance to the patient's NHS code. There will be a sheet of paper that maps the participating families to their assigned codes. This will be kept at the participating clinic under lock and key, and under the custodianship of the local collaborator at each site.

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

Professor Peter Stratton, of the Leeds Institute of Psychological Sciences (Leeds University) has agreed to collate and analyse the data.

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

Professor Peter Stratton will act as custodian of the data.

**A43. Who will have access to research participants' or potential research participants' health records or other personal information? Where access is by individuals outside the normal clinical team, justify and say whether consent will be sought.**

members of the research team:  
 Prof. Peter Stratton  
 Dr Julia Bland,  
 Dr Anne Ward,  
 Dr Emma Janes,  
 Ms Judith Lask.

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

5 Years 0 Months

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

The data will be stored for up to five years in a Leeds University computer. Professor Stratton will continue as chief custodian of the data, but it will be available to members of the research team.

**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
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

*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:*

The protocol has been subject to peer review as part of the process of obtaining South London & Maudsley Trust Research and Development approval.

**A45-2. How have the statistical aspects of the research been reviewed? (Tick as appropriate)**

- Review by independent statistician commissioned by funder or sponsor
- Other review by independent statistician
- Review by company statistician
- Review by a statistician within the Chief Investigator's institution
- Review by a statistician within the research team or multi-centre group
- Review by educational supervisor
- Other review by individual with relevant statistical expertise

*In all cases give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.*

Title:            Forename/Initials:            Surname:

Department:

Institution:

Work Address:

Postcode:

Telephone:

Fax:

Mobile:

E-mail:

*Please enclose a copy of any available comments or reports from a statistician.*

*Question(s) 46–47 disabled.*

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

Difference in questionnaire scores pre and post-family therapy.

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

- (1) Relationship between self-evaluation of difference by family member and that demonstrated by the questionnaire.
- (2) The relationship of the therapist's perception of difference to that demonstrated by the questionnaire.
- (3) Whether family members find filling in the questionnaire acceptable. Linked with this is the importance of ascertaining the response rate.
- (4) Ascertaining which items on the questionnaire are the most sensitive to change.
- (5) Analysis of Qualitative data (i.e. questions which invite a free response from the respondent, for example a few words or lines describing their family) will be important and will shape revision of the questionnaire.
- (6) Assessing the 'internal consistency' of the questionnaire.

**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.*

We are hoping to recruit 200 families in total. We will have a 'stop rule', where data collection must occur within a maximum period of 2 years, and will cease if 200 families are recruited before this time, or when the two years are up.

**A51. How was the number of participants decided upon?**

We sought statistical advice on the protocol from Dr Sabine Landau, who explained that we required at least ten questions for each of the 5 hypothesised domains, and that we would ideally require around 150 complete responses (and certainly no less than 30) in order to proceed to do a factor analysis. A figure of 200 families was chosen to account for 'drop out' and missing information (for example, a family may consent to completing the questionnaire at the beginning of therapy, but may for whatever reason elect not to do so at the end). The factor analysis is designed to enable us to ascertain whether there is an underlying dimensional structure (as we have hypothesised). It will also enable us to determine the internal consistency of the scale and refine the measure for further piloting.

*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

**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.**

It is hypothesised that the measure will provide information on five dimensions of family functioning. We have devised 11 questions that are relevant for each subscale; thus the main body of the questionnaire comprises 55 questions that assess quantitative aspects of family functioning. The remaining 4 items are designed to produce qualitative data on the respondent's personal view of the family's difficulties, what they would like to see change and whether they found family therapy a useful means of addressing their issues. These last questions will be analysed using a combination of quantitative and qualitative techniques.

An empirical study will be carried out in a clinical setting. The responses will then be subjected to a Factor Analysis (to show whether the subscales exist) and the internal consistency of the 55 item scale can be assessed by calculating Cronbach's Alpha (which shows that correlations within subscales are greater than correlations between subscales).

The qualitative data will be subjected to qualitative analysis, using a conceptual analysis and grounded theory framework.

**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:*

Phase one piloting is to take place within a number of Family Therapy Clinics across the UK. To date, 15 centres have expressed an interest in helping us pilot and develop the measure; in effect we are forming a 'practitioner research network' and in this way hope to achieve the desired number of cases within the time period of the study

**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
<input type="checkbox"/> Acute teaching NHS Trusts	
<input type="checkbox"/> Acute NHS Trusts	
<input type="checkbox"/> NHS Primary Care Trusts or Local Health Boards in Wales	
<input checked="" type="checkbox"/> NHS Trusts providing mental healthcare	15
<input type="checkbox"/> NHS Health Boards in Scotland	
<input type="checkbox"/> HPSS Trusts in Northern Ireland	
<input type="checkbox"/> GP Practices	
<input type="checkbox"/> NHS Care Trusts	
<input type="checkbox"/> Social care organisations	
<input type="checkbox"/> Prisons	
<input type="checkbox"/> Independent hospitals	
<input type="checkbox"/> Educational establishments	
<input type="checkbox"/> Independent research units	
<input type="checkbox"/> Other (give details)	

*Other:*

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

The members of the research team will be regularly updated by Professor Stratton

*Question(s) 57a disabled.*

**A58. Has external funding for the research been secured?**

Yes  No

**If Yes, give details of funding organisation(s) and amount secured and duration:**

Organisation: Association of Family Therapy (pay Prof Stratton 10 days/year)  
 Address: AFT 7, Executive suite, St James Court, Wilder  
 –spool causeway, Warrington, Cheshire  
 Post Code: WA4 6PS  
 UK contact: Sue Kennedy (AFT Executive Officer)  
 Telephone: 0192544414  
 Fax:  
 Mobile:  
 E-mail: s.kennedy@aft.org.uk  
 Amount (£): 10days/yr Duration: 36 Months

**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

**Lead sponsor** (*must be completed in all cases*)

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

Association of Family therapy

Status:

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

*If Other, please specify:*

Address: AFT 7, Executive suite, St James Court, Wilderspool causeway, Warrington,  
Cheshire

Post Code: WA4 6PS

Telephone: 01925444414

Fax:

Mobile:

E-mail: s.kennedy@aft.org.uk

**Sponsor's UK contact point for correspondence with the main REC** (*must be completed in all cases*)

Title: Ms

Forename/Initials: Barbara

Surname: Warner

Work Address: AFT 7, Executive suite, St James Court, Wilderspool causeway, Warrington,  
Cheshire

Post Code: WA4 6PS

Telephone: 01925444414

Fax:

Mobile:

E-mail: barwara@aol.com (home phone is 0288786505)

**Co-sponsors**

Are there any co-sponsors for this research?

Yes  No

**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

**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 organisations sponsoring or funding the research that may give rise to a possible conflict of interest?**

Yes  No

**A65. Research reference numbers:** *(give any relevant references for your study):*

Applicant's/organisation's own reference number, e.g. R&D (if available): Rec ref no:05/Q0411/113

Sponsor's/protocol number:

Funder's reference number:

Project website:

**A66. Other key investigators/collaborators** *(all grant co-applicants or protocol co-authors should be listed)*

Title: Dr

Forename/Initials: Anne

Surname: Ward

Post:

Consultant Psychiatrist in Psychotherapy

Qualifications:

MD, MRCPsych, MRCP, MBBCh, BA

Organisation:

South London and Maudsley Trust

Work Address:

Maudsley Hospital, Denmark Hill, London

Postcode: SE5 8AZ  
 Telephone: 0207919238415  
 Fax: 02079192514  
 Mobile:  
 E-mail: Anne.Ward@slam.nhs.uk

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Title: Professor of Family Therapy      Forename/Initials: Peter      Surname: Statton

Post: Director of Leeds Family Therapy & Research Centre  
 Qualifications: BSc, PhD, Dip Psychother, FBPS, AcSS  
 Organisation: Centre for Research, Kinship and Childhood  
 Work Address: School of Psychology, University of  
 Leeds, Leeds

Postcode: LS2 9JJ  
 Telephone: 01133435708  
 Fax:  
 Mobile:  
 E-mail: peters@psychology.leeds.ac.uk

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Title: Ms      Forename/Initials: Judith      Surname: Lask

Post: Course Organiser for Institute of Psychiatry MSc in Systemic Therapy  
 Qualifications: BA, MSc, CQSW, ADFT  
 Organisation: Institute of Psychiatry  
 Work Address: Decrespigny Park

Postcode: SE5  
 Telephone: 02078365454  
 Fax:  
 Mobile:  
 E-mail: JLask@iop.kcl.ac.uk

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Title: Dr      Forename/Initials: Emma S      Surname: Janes

Post: Specialist Registrar in Psychotherapy  
 Qualifications: MBBChBaO(Hons), BSCPath(Hons), DMH, MRCPsych  
 Organisation: Maudsley Hospital  
 Work Address: Department of Psychotherapy,  
 Denmark Hill  
 London

Postcode: SE5 8AZ  
 Telephone: 07879632399  
 Fax: 02079192514  
 Mobile:  
 E-mail: Emma.Janes@slam.nhs.uk

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*Question(s) 67 disabled.*

**PART A: Summary of Ethical Issues**

**A68. What are the main ethical issues with the research?**

*Summarise the main issues from the participant's point of view, and say how you propose to address them.*

(1) Beneficence:

Although the questionnaire is not primarily designed to confer any direct clinical benefit, it is probable (and indeed desirable) that the questions will raise important issues that need to be explored in therapy. It is conceivable that families will appreciate our efforts to learn from their experiences in therapy, in order that we may continue to improve on the services that we provide. In wider terms, it is hoped that the introduction of such a measure in family therapy clinics will be useful in terms of helping family therapists justify their existence, and to secure funding for family therapy which clinicians feel is a resource that is valued by patients.

(2) Non-maleficence:

The questions are designed to probe potentially sensitive areas family discord, and therefore have the potential to provoke thoughts and feelings which might be hard to bear. However, thoughtful and sensitive inquiry into difficult topics forms part of the fabric of family therapy. The fact that painful emotions are often brought to the surface is generally thought to be therapeutic, if they are able to be talked about, explored and safely contained within the therapeutic milieu.

Families do not generally present to family therapy clinics unless they have some degree of insight into the fact that they are suffering and are seeking help to deal with their difficulties.

(3) Autonomy:

The rights of individuals to refuse to participate or withdraw consent is respected. The purposes of the research will be fully explained to all potential participants, in such a way as to enable them to make a properly informed choice about whether or not they wish to participate. Because we are including children from 12 years upwards, if a child wishes to participate the questionnaire would not be administered to them without the express and written consent of their parents.

(4) Utilitarian Principles:

There is a pressing need for an acceptable, reliable and valid marker of family therapy outcome across the UK, and numerous stakeholders are involved. Many clinicians have expressed an interest in becoming involved with our work to pilot this measure. Because of this need, and the great interest that our initial presentations have generated, we are very concerned that we take the time to 'do it right', and not to 'cut corners' in the face of an enthusiastic pressure to fill the vacuum as quickly as possible. We have no wish to jeopardise the future direction of practice-based research in family therapy by conducting an ill thought out piece of research.

*Indicate any issues on which you would welcome advice from the ethics committee.*

*Question(s) 69-71 disabled.*

**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 the Site-Specific Information 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:****Principal Investigator for the study at this site:**

Title:

Forename/Initials:

Surname:

Post:

Work Address:

Postcode:

**PART B: Section 7 – Declarations****Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. 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.
4. 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.
5. I undertake to submit annual progress reports setting out the progress of the research.
6. 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.
7. I understand that research records/data may be subject to inspection for audit purposes if required in future.
8. 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.
9. 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 held by the main REC until at least 3 years after the end of the study.
  - May be disclosed to the operational managers or the appointing body for the REC in order to check that the application has been processed correctly or to investigate any complaint.
  - May be seen by auditors appointed by the National Research Ethics Service to undertake accreditation of the REC.
  - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

*Optional – please tick as appropriate:*

- I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature: .....

Print Name:

Date: (dd/mm/yyyy)

**Declaration by the sponsor's representative**

*If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the sponsor nominated to take the lead for the REC application.*

I confirm that: *(tick as appropriate)*

- This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
- An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.\*
- Any necessary indemnity or insurance arrangements, as described in question A35, will be in place before this research starts.
- Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
- Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
- The duties of sponsors set out in the NHS Research Governance Framework for Health and Social Care will be undertaken in relation to this research.\*\*

\* Not applicable to student research (except doctoral research).

\*\* Not applicable to research outside the scope of the Research Governance Framework.

Signature: .....

Print Name:

Post:

Organisation:

Date: (dd/mm/yyyy)

### Site-Specific Information Form

**Does this application relate to a research site for which the NHS (or HPSS in Northern Ireland) is responsible or to a non-NHS research site?**

- NHS site  
 Non-NHS site

*This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.*

**In which country is the research site located?**

- England  
 Wales  
 Scotland  
 Northern Ireland

*The data in this box is populated from Part A:*

Short title and version number:  
 Family Therapy Outcome and Service Evaluation Questionnaire 01

Name of NHS Research Ethics Committee to which application for ethical review is being made:  
 Charing Cross

Project reference number from above REC: 05/Q0411/113

Name of NHS REC responsible for SSA:

SSA reference (for REC office use only)

**1. Title of the research** *(populated from A1)*

Full title: Pilot study of the SCORE(Systemic Core Outcome and Routine Evaluation)self-report questionnaire as a measure of outcome and service evaluation in family therapy  
 Key words: Family therapy outcome research, self-report measures of family function, practice research networks.

**2. Name of Chief Investigator** *(populated from A2)*

Title: Forename/Initials: Surname:  
 Dr Julia Bland

**3. Name of organisation acting as lead sponsor for the study** *(populated from A59)*

Association of Family therapy

**4. Research reference numbers if known** *(populated from A65)*

Applicant's/organisation's own reference number, e.g. R&amp;D:

Rec ref no:05/Q0411/113

Sponsor's/protocol number:

Funder's reference number:

Project website:

Declarations