SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST

RESEARCH DEPARTMENT

GUIDANCE FOR WRITING PROTOCOLS FOR

THE INDEPENDENT SCIENTIFIC REVIEW PROCESS

These notes are intended to assist the researcher in writing a sound protocol.

Experience shows that some of the more common reasons why applications are unsuccessful include:

- the absence of a clearly articulated question
- unfocused methodology
- lack of adequate information about sample size, power calculations, recruitment rates
- lack of involvement of appropriate experts in the design of the project
- unrealistic timescales and costing

We suggest you obtain expert advice as early as possible in areas outside your own field of expertise. Advice on study design, power calculations and data analysis is available from the Statistics Clinic held at the Research Department.

You may find collaborators from other disciplines helpful in strengthening both the proposal and the research team. Approach your Research Lead for advice.

Specific additional requirements for studies involving an investigational medicinal product (IMP) are detailed in shaded boxes. Clinical Trials of Investigational Medicinal Products (CTIMPs) must be conducted in accordance with the UK Clinical Trials Regulations 2004 and subsequent amendments. The protocol for a CTIMP must reference these regulations and must be in compliance with these regulations. In addition it is important for all studies, but particularly for IMP studies, that measures are in place in the protocol to reduce risk in every area possible. It is helpful if the protocol is explicit in identifying and explaining measures included to mitigate against risk.

Please also refer to Standard Operating Procedures (SOPs) available from the STH Clinical Research Office.

GUIDANCE

Section 1: Protocol Title page

- **1.1 Details of applicants:**
  Lead applicant - This should be the name of the person who will be undertaking the study and the individual to whom all correspondence about the application will be addressed. You should give an e-mail address and telephone number. In the case of student research, both the name of the student and the supervisor need to be included.

  Co-applicants – This should include the name, position, email address and telephone number of co-applicants.

  Each Research team must include a consultant and/or senior academic.

In accordance with ICH GCP, please note that for IMP studies, the Chief Investigator can only be a qualified physician (or dentist, when appropriate),

- **1.2 Details of Sponsor:**
  Provide name & address of sponsor. This should be confirmed with your assigned Research Coordinator at the Research Department.

- **1.3 Title of project:**
  The title should be the same as that of your application to the STH Research Department and Research Ethics Committee.

The title should include summary of study design, Investigational Medicinal Product (IMP) & placebos/active comparators, nature of treatment, indication, patient population and setting.

- **1.4 STH project reference number:**
  This refers to the number accorded your project when you registered your intent to carry out a project with the STH Research Department.

- **1.5 Protocol version number and date:**
  A version number and date should be included with each protocol to allow identification of amendments to the protocol during the progress of the study.

  It is recommended that the final protocol submitted for ethical approval is numbered version 1.0 and dated with the date of finalisation (rather then named "final" which can cause confusion when amendments are requested by the Ethics Committee).

- **1.6 Signatures of Chief Investigator and Sponsor:**
  Include assignment of signatory and date of signature. Please include this section during the scientific review process but only collate signatures when submitting final version of protocol (for MHRA Clinical Trial Authorisation and Ethics submission) after Independent Scientific Review approval has been granted.

- **1.7 EUDRACT & CTA number:**
  Please liaise with your assigned Research Coordinator for the EUDRACT number and CTA number. The sponsor will apply for both with your assistance.

- **1.8 Phase of trial:**
  Please indicate whether your study is a phase I, II, III or IV study.

- **1.9 STH Directorate affiliation:**
  To which STH Directorate does your study belong?

Section 2: Research question(s)
Is there a clearly defined, answerable, research question?

- Main research question(s): give a formal statement of the precise question the research is intended to answer and/or the hypothesis it is intended to test. It is important to focus on a single main question. For example, does the project concern itself with all the sufferers of a particular condition, or only with a sub-set? Do not feel that you have to address the total service problem, but be clear about the part you are going to address. Distinguish the key prospective question(s) to be answered, from the data set to be collected, as distinct from potential use of the data to carry out retrospective analysis. How generalisable will your results be?

- Secondary research question(s): this should be any subsidiary question(s) *within the main aim*, which the research is intended to answer. Where there are secondary questions, it would normally be expected that these would be few in number. Lack of focus within a project, through trying to address too many aims or collect too wide a range of information, is a common problem and can prevent any useful results being obtained.

Section 3: Abstract
Include a brief abstract outlining they key issues contained in your protocol. It should be readable by a professional non-specialist in your research area.

Section 4: Aim of the study
State the objectives and purpose of the study. Is the research original? Will it make a useful contribution to the field?

Section 5: Background
Clinical and scientific relevance: Is the research question an important one - i.e. is there a real clinical problem here, or a gap in knowledge, which needs filling? Indicate that a thorough review of research in this area has been undertaken.

Indicate how the project relates to the STH directorate to which it belongs?

You need to state clearly the benefits, both to patients and to the NHS, which would follow if clear results were obtained and subsequently applied. You should say explicitly what the potential practical value will be of the results of your research.

It may be that there will be no potential for direct clinical impact from your project. For example, the results may form the basis for further research that will have benefits in the future. If this is the case, it should be clearly stated as well as the way in which further research would be able to build on your results.

For research involving an investigational medicinal product (IMP)
Include medical condition or disease under investigation and explain how the patient group under study differs from the licenced indication(s) and/or from previously studied patient groups with particular regard to the likely safety of the IMP in the population under study, making reference to measures in place in the protocol to reduce risk in this patient group (eg exclusion criteria for subgroups at higher risk, safety assessments, reduced IMP dose etc).

Provide a description of the IMP and include a summary of findings from non-clinical and clinical studies that is relevant to the trial. In addition to summarising the known benefits in human subjects, pay particular attention to:

I. Known risks (side effect profile), including any patient groups at particular risk. Pay particular attention to potentially serious side effects, including an assessment of their likelihood and making reference to measures in place in the protocol to reduce the risk of serious side effects or to detect them at an early stage. Also include any long term risks from the IMP (which may continue after the study is finished and any measures which will be necessary to monitor the patients for this in long term follow up
II. Likelihood of unknown risks (is the product already widely studied, is the side effect profile likely to be different in the current study population?). Again please make reference to measures in place in the protocol to reduce the risk of unknown side effects or to detect them at an early stage.
III. Known clinically relevant drug interactions (pharmacokinetic or pharmacodynamic) and the potential for unknown drug interactions to exist. Make reference to measures in place in the protocol to reduce the risk to participants and to the data from drug interactions.

Give information on any on-going trials (if applicable).

Scientific justification
In this context, 'scientific' is a broad term and indicates a rigorous, systematic approach rather than defining a particular category of research.

Student research needs to conform to university regulations in terms of the originality of the study.

Research Governance statement
Statement that the trial will be conducted in compliance with the protocol, GCP and applicable regulatory requirements.

Section 6: Plan of investigation

- **6.1 Methodology:** you should describe and justify your methods in some detail – what you will do, how you will do it and why you have chosen this approach. You should consider whether the proposed methods are appropriate – for instance will they address the question being asked, are they likely to produce a useful answer, and are they designed to reduce the risk of bias?

  Feasibility: Acknowledge any specific difficulties faced by the research. All research is difficult. Failure to recognise, or acknowledge potential difficulties could be to your detriment in successfully completing the project. Potential obstacles could include problems with measurement, methods of describing case-mix, uncertainty of recruiting or finding the necessary numbers of cases. Don't dwell on potential problems, but make sure that the referee knows that you have thought of them and have taken them into account.

- **6.2 Summary of study design:** The nature of the design adopted (e.g. **randomised controlled trial, cross-over study, levels of blinding**) must be **clear and explicitly justified** as an appropriate one, i.e. suitable to answer the question or test the hypothesis posed.

For research involving an investigational medicinal product (IMP)
The following details should be included in the summary:

I. A statement describing precisely the primary and secondary endpoints to be measured during the trial.
II. Justify your choice of primary outcome measure in terms of its validity and its ability to detect a clinically important change / difference. If your primary outcome measure is subjective describe what steps you have taken to blind the study treatment or describe why blinding is not possible and how you will address the potential bias this may introduce.
III. A summary of the study procedures to include details of the sequence and duration of all study periods and trial procedures. This may include screening, randomisation, study visits, end of study visits and follow up. It can be useful to add a flow chart or table to summarise sequence of events.

- **6.3 Setting for the project:** where will the project be carried out? Is the setting appropriate - e.g. if you plan to do your study in an outpatient clinic, is this the best place?

- **6.4 Participants:** Provide a description of the population to be studied. You should consider and include:
  I. Why this population is suitable
  II. How many eligible subjects are available and how may many do you expect to participate
  III. How many centres will be involved

  Details of subject eligibility must be clearly stated. List the inclusion and exclusion criteria to identify who is eligible for the study.

For research involving an investigational medicinal product (IMP)
Make every effort to ensure that your inclusion and exclusion criteria are well defined and unambiguous.

I. Consider the need to exclude comorbidities or other subgroups at particular risk from the IMP
II. Consider the need to exclude certain concomitant drugs (drug interactions etc).
III. Consider the need to avoid exposure of pregnant women to the IMP (see section 6.11)
IV. Weigh the need for additional exclusion criteria to ensure a homogeneous study population likely to yield a homogeneous response to the intervention against the merits of broad inclusion criteria and widely applicable results.

In each case justify your choice of inclusion and exclusion criteria wherever possible.

State who will be responsible for confirming patient eligibility and at what stage in the recruitment and randomisation process eligibility will be confirmed. Describe any anticipated difficulties in confirming eligibility before study treatment is assigned any measures which will be taken to avoid the inclusion of ineligible patients

- **6.5 Sample size:** You should also consider whether the proposed **sample size** will be appropriate to obtain meaningful results? You need to state what your sample consists of, how you have identified it and why. Will the sample be representative of the population?

  You should give the basis on which you have calculated the required sample size, for example:

  I. Which outcome variable has been chosen on which to base the power calculation and why
  II. How was the adopted estimate of variability arrived at - from the literature, from a pilot study etc
  III. How you arrived at the benchmark of what should be considered a clinically - or otherwise - useful effect
  IV. What probability and power levels have been adopted

  Exceptionally, if your study is preliminary, descriptive or uses methods which do not require this, say so explicitly and why.

For research involving an investigational medicinal product (IMP)
Explain what assumptions have been made in calculation of the sample size with regard to the risk of non-compliance, drop out, and cross over. Explain any steps you have taken to minimise these risks to maintain the power of the study.

- **6.6 Recruitment:** How will you identify, approach, recruit and consent your participants? Is it likely that there will be problems in obtaining the numbers required for the study, whether this is patients, clinics or tissue samples? Check that estimates of recruitment of participants are realistic and that your proposed milestones can be met. One of the major problems faced in research projects is failure to obtain as many samples/participants as the researchers initially anticipated.

For research involving an investigational medicinal product (IMP)
State whether this study might include potentially vulnerable patient groups or patients in vulnerable situations. What steps will you take to ensure fully informed valid consent? Who will take consent?

- **6.7 Outcome measures:** you should describe what will be measured, when, and how, to show whether or not the question has been answered. A visit schedule will probably be helpful in explaining the path of the patient through the study.

  If you propose to include general or specific measures of health status before and after an intervention to measure health outcome/gain, you should ensure that you obtain appropriate advice on how to do this, indicating the instruments to be used and brief evidence of their suitability.

For research involving an investigational medicinal product (IMP)

Outcome measures will include assessments of efficacy and safety. Safety outcome measures and adverse events can be addressed in section 6.10.

I. Outcome parameters (eg clinical response, clinical signs and symptoms of infection, severity of infection, and microbiological assessment, etc), should be specified and details provided on the methods and timing for assessing, recording and analysing efficacy and safety parameters.
II. Detail and justify any blinding of measurements and any other measures to minimise bias.
III. Describe any difficulties you anticipate in completing the follow up assessments correctly. Include steps to reduce the risk of follow up assessments being incorrectly conducted.
IV. Are there any clinical risks associated with any investigations required by the protocol which are not part of standard care for the patients included in this study (eg additional X rays, endoscopies, biopsies) If yes, justify the use of these investigations and describe the measures you will take to minimise the risk associated with these investigations

- **6.8 Statistical analysis:** If you are carrying out statistical analysis, you should describe what the analysis is intended to do (e.g. you may intend to make a comparison, between groups, of the proportions of individuals satisfying particular criteria, or you may want to compare the mean values of a quasi-normally distributed variable before and after an intervention). You need to think at this stage about:
  - What steps you will take to ensure data integrity
  - What percentage of data you might expect finally to be missing
  - What arrangements you will make both to minimise this and to ensure accuracy
  - How missing data may affect the analyses, both in terms of attrition/power and in terms of selection or reporting bias.

- **6.9 Intervention:** Detail the intervention, where this is appropriate to the study, indicating clearly the participant's involvement throughout the course of the study. NRES suggests the use of a flow chart.

For research involving an investigational medicinal product (IMP)

Intervention refers to the treatment under investigation and any active control treatment. Detail of the product may be found elsewhere such as in the Investigator Brochure or the Summary of Product characteristics (SmPc). The protocol must include:

I. Name & description of the trial treatment(s) and comparators (to include full generic name, if licensed in UK trade name)
II. Licensee name
III. Description of the route of administration, dosage regimen and treatment periods.
   a. Is the dosage, duration of use and route of administration of the study drug the same or broadly similar to that which has been either routinely used or previously studied?
      i. If no, please describe how the administration of the study drug in this study differs from previous experience and assess whether this represents an increased risk to the patients
      ii. Where an increased risk is identified please describe what, if any, measures are in place in the protocol to mitigate against this risk.
   b. Does the use of the study drug in this study involve any dose calculation or dose escalation or otherwise complicated dosing regimens?
      i. If yes, is there any potential for dosing errors?
      ii. If yes please describe what steps you have taken or will take to reduce the chance of a dosing error being made.
IV. Detail of who will be prescribing and who will be administering the product e.g. doctor, patient, nurse and any specific training required.
V. A description of the packaging and labelling on the IMP (include details on study specific preparation or dispensing procedures)
VI. Detail on shelf life, arrangements for storage etc (may refer to delegation to STH Pharmacy – this must be agreed with Pharmacy)
VII. Describe procedures for monitoring and follow up on subject compliance
VIII. Describe procedures for monitoring drug accountability.
IX. Describe how subjects are allocated to treatment. Include detail on and justification for the type of randomisation to be used, how randomisation will be implemented (who, where, how), approach to be used to maintain blinding.

X. What steps will be taken to ensure study treatment allocations are concealed pre-randomisation?
XI. For blinded studies what steps will be taken to maintain the blind during study drug treatment and follow up?
XII. Description of medication/treatment(s) permitted (including rescue medication and medications not permitted before and/or during trial. Consider possible interactions or effects that could confound study results or compromise safety.
XIII. If applicable, is any 'rescue' medication available to reverse the action of the study drug and, if yes, is its use incorporated into the protocol

What are the plans for ongoing treatment of patients finishing the trial? Does any change in treatment or continuation of treatment at the end of the study raise any safety concerns and, if yes, how will these be addressed?

- **6.10 Safety assessments:** Detail any safety assessments which will be required and specify what adverse event data will be collected.

For research involving an investigational medicinal product (IMP) the protocol must:

I. Specify safety parameters and the methods for timing, assessing and recording and analysing of safety parameters.
   a. The procedures for eliciting reports of and for recording adverse event and inter-current illnesses should be described as well as a description of the type and duration of the follow-up of subjects after adverse events
   b. Safety parameters to be routinely measured: eg haematology, clinical chemistry, and urine test results, vital signs, physical examinations, and electrocardiograms
II. Explain how information on AEs will be elicited from subjects at each study visit, and how they will be recorded and reported.
III. Detail review procedures to ensure AEs are not missed.
IV. Give standard definitions of SAE's, SUSARs and assessment of causality and expectedness as laid out by the EU Directive and described in CT3.
V. Define SAEs for the trial which are expected (known adverse effects of the IMP or comparator)
VI. State which SAEs will not be subject to expedited reporting (if any)
VII. State the reporting period during which SAEs will be subject to expedited reporting. This will usually be from the date of informed consent until 30 days after the last administration of IMP.
VIII. Detail the procedure to be followed in the advent of an SAE including reporting procedures to the sponsor and Research Department. (In accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004 and STH procedures, an investigator shall report any serious adverse event which occurs in a subject at a trial site at which he is responsible for the conduct of a clinical trial immediately to the sponsor)
IX. Describe the type and duration of follow up of subjects required after an adverse event and who has what responsibility for follow up
X. Detail the procedure to be followed in the advent of an SUSAR
XI. Detail who will be responsible for preparing the annual Drug Safety Update Report and for performing trend analysis on SAEs which occur in the study

- **6.11 Pregnancy**

For research involving an investigational medicinal product (IMP)

Describe what risks are associated with the exposure of pregnant women to the IMPs, and NIMPs involved in the study and any study procedures which potentially pose a risk (eg exposure to radiation):

Describe what risks are associated with pregnancy occurring in a partner of a male patient who is exposed to IMP:

I. Where relevant risks are identified what measures will be put in place to ensure that:
   a) pregnant women are not included in the study (add specific exclusion criteria to section 6.4 where necessary)
   b) women who have the potential to become pregnant are not included or adequate contraceptive methods are in place (add specific exclusion criteria to section 6.4 where necessary)

c) men with partners of child-bearing potential are not included in the study unless adequate contraceptive measures are in place (add specific exclusion criteria to section 6.4 where necessary)
d) pregnancy occurring during the study is identified early (add specific outcome measures or investigations to section 6.7 where necessary)

II. Where relevant describe the procedures for reporting pregnancy and following up pregnancies which occur during the study to their conclusion. Where follow up of pregnancy occurring in a partner is required separate information sheets and consent forms for the pregnant partner will be required.

- **6.12 Subject withdrawal, breaking the blind and trial stopping/discontinuation rules:**

For research involving an investigational medicinal product (IMP)
Describe the subject withdrawal criteria and procedures including:

III. When and how to withdraw subjects.
IV. Type and timing of data to be collected for withdrawn subjects.
V. Whether and how subjects will be replaced.
VI. Follow up procedures for subjects.

Describe under which circumstances the randomisation code may need to be broken and the procedure for this including in emergency situations.

Describe what plans you have for review of the continuation of the study and detail the procedures for decisions on discontinuation of trial e.g. interim analyses, Data Monitoring Committee (DMC). State what documentation needs to be completed

- **6.13 Instruments:** The suitability of the instruments you propose to use must be established, e.g. are they sufficiently sensitive to pick up variation in the particular target population(s)?

  Please include your **data collection tools** including **screening tools, questionnaires and case report forms** plan for your study in your submission. Are all tools and questionnaires validated? Guidance on planning data collection for research projects and generic CRF completion guidelines are available from the Research Department.

  Any **unusual or novel techniques**, or those originating in disciplines remote from medicine, should be justified at slightly greater length.

  If you propose to include **service costing data**, then ensure that you obtain appropriate advice on how to do this, indicating clearly the degree of accuracy and representativeness you wish to claim for these data. RDS and ScHARR's health economists are well placed to advise.

For research involving an investigational medicinal product (IMP)
Data collection, handling & record keeping:

I. Describe the source of data, the time points for data collection and who collects what. Explain how and why data is being collected.
II. What steps will be made to ensure the quality and validity of key outcome and safety data e.g. source data verification, data double entry.
III. Describe procedures for the security and storage of data and procedures for retention of source data including location & duration. Identify who is responsible for this?
IV. Include statement on Data Protection Act e.g. data will be collected and retained in accordance with the Data Protection Act 1998; please ensure that you are familiar with the principles of the Act.

- **6.14 Quality control & assurance:**

For research involving an investigational medicinal product (IMP)
Specify the arrangements for monitoring & audit and detail any other steps taken to ensure quality for the research. Please note that we require the Monitoring Arrangements Plan, fully completed and signed by the Chief Investigator before R&D authorisation.

- **6.15 Project plan:** Is the estimated duration of the project appropriate? You should give a work plan, which lists the main stages and targets within the project and a timetable for completion of each phase of the work, including analysis, write-up and dissemination.

  If your application is supported, the project plan will be used as an aid to monitoring progress of the project. A diagram is often helpful.

For research involving an investigational medicinal product (IMP)
Describe your plans for a steering committee and/or safety/data monitoring committee, including the frequencies of meetings, what will be reviewed and the independence of these committees from of the study.
Definition of end of trial e.g. database lock, last patient last visit (LPLV).

Section 7: Statistical opinion
Where applicable, append evidence/report of a favourable statistical opinion. Discuss the evidence supplied.

For research involving an investigational medicinal product (IMP)
Statistical advice must be sought at the design and protocol finalisation stage to ensure study design is satisfactory. Append evidence of a favourable statistical opinion. Discuss the evidence supplied.

Section 8: Project management
Please indicate:

I. How you (and your research team) intend managing the project to ensure that it delivers its intended outcomes on time
II. What review and reporting mechanisms will you be using
III. Who will have overall responsibility for the study
IV. Who will supervise, monitor, and review work undertaken, data collated and analysed.

Section 9: Expertise of the researcher and associated team
Explain how the team possesses sufficient expertise to deliver a successful outcome.

I. Are you in a good position to carry out the particular piece of work? For example, you may have previous experience of the field, have already carried out a pilot, have baseline data already available, have access to an adequate supply of patients.
II. Does the research team either include people with expertise in all the areas of work required by the project, or have access to people with the relevant expertise at the appropriate points in the project?
III. Do you have assured support from clinical and/or professional colleagues and have access to required facilities?

Section 10: Ethical issues

Please address the following when writing your protocol;

I. Have ethical issues been addressed?
II. Is the proposal ethically sound?
III. Are there particular ethical issues that may arise in a project of this nature?

Explain how you have addressed the following questions:

I. Are the participants protected from undue risk?
II. Are their rights to information and consent, confidentiality and privacy respected?
III. What security methods are to be used to protect the subject's identity when collecting, analysing and storing data?
IV. In what form and how long will data be stored?
V. Are there any issues concerning racial and cultural diversity?

Please submit any patient information sheets and consent forms with your application. Template information sheet and consent form can be found at http://www.nres.npsa.nhs.uk/

Your patient information sheets and consent forms should reflect the rights of patients to withdraw at any point.

Section 11: Involvement of service users
Indicate the level and nature of any involvement in the planning, conduct and/or dissemination of your project by service users or their carers.

Section 12: Methods for disseminating research results
The results of research undertaken with Trust resources are expected to be submitted for publication by the researcher. You should therefore include a short account of how you plan to disseminate the results of your work. This may involve more than publication in a respected journal. Your plan should encompass, where appropriate, a considered follow-through into training programmes of other professionals and presentations to service users.

The research programme for which the STH Trust acts as Sponsor is in the public domain and the Research Department may publish details of the research project as part of the Trust's R&D Programme. Such studies are also included in the national registers.

Section 13: Strategy for taking the work forward if the research project is productive
If your research project is productive, what will your strategy be for taking this forward? Will you be undertaking further research based on the results? Do you intend to apply to funding bodies for continuation of support?

Section 14: Intellectual Property arrangements
A Framework & Guidance on the Management of Intellectual Property in the NHS (2002) sets out the arrangements for NHS staff, which will help to ensure that intellectual property derived from NHS R&D is owned and exploited in the best interests of the NHS.

This documentation is available on the Department of Health website at http://www.dh.gov.uk

STH arrangements for IP are set out in the Policy for the Management of Intellectual Property. IP generated by Trust researchers is managed by Medipex Ltd (NHS Innovation Centre for the Yorkshire & Humber region).

IP generated by university researchers is managed by the universities' Research Offices.

Section 15: Costing the project:
When costing your application, be sure you have included everything you will need. Accurate identification and how much it will cost can be difficult for less experienced researchers. For example: transcription of interviews or data analysis take much longer than you might realise - for every hour of interview you should expect to have to allow 4-5 hours of transcription time. The Finance Department and the Research Department can advise on the costing process. You are strongly advised to use the principles outlined in the STH Finance form to identify your costs. The costs are broken down into logical stages such as personnel, start up, recruitment, screening, processing, analysis and reporting.

Irrespective of whether there is **funding** associated with the project, **all costs** should be identified accurately**.** These should include direct research costs (salaries and consumables – see below) as well as the use of clinical resources both for the host directorate and for support services. These need to be agreed with the clinical director / general manager in the location where the research is taking place and, where applicable, with the manager providing the support service.

I. *Staff costs*: for each additional staff member requested the following information is required:
- A description of the type and grade of staff required (e.g. Geneticist B15-17)
- The proportion of a whole-time equivalent (WTE) required and an indication of which months of the project the appointment will cover (e.g. 0.5 WTE for months 2-8), and the assumed start date
- Basic Pay, National Insurance, and Employers' Superannuation – all identified separately
- All costs should be quoted at pay levels in force at the time of application. Please indicate the effective date of the last pay award to be settled for the grade of staff to be appointed, and whether there is a further award pending. Costs need to take account of pay and price levels for the duration of the project, reflecting any outstanding pay awards
- Where staff are to be employed on an incremental scale this should be reflected in the costings.

II. *Other recurrent expenses*: these include maintenance costs for equipment outside the guarantee period and running costs (e.g. stationery, postage, laboratory consumables, audio tapes, telephone and travelling expenses etc) proper to the project.

III. *Equipment*: it is expected that basic equipment will be provided by the applicant's department. For new equipment all prices should be quoted gross, including VAT where applicable.

IV. If a *computer* is needed, you should remember to include software licensing costs. You should also check that you would satisfy the requirements of the Data Protection Act. If you plan to store any data from which individuals can be identified, you should consult with the Trust Data Protection Officer,

Peter Wilson (peter.wilson@sth.nhs.uk) on ext. 65153.

V. *Other non-recurrent expenses*: this includes items like, one-off fees for advice/consultancy, the costs of presenting the results of the research at conferences, or submitting them for publication.

Note: Staff working on research projects will need substantive or honorary contracts with the Trust or University, in accordance with its establishment practice.

Justification for resources requested
Where you are applying for funding, you need to explain why you need the staff/items for which you are requesting funding. It is not enough just to list what is requested. For example, if you are requesting staff costs, explain why the project needs that particular type of staff, and why the grade quoted is the appropriate one. In the case of equipment, are you sure that there is no existing equipment which you can use – a very good case would be needed for basic items which should already be available in your department. R&D funds are not normally used to fund standard office equipment or standard computer hardware and software.

In general R&D funds are not used to fund additional sessions for people already in full-time employment, paid by the NHS or by a University unless it can be shown that the money will pay locum costs for another individual to carry out some of that person's normal duties, thus releasing them to do R&D work.

If salaries are requested, always include any increments due during the course of the project. You should indicate effective date of latest settled pay award.

Section 16: Funding source
The potential funding source needs to be clearly stated: e.g. SHCT charitable account, STH agency account, University account, other, none. There should, of course be sufficient funds in the account to cover the costs of the intended project.

Section 17: References in support of the protocol*:* these should give the full journal reference.

Section 18: Curriculum Vitae
Please include a brief CV, including a list any current grants and your publications during the last five years.

Section 19: Other information

For research involving an investigational medicinal product (IMP)

I. Name, title, address and telephone number of the qualified physician who is responsible for all study related medical decisions (if different to the Chief investigator).

II. Names and addresses of the clinical laboratories and other medical and/or technical departments and/or institutions involved in the study.