IPCRG RESEARCH STANDARDS

1. The proposed research should normally address a question raised in the IPCRG's Research Needs Statement or relate to tuberculosis that was specifically excluded from the Research Needs Statement. Other topics will need to fully justified, and are unlikely to be prioritised
2. Applicants must carefully consider and meet regulatory recommendations that apply to the country where the research is being done. We consider the UK standards to be a good benchmark and recommend the General Medical Council publications 'Good Medical Practice' and 'Good Practice in Research' if there is insufficient guidance in your country. In the case of databases, where regulations may not be available, considerations of consent and patient benefit should be addressed.

3. Where the study is multi-national, national regulations and best practice should be the ones followed by each participating country. If there is insufficient guidance in your country we recommend the standards laid out in GMC publications described above.

4. There is a full protocol that has received ethical approval from the relevant national authority. There may be circumstances (e.g. service evaluations, use of anonymous databases etc) when ethical approval is not needed. This should be confirmed, in writing, by an ethics committee stating that formal ethical review is not required. Note that if there is sharing of databases across regulatory boundaries there may be a different permission or consent required. If ethical approval can only be provided after funding is secured, then the IPCRG would expect to be sent copies of the ethical and any relevant governance approval before any funding is released.

5. The sample size should be adequate to answer the research question with acceptable margins of error and clearly justified in the proposal. As the rate-limiting step for most studies is recruitment of patients, we would expect to agree a realistic timescale for recruitment and that timescale will form the schedule that triggers payment.

6. In order to achieve high external validity for primary care populations and to limit recruitment problems, exclusion criteria should be kept to a minimum. Clearly, there will be a need to specify the particular group of interest (e.g children if a study relates to management of asthma in schools, or people with COPD who have had an admission if a trial is testing tele-monitoring to prevent readmissions) however, in order to reflect primary care populations inclusion criteria should be as inclusive as possible and any exclusion criteria fully justified.

7. No additional funding from IPCRG will be made available for the project other than that requested and reviewed in the original proposal. Cost-neutral extensions will be considered. IPCRG will also use its standard research contract terms to limit its exposure to risk.

8. Leadership of the study is critical, and sufficient time both for senior management and adequate suitably qualified researcher(s) should be built into the project. We would normally expect one or two co-applicants to be named, to enable the study to function smoothly in the absence of the PI for whatever reason. Where the study is cross-national, the co-applicants should be from different sites and they should share the responsibility of assuring the project progresses, data are collected to the agreed schedule and the project is concluded on time and to budget. Applicants must describe how they will manage the study, who will do what and when, and who

will oversee the study (ideally independently for a study of any magnitude). Reviewers will be asked to comment on whether the plans are practical and the suitability of the leadership team in terms of track record, competence, reputation and available time.

9. The IPCRG mission is to disseminate research for the public good therefore dissemination of the findings, whether negative, positive, or inconclusive, is essential. Hence the applicant should describe the options for dissemination including both open access peer-reviewed journals and other IPCRG or national publications in a range of languages. The budget should include any open access publishing and/or translation costs.

Research Sub-committee

7 April 2011

Tips to improve patient and clinician recruitment

Collaboration with GPs

- Use experienced researchers
- Plan properly
- Use multiple recruitment strategies
- Recognise that there are country differences that may require different approaches and recruitment strategies
- Establish GP research networks, co-ordinated by an academic department
- Offer mentorship to less experienced GPs
- Recruit general practices with multiple GPs
- Pilot recruitment methods
- Develop the research question in conjunction with GPs
- Recruit GPs through presentations, educational outreach, use of local opinion leaders
- Study team to facilitate GP involvement within the study
- Use reminders
- Produce printed educational materials
- Feedback recruitment performance
- Maintain personal contact
- Use skillmix to reduce burden on any individual eg study nurses to recruit and gain consent
- Consider incentives

Patient recruitment

- Keep broad patient eligibility criteria where possible
- Consider incentives for patients
- Recruit sufficient numbers of GPs to generate adequate sample size
- Discuss recruitment with the patient's own GP and involve them where practical – eg signing the letter to the patient
- Straightforward data collection tools
- Anticipate barriers to recruitment eg restrictive entry criteria or participant non-acceptability of data collection tools and address them.

Recommended reading

Prescott RJ, Counsell CE, Gillespie WJ, Grant AM, Russell IT, Kiauka S, *et al*. Factors that limit the quality, number and progress of randomised controlled trials. *Health Technol Assess* 1999;**3**(20).

Dean SC, Harper CE, Cappuccio FP, Rink E, Dirckx C, Arnout J, Zito F and Iacoviello L on behalfof the European Collaborative Group of the IMMIDIET Project. The challenges of cross-national research in primary health care across Europe. Family Practice 2005; 22: 341–346.

Foy R, Parry J, Duggan A, Delaney B, Wilson S, Lewin-van den Broek N, Lassen AT, Vickers L, Myres P. How evidence-based are recruitment strategies to randomised controlled trials in primary care? Experience from seven studies. Family Practice 2003; 20: 83-92.

Asch S, Connor SE, Hamilton EG, Fox SA. Problems in recruiting community-based physicians for health services research. J Gen Intern Med. 2000;15(8):591-9

Cave A, Ahmadi E, Makarowski C. Recruiting issues in community-based studies: some advice from lessons learned. Can Fam Physician. 2009 May;55(5):557-8.