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Chapter 1. Introduction

This guide is intended as a resource to help researchers in primary care with the practicalities of participant recruitment. It draws on information from a variety of experienced research active professionals from a range of settings who kindly gave their time in discussions about how they and their organisations approach the task of recruiting to studies in primary care. It is hoped that by sharing their ideas and practices through this resource, others will be inspired to adopt procedures which they may not have previously thought of and that in doing so will achieve their targets.

It was developed by the NIHR Primary Care Research Recruitment Methods Group, a national collaboration (see www.nspcr.ac.uk), with funding from the NIHR Primary Care Research Network (see http://www.crncc.nihr.ac.uk/index/networks/primarycare.html). Revisions and updates have been undertaken with funding from the NIHR National School for Primary Care Research.

This guide is the third version and we are hoping to continue to revise it. It deliberately uses some terms from the commercial world and applies them in a social marketing model to help us think differently about our approaches. Users are encouraged to give feedback and constructive criticism.

Background
A number of publications have described the challenges associated with trial recruitment in the United Kingdom and elsewhere, some of which have even led to trials being abandoned. Up to 60% of trials need an extension or don’t recruit to target according to recent reviews, and concerns about this are widespread in academia and industry. Although evidence is sparse, one study of 114 UK trials in all health care contexts funded by the Medical Research Council and Health Technology Assessment programme, found that 31% recruited successfully, and 45% recruited less than 80% of their target. Just over half of all trials required an extension. Similar findings from a smaller survey of published primary care trials found that approximately one third recruited to timetable, one third required up to 50% more time than planned and another third required over 50% extra time than originally planned.

Little is known from the published literature about factors that definitively predict success, but from the larger study mentioned above it is suggested that although few have been systematically evaluated, a wide range of factors would be expected to influence recruitment.

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3 Planning Recruitment Options: Strategies for Primary Care Research (PROSPeR) – A recruitment resource linked to articles in the published literature gives helpful pointers, although little has been done to systematically test recruitment methods PROSPeR was developed by the NIHR Research Design Service for East Midlands, available via the internet: http://www.rds-eastmidlands.org.uk/resources/doc_details/15-prosper.html
With a key focus for the NIHR PCRN and NSPCR on the achievement of on-target recruitment in primary care, an accessible guide that brings together the wealth of experiences of academic, commercial and other experienced primary care research professionals, could be a useful resource.

A series of discussions were undertaken to collect data and subsequent feedback from key informants. A framework for a guide was then drawn up under sections relating to the different pragmatic elements and phases highlighted by informants as being important when recruiting participants into healthcare studies. This was further refined as a result of four focus groups with additional groups of research active stake-holders in 2008. Quotes added in this third version (November 2009) are included with the agreement of a further group of key stake-holders who were interviewed for a feasibility study in early 2009.\(^6\)

Last, but not least, this is an area of growing interest to patients and the public who are increasingly engaged in working with us from the beginning where feasible, or as early as possible, to help develop the best research.

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\(^6\) ‘Trials within trials? Researcher, funder and ethical perspectives on the feasibility of testing recruitment methods in primary care’ (In press)
Chapter 2. Recruitment Essentials

We should bear in mind that our aim in recruiting people into studies and trials is to find evidence that will bring benefit to patients and the public. There has been a shift away from doing things to patients to a model in which we are working with patients for public benefit.

In order to achieve target recruitment numbers, good research planning and project management are essential and consultation with appropriate stake-holders, feasibility work and thoughtful scheduling are all vital.

“We spend a lot of time advising people at the study development stage, obviously to think very carefully about the piloting and feasibility. And then piloting before you do the main study; ensuring that you have plenty of time between each of these stages, to reflect and learn. The issue often is that people’s pilots run into the main study. And really, it’s very difficult to change anything….. Because you can’t really implement a lot of the changes. It means you have to re-write all your study documentation. And actually finishing your pilot in week three and starting your main study in week five …..is not going to be feasible.” (Funder)

1. First impressions count

Whether you are recruiting collaborators or participants, it’s really important to realise that first impressions make a huge difference to whether people agree to be involved or not. First impressions depend on the how meaningful the material you present is, as well as how effective the personal interactions are with potential collaborators or participants. It is important to understand who your target group is so that the messages can be tailored accordingly. To understand their needs and how to identify or approach them in a way that is effective, social marketing work is worth undertaking at an early stage in your plans. This will help you to identify: who needs to know, the tone of your message, the study identity, what is special about your study7 and its characteristics.

1.1 Consult with primary care collaborators at early stage

To get your message across to collaborators in a meaningful way which will appeal, it helps to approach a few potential collaborators (e.g. GPs) early. There are three reasons. Firstly they may give helpful input into the composition of the content of the publicity material and secondly they may make useful suggestions about how to approach other collaborators about the study. Thirdly, because clinical care delivery operates to different time-scales than research, by consulting with primary care early, you can prepare collaborators for involvement so they are lined up, ready for when you actually want to start recruiting.

1.2 Understanding Primary Care in Context

Once you appreciate the primary care context, it will help you to plan. NHS service organisations are mostly more interested in good health ‘now’ and promoting prevention work than in research. Health centres operate in different ways – some may be more formal than others. Before you begin, find out how often internal meetings such as practice meetings are held, and how long it will take to book a meeting. Also be aware how busy most practitioners are. Research may be seen as a bit of an indulgence as it is often some time before it has impact on care. At the meeting you may not have long to get your message across and ‘sell’ your study. So you may need to figure out

7 In social marketing this is known as its ‘unique selling point’.
how to persuade your target collaborators about the importance and relevance of your study to them and their patients in a very brief exchange.

“There the managers (of a PCT service) were concerned that it was going to increase the workload for their own department, which isn't the case at all. Participants are patients that would have been going through the service anyway on the whole, and they're getting their initial assessment from me, so that's taking one step out of the process..... And certainly, having been to this Target Day and talked to quite a lot of GPs there, the impression I got was, 'Well, what's in it for us?', sort of, attitude from the GPs. As they couldn't particularly see any great benefit to themselves, or to their practice, rather, there didn't seem to be an awful lot of interest.” (Chief Investigator)

1.2.1 Will care pathways affect your research?
Local care pathways, if they exist for the topic you are studying, will describe options and steps for treatment for any particular indication, for example when treatment or referrals are triggered. This may be important to know before you begin recruitment as your study recruitment plans need to fit in with what happens locally.

“I think probably one of the biggest things (about service staff being involved in research) is just a change in procedure; it’s not the normal process the patient’s care goes through and, certainly, some clinicians find it difficult to change or incorporate a slightly different routine into their normal day-to-day practice. I think they're always worried that it's going to incur more work and more paperwork, because nobody's got extra time, obviously. I think that's one of the biggest things. From my study, I don't think there's been an issue in terms of being difficult to deliver the treatments, although that's different to recruitment anyway. I think it's more that they can't go through that normal process that they'd look at the referral, they'd get the patient in, they'd treat the patient. They've got to put in an extra step (for the research); contact me somehow or other, and then wait to know what to do with the patient.” (Chief Investigator)

1.2.2 Linkages/shared agendas
How will your study link into the clinical care agenda? This may be important in terms of persuading people the study is worthwhile. If there is potential for immediate benefits to at least some patients through participation as well as longer term gains, it may make the difference to participation rates. Equally, if there has been direct input from patients/the public to help demonstrate how this study might make a positive impact, this could be persuasive.

“There would be a big barrier there if what you were doing didn't strike any resonance with the people in the practice, if they think the research was irrelevant and a waste of time to them, then I’m sure the recruitment rates would be lower then as well. The practice just wouldn’t take part in the study, so it’s got to be relevant. …..hopefully you’re only doing it because it’s an important and relevant study to primary care.” (Chief Investigator)

1.2.3 Consider barriers and incentives to clinicians
If you involve a friendly, ‘grass-roots’ (rather than academic) practitioner early, they can help identify barriers and incentives to participation from a practising clinician perspective. Some factors are related to research in general, and some to your study in particular. The more the

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8 For examples of primary care pathways contact local NHS organisations.
study resonates with the clinical care agenda or is in an area they find of special interest, the more likely they will be to commit. Examples of barriers are how much extra work they will need to do for you, whether the research will cause disruption to the centre and potential impact on the doctor/patient relationship.

“I think even more important than reimbursing, is limiting the imposition of work on the practice and that was made much more difficult by the data protection act in 1998.” (Chief Investigator)

1.2.3.1 Research impact on doctor/patient relationship
Some researchers fail to appreciate the potential of their study to impact the therapeutic relationship. Perhaps by entering a patient into the study, the clinician may feel they are signalling to the patient that they are unsure which treatment is best, which may make them or the patient feel uncomfortable. Consider whether it would be helpful to offer training to the clinician about broaching the subject of research§ with their patients. If so, this needs to be planned well in advance of actual recruitment and offered to potential collaborators when first approaching them.

1.3 Consider barriers to patient participation
It is as important for researchers to consider and take into account barriers which may prevent patients from participating in research, as barriers to clinicians. Some barriers may only become apparent after consultation with lay people or user groups, or even after the research has begun. Could your study underwrite travel costs or organise travel if this is to another centre?

“We had the odd phone call from them saying they didn’t want to take part, because they thought it was going to involve trips up to the hospital - when they heard that it was all going to be done in their local general practice, they were much more positive about that.” (Chief Investigator)

1.4 Feedback from patients on their experiences
Plan to ask patients about their experiences of being involved in the study, as this may help to identify ways of improving the participant pathway through the study (which could impact on follow-up data collection, for example). Some researchers prepare an ‘exit’ questionnaire for this – particularly useful to researchers for ironing out barriers early on. Asking for feedback also serves the function of making participants feel valued for their time and commitment, over and above any benefit they may receive.

1.4.1 Source of participants’ reactions to research
A useful resource giving comprehensive access to data about participants’ feelings about being asked to take part in research is available on line. Patients were interviewed about their research experiences by an Oxford-based group and the following sites carry interviews with patients about:
Being asked about taking part
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3632/topicList
Information and questions
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3633/topicList

§ Some research teams report finding it useful to run such training events for their studies
2. Costing up your recruitment procedures
The recruitment budget will vary by type of study, the amount of infrastructure resource needed, staff time and roles. It is always difficult to achieve an exact figure for the cost to collaborators for each patient recruited, so many researchers derive average costs and may reimburse centres according to a formula. Which approach suits your study best, a flat fee, a composite of an initial fee plus a fee per participant recruited?

2.1 Estimating costs
To estimate costs, mentally walk through the study recruitment procedures, identifying who is doing what, for how long. For each staff grade a different rate will apply. Then you will need to divide the total by the numbers of participating centres. For example, you may wish to recruit 100 participants from 10 centres, and this may involve screening for and identifying 10000 people from medical records. Practice managers or senior receptionists may need to conduct a search of records, extract the names and addresses, then a GP may need to screen the list to exclude unsuitable people (e.g. recently bereaved or hospitalised). Once this is done a clerical assistant needs to conduct a mail-merge and stuff and frank envelopes to send out letters on your behalf. How long will this all take? If you are using a room for study assessments, you may be able to pay a small fee for use of the room. All these need to be included in your costs.

2.2 Monitoring the budget
Someone needs to keep track of expenditure and keep tight control of the budget by regular monitoring. Study teams find that contingency funds are useful for unexpected expenses.

3. Permissions
Before you start, you need to ensure appropriate permissions are in place to begin your study. There is a co-ordinated system now for gaining permissions for NHS research, known as CSP – for more information see: http://www.crncc.nihr.ac.uk/index/clinical/csp.html and this incorporates research management and governance and ethics committee opinions. This is accessed via the Integrated Research Application System (IRAS): https://www.myresearchproject.org.uk/

Not all researchers are aware that each general practice is considered a separate site needing approval:

“Under our guidelines (National Research Ethics Service) each GP surgery would be a separate site that would need approval from the ethics point of view... Probably one of the biggest things is defining what the site is - if it’s a practice - who is actually responsible for the management? And who is actually responsible for the research governance? Who do we work with on that?.....it might be a barrier for people looking to get involved in trials, when they understand perhaps that they’re an entire site, and that they’d have to go through to a governance and an ethics process to get on board with a trial. ....it can be even more daunting, the fact that a GP surgery would be required to have the same level of review, like an entire hospital trust, to be involved in the research.” (Ethics Committee Representative)

3.1 RM&G
For more information and details about research management and governance there is an advice website: http://www.ukcrc-rgadvice.org/aboutus/Pages/default.aspx and a toolkit: http://www.rdforum.nhs.uk/toolkit/toolkit0305.htm
3.2 Ethics
For information on National Research Ethics Services refer to: http://www.nres.npsa.nhs.uk/
Researchers also need to be aware of the Mental Capacity Act, particularly for trials concerning consent and vulnerable people:

“A lot of the trials will tend to sample elderly members of the community and therefore the issues are around consent and assent. Now obviously with the introduction of the Mental Capacity Act and its implications, it’s around the issue of the ability of the participant to consent and if not what then happens in terms of giving assent? So we then have this debate around if somebody else is going to give consent, or what happens if a participant loses the ability to give consent during the duration of the study. How then that would be managed by the researchers?” (Ethics Committee Representative)

3.3 Research Passport
Under certain conditions, you may require a research passport which will enable you to carry out your study at different centres - http://www.crncc.nihr.ac.uk/index/clinical/passport.html

3.4 Medicines for Human Use and Regulations
For information about the regulations and what to do about research using medicines, see the Medical Research Council Clinical Trials Toolkit - http://www.ct-toolkit.ac.uk/

3.5 Incorporating contingency planning
Experienced researchers advocate the incorporation of contingency recruitment plans in their protocol and ethics applications. The time-consuming process of securing agreement to protocol changes by ethics committees will thus be avoided by planning for alternative means of recruitment or additional staff within the initial application.

“When you write your application, you write in what your recruitment methods are going to be, and what your likely response rates are. We didn’t know, so we made the best guess we could, then we said in our protocol that if we didn’t get a good enough response we would conduct the second wave of recruitment. And we did. (Describing a contingency plan within the protocol) Because we didn’t know we had to do that, so we had to invite about 50% more again. And achieved our target that way.” (Chief Investigator)

4. Patient & Public Involvement
Increasingly, patients and the public are getting involved with the research community to offer a perspective on their experiences of services and of being involved in research. They may be members of trial management groups, committees and boards. This can also be referred to as User or Consumer Involvement and is different from being a trial participant.

Patient and public involvement in research can be a valuable way to gain information about how and where to contact patient groups, what the study information leaflets might look like and getting comments and suggestions about practical issues relating to participating in a trial which can often only come from someone who has been there as a trial participant.

Other related ideas to think about:
• Having a named and consistent contact
Ensuring the contact can share information about other organisations specialising in the disease area e.g. Association for Medical Research Charity members

Further information is available at:
http://www.crncc.nihr.ac.uk/index/patients
http://www.invo.org.uk

5. The study name and logo – unique, short, memorable
The study name and logo need to be memorable and have impact and meaning. Brainstorming with non-research colleagues, focus groups with potential collaborators and participants, can all help you to decide what the unique badge of your study should be. Should you, for example, call it ‘A study to evaluate non-medicinal pain relief’ or ‘Painbusters’ accompanied by a potent symbol to indicate relief from suffering? However, you should try to avoid complex acronyms which seek to include letters from all the words on the proposal.

5.1 Study publicity and information material
All publicity about the study should have a ‘brand’ and look the same and include the study name and logo. This will help recipients to identify communications about your study.

5.2 Keeping it clear, brief and simple
It is best to avoid jargon and keep all communication clear, brief and simple as far as possible. User involvement is recommended to help you. The NIHR CRNs have a Lead for Patient and Public Involvement may be able to advise:
http://www.crncc.nihr.ac.uk/index/patients/why.html
or consult INVOLVE:
http://www.invo.org.uk/

Ethics Committee members in particular voice concerns about the language and complexity of patient information documents as well as the burden on patients which may present barriers to recruitment.

“I suppose it depends on the nature of the trial and particularly with RCTs. Often we see very complex information (documentation for participants) often written by drugs companies, at times in very complex language. We try to find a way to help the applicants (researchers) to find a better form of language that enables people to give informed consent. So we’ll focus on that - the supporting documentation. Often with complex RCTs, we ask for a summary of the study to accompany a more detailed document…. Then it’s a question of thinking through what’s required of people and the likelihood of compliance over the duration of the study. If there are a number of interventions or their health status, physiological state, or mental health state has to be monitored over time, how intrusive is that? Is it going to cost them both in time and actual travel expenses? So thinking through those kinds of measures, so how onerous is it?” (Ethics Committee Chair)
5.2.1 Language
It is very important that you make sure the average recipient will be able to understand what you are trying to convey in your information documents and materials. Get service user input and pilot your information sheets at the beginning of the process if at all possible.

5.2.2 Content
Ensure you have included all you need to say about different aspects of the study. Be explicit about what is involved, time, flexibility of research appointments, feedback, potential rewards, possible benefits, information about help with transportation if appropriate. Transparency and honesty is key - the downsides as well as the potential rewards (e.g. stopping a trial early) need to be openly explained too, with clearly explained support information about how such events may be dealt with. Service users will be able to help assess the content of your information leaflets.

5.2.2.1 Tailoring to target group
Focus groups can be very helpful to enable you to tailor your information to your target group. You may need to do confidence building (hard-to-reach groups in particular) to ensure they are comfortable with the idea of the research and explore ways to frame the research in terms they can understand, avoiding misperceptions. In a sense this applies to both collaborators and participants.

“Misperception, which is a broad phrase for ‘they don’t understand what we want’ can be a problem. It is study specific, but is both at the recruiting practices stage and the recruiting patients stage. An example is nurses who don’t really understand a Phase Four trial. When they receive a request to be involved in ‘research’ they’re thinking, very understandably, about licensing trials whereas in a Phase Four trial you’re often far more pragmatic, far more flexible in how you wind up running the study. A Licensing Trial (by contrast) is incredibly rigid .....” (Trial Manager)

5.3 Appearance: style and colour
Decide on typefaces, type size and colours of written materials (inks and paper) so that your study is instantly recognisable to recipients. It may be helpful to consult someone with expertise in graphics and communication. You can also use the input of AMRC members to support this process e.g. The Multiple Sclerosis Society which provides specific advice on how information should be presented to support people with MS who have problems with sight.

5.3.1 Contact information
Be sure to include the correct contact information on all your communications, with names, emails, telephone and fax numbers as required. Ensure that participants are given clear information about their recruitment site, especially if it is not their usual health centre. Include a map, transport details, information about parking and telephone number(s).

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10 See, for example http://www.campaignforplainenglish.co.uk/
11 AMRC is the Association of Medical Research Charities – see www.amrc.org.uk
Chapter 3. Recruitment Plan

1. Study Manual
Establish a study manual. This is for the research team as well as collaborators and facilitators. The manual should be an easy reference folder, containing the most up to date protocol, information sheets, agreements, schedules for payments (if any), standard operating procedures (SOPs), especially for recruitment, inclusion and exclusions criteria, samples of data entry forms and instructions and contact details for the research team. The recruitment plan (with targets per recruitment centre) should also be in the manual.

“The easier you make it for people, the easier you get recruitment. So we are doing a study at the moment, which is this multi-centre trial .... We’ve got a nice simple clinical data form: the procedures seem to work well - procedures that have been used previously in the observational study that most of the GPs have done. And so recruitment for that seems to be going well, I would guess part of that is relatively nice, accessible paperwork. Anything that makes it less acceptable for patients or for doctors, whether it's the procedures or the intervention, hampers recruitment I would say.” (Chief Investigator)

2. Time-scales for recruiting collaborators and participants
The time-scales for recruitment which are set out in protocols are usually based on some feasibility work and a best guess. It may take longer than expected to recruit collaborating sites and it often takes longer than anticipated to recruit participants. For centres, it can be worth keeping a waiting list of interested parties or practices if you already have sufficient numbers to begin with, in case any fall away due to unforeseen circumstances.

“In the run up to it we actually ran lots of qualitative work with patients and the practice staff to try and get their perspectives on what we were doing, both in terms of intervention and our recruitment methods. .....We had a user group, the patient group. We also ran focus groups with the target group and interviews with people with (illness/condition) and so forth. For a year we did this to try and get their perspectives. It was clear - they all warned us how difficult it was going to be - and they were right.” (Chief Investigator)

2.1 Staggered recruitment
There are two ways of staggering recruitment – by centre and by monthly targets. Firstly, it is often a good idea when starting a study to stagger start-up of centres by starting with one or two ‘early adopters’. This can help in terms of management of recruitment queries or fine-tuning processes before you bring additional centres on-stream. It gives the opportunity to develop clearer instructions if needed, so that centres coming on stream subsequently have the benefit of the ‘early adopters’. Secondly for all centres, it is wise to set the targets for the first few weeks or months lower than the weekly or monthly average, to enable collaborators to get used to the processes and incorporate the study into the centre. Successful recruitment breeds positive attitudes and encourages continued participation. If targets are set too high initially and then not achieved, this can demoralise centres and study facilitators, leading to disenchantment and abandonment of the study altogether.

2.2 Recruitment variations
There may be a number of factors which could affect recruitment levels of both collaborators and participant - some general (e.g. season), and others more specific. Examples of factors affecting
recruitment of collaborators could be high activity seasons like flu vaccination times, or new local NHS initiatives being imposed which create extra work for staff. Examples of factors affecting participant recruitment include ethnic make up of the population likely to impact attendance, such as festivals and customs. And if the study is multi-centre, there may be different variations to take account of in different regions. Knowing what these might be can help with planning.

3. Recruitment arena
Investigators wishing to recruit in primary care might be well-advised to consider whether general practice is the best study recruitment arena or whether alternative contexts may produce greater participation. Recruitment planning should include an exploration of alternative options. It might be possible, for example, to achieve recruitment by directly targeting specific groups or communities or utilising NHS organisations other than general practice.

3.1 Alternative recruitment arenas
It’s worth thinking ‘outside the box’ about alternative recruitment arenas. Community pharmacy, care homes or general dental practitioners, for example, could be alternative research recruitment locations. Some research organisations, especially commercial ones, by-pass primary care and recruit direct to the public via radio or press advertising. Some researchers have successfully recruited through community organisations such as faith groups, voluntary or non-governmental organisations, libraries, YouTube, Facebook, leisure centres or supermarkets.

4. Feasibility
Feasibility work for recruitment usually pays dividends, although it can be time consuming. Feasibility may involve assessing how many patients might be available at centres and piloting recruitment procedures as well as study information material. Piloting information sheets with a sample of NHS clinicians and a sample of lay people is worthwhile because how your study is perceived by those you approach will have a direct impact on recruitment and therefore on recruitment planning.

“Just sometimes that a GP will say, ‘Oh yes I see hundreds of patients’ ‘... yes, I can recruit X number by ...’ and then when it came to it they just didn’t show up for that particular bit. Sometimes I know it’s because they like to say they’ve got more patients suitable than they really have, but actually I also do know that there are just times that the right sort of patient is suddenly... you know, they disappear into the woodwork and they’re not there to be recruited.” (Chief Investigator)

4.1 Prior to study being funded
Pilot work undertaken prior to securing study funding can have two benefits. It can test the feasibility of the proposed recruitment method, and it can strengthen the application for funding. Feasibility undertaken prior to funding may be carried out with a centre which is already very experienced in collaborating with researchers. However recruitment forecasts extrapolated from pilots can be over-optimistic, as such centres may respond differently to centres where research is not a mainstream activity.

“But you know, pilots are often done in practices that are enthusiastic and keen, and there’s a lot more detailing really. There’s a lot more contact with the practice when you’re actually going in and talking to them and preparing the pilot.” (Chief Investigator)
“We took local conditions into consideration, and even with our feasibility phase where we approached a small number of practices to estimate our recruitment rate to just double check what we thought we might achieve. Basically our recruitment has been slower than we outlined in our proposal and found in our feasibility phase. So if we were assuming a particular rate of patients referred every month by practice and therefore targeted a certain number of practices at the outset, we’ve had to at least double the number of practices that we’ve taken on board the study for extra support, because the rate of patients referred per month is much, much lower than we would have expected.” (Trial Manager)

4.2 Pre-study implementation
A further pre-study implementation phase with less research-oriented centres will ‘road-test’ recruitment processes and may pave the way to smoother induction into the study.

5. Participant accrual targets month-by-month
Recruitment targets do not need to be the same during all phases of a study. When planning recruitment, many teams make the mistake of setting their monthly targets per centre as an average derived from the target total divided by the number of months. This can have a demoralising effect early on, as it is often in the first couple of months that teams are teasing out the practicalities in their recruitment processes. A graph of anticipated recruitment is useful so that the study team can plot actual accruals against anticipated targets. They can then see at a glance what the current position is. It’s worth having a plan in place to take action if the actual accruals fall below a certain pre-set level (see contingency plans 6. below).

5.1 Set-up phase targets
It is wise therefore to consider whether there is likely to be a slow start up as centres get used to the requirements of the study and incorporate this into targets, by increasing the target rate once the study has ‘bedded in’.

5.2 Forecasting periods of low recruitment
In addition, the recruitment time-scale should take account of likely impacts of variations such as seasons, religious festivals, holiday periods, and periods which may be particularly busy for NHS institutions (see 2.2 above)

6. Contingency plans
Contingency plans for dealing with low recruitment could include plans for inadequate collaborator recruitment or drop-outs, low participant recruitment, and changes in study facilitation staffing levels. What steps can you take to minimise such challenges?

6.1 Anticipate barriers/shortfalls
There are several ways to plan for and tackle low recruitment. By formulating contingency plans within the protocol, teams can avoid delays compared to doing this post hoc because it will remove the need to get ethics committee and funding body approval for the changes. But even with such contingency plans in place, the reality on the ground can call for additional rescue solutions.

6.1.1 Rescue recruitment
If investigators have thought about potential issues, they may have plans in place to deal with them. Sometimes shortfalls in recruitment are due to problems within the collaborating centres, and other times it is to do with the pool of participants. It is important to identify which. One way
to improve recruitment when the cause is located as being due to collaborator factors might be to offer education sessions to GPs.

“We put on a lunchtime seminar series (‘drop-in’ sessions) where GPs were invited to come for a free lunch, see some very short presentations - not just the study I am involved in, but other (specific topic) health studies. A free lunch, a chat with all the researchers, I suppose a kind of problem discussion session, so they could tell us what they could see were the barriers there and ways that we might be able to overcome those. They were well attended.... As a result, certainly, some of those practices have been able to give us patients.” (Trial Manager)

6.1.2 Detecting and troubleshooting problem areas
Study co-ordinators and facilitators may help keep recruitment barriers and short-falls to a minimum by developing good relationships with collaborators, keeping in touch on a regular basis, and checking intermittently that everything is going all right or by checking whether there are issues of clarity or particular local barriers that the centres have encountered. Detecting and troubleshooting problem areas can by assisted by planning regular contact. For centres where recruitment is proceeding well, this will be less important, but it is still good to keep in touch. Some stake-holders suggest recruitment plans should have some flexibility to accommodate local collaborators’ needs.

“So just trying to find flexible ways of offering new things to the GPs and their staff, to try and encourage them to help us recruit...... Still we weren’t getting the numbers we needed. So we had a think, and we decided that perhaps there was something about the way the GPs felt comfortable or uncomfortable about bringing up the topic of a research study with the patient who has a new episode of (illness). They would like to promote our study, but actually they found due to time constraints and perhaps not knowing quite how to do it, or quite how to explain the study in the easy way I would, because I do it every day, perhaps that was making it difficult for them to do it. So we decided the easiest way, both in terms of logistics and perhaps least invasive way for the GPs was to offer a series of seminars on the study and on recruiting to primary care and (specific topic) trials in general.” (Trial Manager)

6.1.3 Widening Collaborator Pool
Even if the initial target number of collaborators has been attained early on, it is worth having a ‘waiting list’ of centres, so long as you make it clear that they may not be needed for the study. It is also worth gaining permissions for research to take place in additional localities, so that recruitment can be extended geographically if required. Networks such as NIHR PCRN and MRC GPRF may be able to assist with widening the pool of collaborators. They will be able to identify local networks or practices which have capacity to undertake additional work. Other solutions could be to shift to a different group of collaborators or a different recruitment process (see 3. and 3.1 above)

“We’re now adopted by the NIHR CRN and we are in the (topic-specific) Research Network and the Primary Care Research Network, so we have been able to establish links with research nurses employed by those networks, who are able to do some of the work out in the practices. So they make the initial contact with the practices, they do the small amount of administrative work that’s necessary to send out the invitation, and that’s certainly been very fruitful. The networks, of course, have only relatively recently been established, and actually having people in post to do that was quite slow. I think if we were starting afresh now, we would be in a much stronger
position to get more practices in a shorter time, because these networks are established now.” (Trial Manager)

6.2 Revising approaches to participants – Learning from experience
Sometimes it seems no matter what you do, the pool of potential participants disappears just when you start recruiting (‘Lasagna’s Law’). Is the patient information sheet fit for purpose? It may need to be revised with lay-person input (as mentioned above, Chapter 2 section 4. PPI in the preparation of such material should have occurred when planning the study). Is it something about the way the study is explained? Who is explaining the study to the potential participants? Do they need training in how to approach them about research? Is it that they are just too busy and the only way is for a study facilitator to be involved? It’s worth discussing with the study team, research network facilitator, practice staff involved in helping you, to ascertain how you need to revise your strategy. Could it be that appointment times don’t fit in with the lifestyle of your target population? Or do they need help with travel arrangements? Could assessments be carried out in patients’ homes or at another convenient location? But if it is something more fundamental, such as needing to adjust the inclusion and exclusion criteria or allocation to treatment, you may need to amend the protocol.

6.3 Amendments to protocol
Changes to protocol will need approval of ethics committee(s) and funder(s) unless they are part of a contingency plan already stated in the protocol. If radical changes are needed, a protocol variation needs to be agreed, and this will take time and delay recruitment even more. For this reason it is worthwhile considering contingency arrangements at design stage.
Chapter 4. Recruiting Collaborators in Primary Care

1. Characteristics of suitable collaborators

Before you start recruitment it is worth thinking about the characteristics you require from your research collaborators. Who should your collaborators be? Is general practice the most suitable, or could you recruit equally well from community pharmacy or another community organisation? Do you need a centre which has previously undertaken research, or your kind of research? Do you need a certain amount of space or resources, for example an interview room? If a general practice, is the practice manager the best person to approach initially, or perhaps there is a GP in the practice with a particular interest in your topic.

2. Incentives: Why should they be interested?

To get organisations to collaborate you need to think about incentives. What is it about your study which will ‘sell’ it, particularly to the clinical staff? Would it be helpful to get the endorsement and support of the PCT first? How will you do this? You need to think about the topic from the service perspective (‘good health now’ rather than research), and what your study might offer them in addition to their costs. What can you offer the clinicians, the patients, or the practice, whether in the form of direct or indirect benefits? Would it be helpful to badge benefits under simple dimensions such as advantages to patient health; profitability and workload, as has been suggested by one informant? Will less experienced practices be more likely to collaborate if offered support or buddying by a more experienced practice? Furthermore, might there be barriers at service organisation level? According to one funding body representative, one key barrier to recruitment is lack of local PCT support which may hinge on real costs to the Trust, such as excess treatment costs.

“Well, there’s a third level which is the organisational one, which is the support, .... potential support from PCTs, and crucially the excess treatment costs are a problem. They can be a problem especially in the situation of primary care where the PCT itself may have to directly fund one of the interventions, shall we say physiotherapy or something like that. So if the PCT is required to take on additional staff to make the thing take off locally then that becomes a potential real barrier. So we’ve certainly seen trials that have struggled where there’s that (barrier). But at an individual practice level, I guess there are two things: one is you do obviously need a champion in the practice who’s interested enough to do it and if there is, that’s a big help. But crucially -- it may be a bit better now, but I think the main problem we’ve seen is that GPs particularly have just had other priorities, particularly sort of management priorities that they’ve had to deliver on. So - to slightly over simplify it - GPs have had much higher priority for delivering on the Quality and Outcomes Framework, for instance, than the recruiting to trials. And there have been some situations where one has seen very really highly engaged practices, largely because there has been a little bit of funding - not necessarily a major profit but a bit of funding - to at least cover their costs, and where they’ve seen this as absolutely integral to some of their sort of ways of working.” (Funder)

How relevant is this research work to them? Are you able to clearly convey the uncertainty about treatment outcome (equipoise)? Ask a friendly clinician who is not involved in the study what it is about this research which others might be drawn to and whether your explanations are clear. If you have piloted your research, you may be in a position to state the benefits more unequivocally. If new to research, it may be helpful to offer support from a ‘buddy’ practice which has experience.
“I suspect that one of the reasons that some of them were easy to recruit to is that the topic was of considerable interest, both to practitioners and patients and that gives you a synergy of recruitment, where there was no problem at all. So the x trial for example, once we had established which practices were likely to recruit, the recruiting was not difficult... Recruiting patients was beyond our expectations, as their response rate was in the 80% in a very complex and demanding study.” (Chief Investigator)

2.1 Direct benefits
Direct benefits are worth stating clearly when you approach centres asking for their help. Will your study provide an additional service, or positive impact on the general practice drugs budget? Will it produce information which is useful for practice audits or QOF indicators? Can you offer payment to reimburse staff for the time they spend helping you to run your study, and if so how much? As a result of involvement, will study participants benefit from extra care, early access to novel treatments, additional time and monitoring? Could their involvement in the study decrease their demands on appointments and even reduce their need for prescriptions? Some very research-active practices state that screening their lists for potential participants produces an unintended benefit - that they become alert to patients needing follow-up action. So not only can potential participants benefit, but other patients can too.

“The only incentive I have to say, the one that works the best - and it’s a sad but true fact - is extra money, and that’s true for both GPs and hospitals. It’s very interesting how when a centre goes, ‘No, we absolutely do not have any more patients’ and then you go, ‘How about another X pounds if you can find them?’ and miraculously patients do appear. So, yes, financial incentive definitely does work.” (Trial Manager)

2.2 Indirect benefits
Indirect benefits may follow involvement in your study. How can you sell these to potential collaborators? For example, research as an opportunity to do something a bit different from day to day duties, having a positive impact on how the centre organises itself, or offering clerical staff variety in their day-to-day tasks. Collaborators may feel more motivated if they feel their patients involved in the study may feel generally more cared for and this could have subtle effects on how they use or view the centre services. Your study could provide additional equipment for the centre to keep after the study is finished. Some research teams issue a certificate for participating and a certificate of excellence for reaching ‘on-target’ recruitment. Other indirect benefits include opportunities for altruism, professional development, and training.

“And then also, think about how your presence in the research team can affect the practice, and if there's anything positive you can give back. So often with our research training for the nurses who take part in the studies, we're ensuring that they're being trained in taking consent to a GCP level. They're getting something back, going away with a skill.” (Chief Investigator)

2.2.1 Altruism
Many people feel good about helping others, even if they derive no direct benefits themselves. You could say altruism instils feelings of self-worth through social contribution.

2.2.2 Professional Development
Your study could inspire staff to find out more about research, grow their own interests in a topic or have access to experienced researchers who might be willing to advise or mentor them. Your unit may be able to offer access to training on research or on the research topic as a way of
increasing skills and knowledge. For example the NIHR CRN run various free courses/workshops for staff involved in NIHR CRN portfolio studies - http://www.crncc.nihr.ac.uk/index/training.html

2.2.3 Offering training on approaching potential participants
It can be difficult for clinicians to approach patients about research within a consultation if research is not part of their usual activities. To improve the likelihood of collaboration, some stake-holders have found it useful to offer training to collaborators on how to do this (see footnote 9).

2.3 Honesty about costs (time, disturbance, discomfort)
As much as it is important to flag up potential incentives, it is also important to be clear and honest about the amount of time and disturbance the study may cause to both healthcare staff and to the patients of the organisations.

3. Collaborator Identification
You may identify potential collaborators through intermediary organisations or contacts, using databases or online resources. Here are some examples.

3.1 Collaborator Identification using Research Networks
The NIHR CRN Primary Care Research Network http://www.crncc.nihr.ac.uk/index/networks/primarycare.html and the MRC General Practice Research Framework http://www.gprf.mrc.ac.uk/ have wide geographical coverage and know a lot about practices in the areas where they operate. Some have information about other primary care organisations such as community pharmacy or general dental practices. Their assistance may enable you to achieve a higher collaboration ‘hit’ rate than you would get by cold-canvasing. Research networks help by pre-selecting target primary care organisations for you based on your needs and on their information about their membership. You should speak to them about your needs and they will advise you. Depending on their resources, they may approach centres on your behalf and introduce your study for you. Commercial networks may also be useful, especially contract research organisations (CROs) which operate in primary care. However, they will charge for their services.

3.2 Identification using NHS Information Services
If you do not wish to use networks or you wish to approach organisations which are not linked to research networks, you can find out about practices, community pharmacies, general dental practitioners from online Government sources http://www.govemment-online.net/primarycarerecontacts.html or by searching for services through NHS Choices website at ‘find and choose services’ http://www.nhs.uk/Pages/homepage.aspx or from which is an online resource from the National Health Intelligence Service http://www.nhis.info/.

3.3 Identification using commercial resources
Commercially available databases which list NHS services can be purchased. This approach is most often used by industry research organisations. (See, for example, http://www.binleys.com/Products.asp?CatID=1)

3.4 Targeting
You may be able to target groups of potential collaborators by attending group events, conferences or through suitable website publicity. For example you could request a platform to approach newly qualified doctors through local ‘vocational training schemes’, special interest
groups or at educational events or conferences run by Primary Care Trusts or local research networks.

“So often it’s the disease area they’re interested in. So for example, we recently recruited for a study looking at (illness) and it was overwhelmed. It resonated with the clinicians, but also, they feel that the research is very integrated into clinical practice. They can see the direct link.” (Chief Investigator)

3.4.1 Targeting through Vocational Training Schemes
The local medical schools or deaneries should be able to provide you with contact details for local Vocational Training Schemes (or you can search for them on the internet). These schemes are aimed at GP registrars and provide them with training and forums to discuss different clinical issues. You may be able to schedule in a visit to present your study.

3.4.2 Targeting through PCT Events
Most primary care trusts run a programme of training for their staff including whole days attended by a range of primary care professionals from nurses to community pharmacists and general practitioners. To find out about local programmes and the possibility of presenting your study, you can contact the local PCT Training Co-ordinator or Manager.

3.4.3 Targeting through Research Networks
The NIHR CRN Primary Care Research Network has eight local networks in England, and there are three others in the devolved nations (Scotland, Northern Ireland and Wales) http://www.crncc.nihre.ac.uk/index/networks/primarycare.html. It is worth asking the local networks about their conferences and other relevant events where it may be possible to publicise your need for collaborators by having a stand, a poster or giving a presentation. The Medical Research Council General Practice Research Framework is another very helpful network: http://www.gprf.mrc.ac.uk/

“The other thing of course that’s really made a phenomenal difference in the last two years, has been the local research network and I think (local area) has, what seems to me to be, one of the best and one of the most developed set of skills and people ..... It really made me nervous a couple of years ago, that, you know, they were going to be recruiting practices and not me. I mean, I know how to recruit practices for my studies, and to give that task away to somebody else is really nervous making. But it has turned out to be a Godsend, because the people there beat the bush, and they have the advantage of being sort of, seen as a neutral broker.” (Trial Manager)

4. Requesting help from NHS Primary Care Organisations
When planning to ask primary care organisations for help, it is useful to know how they work, who the key members of staff are and how best to approach them. This may vary from centre to centre. It is also helpful to have a clear plan of action, appropriate documents and incentives.

4.1 First steps
You need to have clear, brief information about your research, which will be of interest them and grab their attention (see below). You should also have a clear plan of action, whether this includes assistance from a research network, a research champion or other resource. It is useful to have a project recruitment plan which includes how you will make your initial approach (by telephone, letter, fax), when you will follow up your initial contact, how, and how many times before abandoning your attempts. For most general practices the practice manager is the best initial
contact. They can tell you about the structure of the practice, whether any particular staff has an
interest in research, how they normally deal with research requests, and whether it would be
possible for you to visit in person to discuss your research. For other primary care organisations it
is worth calling to find out who you should speak to, for example a care home manager or
director, a senior general dental practitioner, or community pharmacist. It is worth asking how
they would like to be approached and to whom you should address your communications.

4.2 Meetings
It is important to realise how busy healthcare organisations are and that getting a meeting may
require considerable forward planning. Getting through the door may be difficult, so the input of a
local champion who is known to the organisation may help to secure a meeting. Even if an
appointment is agreed, you cannot count on getting much time as urgent clinical issues could
intervene. Remember their focus is on good health now. Research may be regarded as competing
with much more important priorities, unless you can demonstrate its potential benefits and you
may need to get your message across in very little time.

“I think many practices get approached constantly by all sorts of different studies and we
recognise that they can’t do everything. So they have to be driven partly by what interests them,
partly by what’s feasible, logistically, and presumably by the strength of the arguments and
whether they actually believe the study is a good one, being well run and it’s appropriate for
them to take part in. There are an awful lot of pressures on practices, and equally we recognise
that they have finite resources and can’t devote a lot of extra time to research.” (Trial Manager)

4.2.1 About general practice meetings
Although they hold regular meetings, these are frequently held at lunchtimes, planned in advance
and run to a tight schedule. Be aware that research time-scales may not fit with the clinical world,
and a meeting to present your study may not be able to be scheduled at short notice. Always ask
how much time you can expect to be allocated, and be prepared for this to be truncated.

4.3 The approach
Your approach will depend on the study itself. It will depend on whether you are using a research
network to help you and/or a local champion. Many researchers find a carefully planned approach
is useful. This may consist of an initial phone call to establish the best person for initial contact, a
faxed or mailed information sheet with covering letter and reply slip to indicate interest, followed
by a further call to chase and hopefully set up a meeting. Research networks such as NIHR PCRN
may help with these activities.

4.3.1 Use of local champions/experts
A number of research units recommend deploying ‘champions’ who are people of standing in the
local community to help them recruit collaborators. These champions find it easier than outsiders
to set up meetings at NHS sites (or in some cases in community organisations) and add weight to
your request for involvement. A champion may be a clinician who is known locally, from the
medical school or post-graduate training, or they might be a network or community organisation
representative with a relationship to centres or network membership. However, if the champion is
a clinician you will probably need to pay for their time, which can be costly.

4.4 How to convey study information
It is really worthwhile thinking carefully about how you present study information to
collaborators, both in terms of content and format. When making your initial approach, remember
you are contacting very busy people whose priorities are unlikely to include research, and who may be having to deal with multiple demands on their time. Some industry organisations who undertake research recruitment use social marketing to understand their target group (in this case, their collaborators) and how best to appeal to them. They then use the services of communications experts to advise them on how to present the study information.

4.4.1 The message with impact – keeping it brief, clear and simple
Experienced researchers agree, that the presentation of the initial message is of paramount importance. You may have only a few seconds worth of reading to grab the recipients’ attention, before your letter or fax goes in the bin. Keep if brief, clear, simple and eye-catching. Think ‘marketing’ not research. Think colour, style, impact and topic. What is it about, what are the key messages, what will it mean to the practice, the patients, in terms of rewards and incentives? Have you clearly explained equipoise? It’s best to send a very short covering letter (with tear-off reply slip or SAE) to introduce the study highlighting key points about what’s involved and the incentives. Attached should be more detailed information sheets to read, should you have succeeded in grabbing their attention.

4.4.2 Information sheets
A lot of preparatory work should have gone into information sheets. It is really helpful to have identified key issues which are important to the recipient, and to have double checked these by getting input from clinicians who are not researchers. Language should be clear and unambiguous, and present enough information about what the study involves, from both scientific and practical perspectives, what collaboration will involve for the centre and for the participants. Include contact details of the research team.

“When you’re going in and you’re identifying your practices, there’s all the standard stuff about making your literature clear, concise, comprehensible, making sure you’ve had feedback from appropriate - I was gonna say lay-people - but .... clinicians like me, who say actually, if I got this information on my desk, it wouldn’t encourage me to take part or not. I’ve had a lot about that.”
(Chief Investigator)

4.4.3 Scripts
Whether you are presenting the study at a meeting or this has been devolved to someone else in a research network, it is helpful to have a script, to ensure the approach is standardised and all key elements are mentioned.

4.4.4 Posters
Posters which invite participation can be prepared, particularly for display at training events, such as those run by PCTs or as part of VTS schemes. Again, these need to be clear, eye-catching, with contact details of the research team.

4.4.5 Video clips, podcasts and web-casts
Depending on the size, duration and funding for the study, it may be helpful to prepare a short, multi-media presentation to publicise the study and invite collaboration. This could be given to busy practitioners to view in their own time, be part of a presentation at a meeting, or be made available on the internet.

4.5 Support material
Some research units find it helpful to supply additional material to support their request for collaboration, which may incentivise participation or act as a reminder. This support material
could be linked to the study topic or be promotional material with the study name, logo and contact details.

4.5.1 Information linked to study topic
Information could include references to related research articles, treatment guidelines, lists of online resources, contact details for experts in the field, training events and conferences.

4.5.2 Peer support groups or resources
You could offer networking opportunities, such as by offering to put collaborators in touch with other collaborators. If they are not already members of a research network, you could give them contact details of their local PCRN. Additionally, you could guide them to resources to assist participation, such as those provided by the NIHR CRN Training division – see http://www.crncc.nihr.ac.uk/index/training.html

4.5.3 Study promotional material (e.g. mugs, pens etc)
A number of research units and organisations provide study promotional material such as mugs, pens, mouse mats, ‘post-it’ notes, with study logos, website, and contact details. These can be useful as reminders to collaborators, particularly for studies being conducted over a number of years. It might sound trite, but they can also help collaborators feel part of a joint effort and give them a sense of belonging to an altruistic endeavour.

4.6 Anticipated roles of primary care staff in the study
Many experienced primary care research units find it useful to limit their demands on the primary care team. In theory the collaborating team could take on a number of activities, which will be study and resource-dependant, such as explaining the study, consenting the patients, or data collection. Whatever their anticipated roles and responsibilities, it is important that these are clearly defined, and those with responsibility have sufficient training to carry out their allocated tasks (e.g. ICH GCP). Unless collaborators are very interested in the research, or have dedicated time, it usually pays to minimise their study workload. Some research organisations feel recruitment is optimised when they delegate all study related tasks to research nurses, research assistants or network clinical studies officers.

“We don’t ask the GPs to actually recruit as such, we ask them to refer(to the study team)...... we really do the majority of the explanation around the study, we take consent. So what we were asking the GPs to do was understand why we were trying to do the research, identify possibly appropriate patients who came in via consultation, and mention and promote the study, and the value of taking part in this kind of research, to patients...and really just give them a short information leaflet. So we tried to keep the amount of work for the GP to a minimum.” (Trial Manager)

4.6.1 Who will explain the study?
Who will explain the study to potential participants? This depends partly on how the participant is identified in the first instance (see ch. 5). When clinical staff members are given responsibility for explaining the study, they can benefit from training in how to raise the issue of research within a consultation (see chapter 2, above). For academic studies it is quite usual for the GP or nurse to flag up the study. Interested patients are then referred to a member of the research team, research hub or a research network study facilitator. Some research active practices have staff members with dedicated research time. When patients are identified as eligible, the patient will be told very briefly that a study is taking place in the practice, that they may be suitable, and then
they are passed on to the research-active GP or more usually nurse, who will explain the study in detail.

4.6.2 Who will consent the patients?
Informed consent is very important, so it is worth thinking through who takes the role of gaining informed consent. If it is a member of the collaborating team, they should be trained to do this. If offered training, this could be regarded as an incentive. For information on informed consent, visit: http://www.nres.npsa.nhs.uk/rec-community/guidance/

4.6.3 Research interventions
Who is the most appropriate person or people to carry out the research intervention(s)? What exactly is expected? Is additional training needed, and where and how will it be provided?

“A barrier to recruitment is that, for example GPs may - if they feel that what's being asked of them is too onerous as the gate keeper - may refuse to help the researchers and therefore it obviously has the potential to impact on the ability of the researchers to recruit adequate numbers.” (Ethics Committee Chair)

4.6.4 Data collection
Many experienced research units suggest that if at all possible someone other than the GP or clinician should collect and record the data for the study (unless they are particularly interested or have protected time for this). If collaborating staff are to collect study data, this should be made as easy as possible in terms of forms (CRFs), submission and storage.

4.6.4.1 Data entry/Clinical Research Forms (CRFs)
Before you start, make sure the forms for data entry are easy to use and can collect all the information you need (pilot them first). Online data entry can be really useful, as it avoids the need for mailing or storage. You may need to train staff to use the data entry tools. Do staff members with responsibility for data entry understand the importance of meticulous record-keeping, dating and signing any corrections or amendments? Do they know what the study team expect of them? Be clear about how paper forms are stored.

4.7 Key contacts
It is useful to have a key contact at the practice who deals with all research-related matters. You should discuss this with the practice manager, outlining what you envisage their role would entail. Once identified it is worth explaining the research to them and getting them to alert their colleagues to direct any research related queries and issues to them so that they can liaise with you.

4.8 Agreements
It is useful to draw up agreements or memoranda of understanding to ensure everyone is clear about roles and responsibilities.

5. Mode of communication: Mail, Fax, Email, Telephone
Each centre has their preferences about being contacted. If by telephone, ensure you have a number which is not the same as the line for patients. You should also make it clear to the practice how you prefer to be contacted and provide contact details and instructions, e.g. on faxing back recruitment interest forms or secure mail for consent sheets and data forms.
6. Building Relationships
Most experienced researchers agree that good interpersonal skills are essential to ensure you build good relationships with collaborators. Building good relationships start from the first encounter. Experienced primary care researchers suggest regular contact by phone or in person, to ask how they feel the research is going in their centre, whether any difficulties or problems have been encountered and what could be done about them. If this is done in a friendly, flexible but professional manner it can help to identify problems early so that action can be taken. Their experiences of collaboration may affect their future willingness to participate, so it is important that their dealings with research team members are constructive.

“(There are) so many pieces of research going on in primary care, that it’s very easy for them to mix up one trial, one piece of research with another, and so I think having this ongoing - even via e-mail - communication helps. ...And I don’t just communicate with them via e-mail, that’s just a basic every month, standard thing. I try to almost make reasons to ring their practice managers.” (Trial Manager)

7. Follow up to initial approach
How long should you wait after your initial letter to make follow-up contact? If you have been to a meeting to explain the study, how long should you wait until you contact them again to ask what they have decided? How many times should you follow up?

7.1 Phone calls/fax/visit
Decide on the follow up strategy. Will this be by phone, fax or personal visit? If potential collaborators cover a wide area geographically you may not have the staff for personal visits, but if your contact has been facilitated by a research network such as PCRN, they may provide staff to do this on your behalf.

7.2 How many times?
How many times should you follow up? This all depends on your study plan as well as the actual interactions you have with potential collaborators. If you have started to build a good relationship it is easier to judge how much effort to put into this. There may be genuine reasons why you cannot speak to the appropriate person to get their decision or they may be fobbing you off.

8. Payments: who, for what, and how much?
There are centres which are willing to collaborate without financial reimbursement. This is usually when a study is thought to be important or confers rewards other than financial. Many organisations will not consider collaboration without payment, as research is not a core activity for primary care. A schedule of payments needs to be worked out in advance. Work out who will do what, for how long and how many times, to calculate how much you should pay. Are you going to pay a fee for service or a flat rate, or a use combination formula? Will payment be made regardless of numbers of actual patients recruited, or only on the basis of how many enter the study? What about withdrawals and drop-outs? Does an invoice have to be produced? Can you prepare invoices for them to save them time? How long will it take from receipt of invoice to payment? Centres may feel hard done by if only paid for subjects entered if they have put a lot of time and effort into trying to recruit participants who still decline or are unsuitable. Even when payment principles are clear to all, a failure to pay promptly can cause alienation and wreck any chance of future collaboration.
8.1 Examples of payment calculations
Payment may be a simple flat rate fee for agreeing to collaborate, such as £425 in the hope the practice will produce 40 participants. This payment is decided on the basis of anticipated activity. So for recruitment of 40 participants involving the practice manager, clerical staff, nurse and GP time, you might calculate as follows:- searching the records: 2 hours x PM @ £25 per hour; production of list for screening + mail out on behalf of the researchers: 5 hours x clerical @ £15 per hour + screening of list before mail out 1 hour x GP @ £50 per hour, + explaining the study and consenting patients @15 mins per patient – 40 x 15 = 10 hours by PN @ £25 per hour: TOTAL = £425. Another option is to pay a fee for agreeing to collaborate, say £150 plus a £7 per patient recruited. Alternatively you might suggest practices keep a record of staff time spent on various activities and you reimburse them for this. If taking this approach it might be difficult to keep to budget, so this is not advisable.

9. Reminders
When an organisation has agreed to collaborate, how often will you remind them about recruitment, and how will you do this? Reminders can include phone calls, meetings, promotional material, newsletters and visual aids.

9.1 Meetings
Meetings may be useful to remind collaborators about study details, inclusion and exclusion criteria, or to discuss barriers to recruitment and ways to overcome them.

9.2 Visuals (diagrams and laminated sheets)
Many research units give out study sheets or laminated sheets with inclusion and exclusion criteria to help clinicians remember the study. They may be kept in the consulting room on the desk, but could easily be ignored or left in a drawer.

9.3 Promotional material
Promotional material such as pens, mouse mats or mugs with the study logo, website and contact details on them, may be useful reminders.

10. Time-scales
It cannot be emphasised strongly enough that it is vital to allow sufficient time to recruit collaborators. There are several issues affecting time-scales. The pressure of clinical care takes priority and even if meetings are agreed or replies are promised by a certain time, such plans can be derailed by workload. In addition, it is worth being aware of times of the year which are likely to be busy, such as when inoculations are being done, or the flu season, or times when practices are required to incorporate new procedures or policies launched by their PCTs.

11. Contingency Plans
If centres express an interest but cannot actively engage at one point in time, it is worthwhile putting them on a reserve list and getting their agreement for you to make contact again at some point in the future when they might find it easier to participate. But do make them aware that being on a waiting list does not necessarily mean they will be brought in to actively recruit.
Chapter 5. Identification of study participants

1. By-passing primary care
Is it really necessary or appropriate to recruit participants through primary care? Social marketing to understand your intended participants may reveal alternative pathways to participant recruitment, for example through the media, via community organisations, or using a commercial company. When advertising for participants it can be helpful to have a hotline number for people to call, manned by staff who ask a few screening questions.

1.1 The Media
Many contract research organisations (CROs) recruit participants by advertising through local media such as newspapers or local radio or community television stations. Some researchers have successfully used the internet to assist them, whether it is a study website or whether using social networking sites. This may be more beneficial than identification through health care organisations, but bias needs to be considered, and you may need to find ways to verify participant location and other demographic details.

1.2 Community based approaches
When planning the study or putting the protocol into practice, consider whether your target group will be easier to identify through local communities rather than general practice. Examples include faith communities, local clubs, community venues such as supermarkets, libraries, youth centres, and homes for the elderly or young people.

1.2.1 Alternative approaches to community health research
Is your research sample likely to be easier to attain by enlisting the support of a non-health organisation or a care home? If so, you need to identify the person at the top of the organisation who can make the decision whether to allow research and direct their communities to facilitate access. For example, in a care home for the elderly, the director or manager will need to agree and then direct ward staff to facilitate access to residents. If seeking to recruit from an ethnic group, a good starting point could be a local faith group or community group which fits your requirements. Remember to allow for a longer lead-in to recruitment, as negotiations take time and effort.

1.2.2 Communities which are hard-to-reach
Communities that are hard to reach can often most easily be reached via a team member who is part of that community and understands their networks, culture, barriers and incentives. How will you identify someone who can help you gain entry?

1.2.3 Community centres
Community centres may hold events or have regular meetings where it may be possible to publicise your research by an announcement, leaflets, a poster, or a presentation.

1.2.4 Community leaders
Community leaders are usually the gatekeepers. You will need to get their attention and agreement to facilitate entry to their community. They will be able to advise you about the best mechanisms. If consulted at an early stage, their input to the wording of information leaflets could be helpful.
1.2.5 Snowballing
Snowballing is a useful way of finding extra participants, especially from hard to reach groups. You can ask members of a self-help group for a particular disease if they know of others who might be interested in finding out about research participation. They can then act as your ‘champion’ to tell their contacts about your research and pass on your contact details or information leaflets.

1.2.6 Thinking ‘outside the box’
Recruitment may be easier if done within the context of a complementary initiative. For example, events may have been organised to educate a particular group about their condition, so try to attend that event and give out leaflets, or man a stand which explains about your work. Another possibility is to work with relevant organisations (such as voluntary organisations) to stage an event which will educate or inform your target group. The event could be a seminar about the latest research on treatments for the condition, where you can publicise the need for research participation at the same time. The good thing about this approach is that you can give something back to the community from the beginning. Another possibility is to work in partnership, for example with a commercial group, to gain ‘dual consent’ for studies to happen alongside each other as mutually beneficial to both private and public sectors.

1.3 Use of commercial companies (e.g. Contract Research Organisation)
Pharmaceutical companies tend to use contract research organisations (CROs) to deliver studies. Many have expertise in specific areas, dedicated, experienced staff, and access to specialist skills. Depending on the study, it may be more cost effective to use such an organisation to undertake the whole process of identifying suitable participants, advertising and explaining the study. These organisations often use a hotline which interested individuals can call.

1.4 Hotline number for triage/screening
Whether used by an industry or academic group for recruitment, it can be very helpful to have a hotline number. People who are considering participating can call in and find out more about the research without commitment. The hotline can also be a way of screening for suitability, thus preventing wasted visits by the study team/recruitment staff.

1.5 Triage to screen potential participants
A member of the research recruitment team can be allocated the role of triage. Standardised questions need to be prepared to reflect inclusion and exclusion criteria. This can be time-consuming, but save time in the long run.

2. Identifying Participants in Primary Care
For primary health care studies it is most common for researchers to recruit participants through general practice. However, thought can be given to other settings within primary care, such as general dental practices or community pharmacies. Eligible people who use these organisations can be identified in various ways, for example by searching electronic records, by identifying them in waiting areas, or during consultations. Researchers need to understand the importance of data protection, confidentiality and statutory requirements.

“I think there is a lot more concern about data protection issues. We certainly have a lot more queries from patients as to how we got their details, how come they’ve been invited, and that never used to be the case.” (Trial Manager)
2.1 Data protection and confidentiality issues
When planning strategies to recruit participants and how those participants are identified, researchers need to know about data protection and confidentiality of patient information. The MRC website has advice on this at its website:
http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm
and the RDForum has links to a document you can download which includes information on confidentiality, consent and data protection (see especially items 6.1 and 6.2 in the document):
http://www.rdforum.nhs.uk/021.asp

2.2 Retrospective electronic approaches
In order to identify potentially suitable patients to approach it is common to identify them through electronic records. Firstly this can be done retrospectively by constructing search strategies to enable a list to be generated of registered patients who conform to certain inclusion and exclusion criteria. At the time of writing the DH are conducting a consultation about views of clinicians, patients, service managers, stake-holder organisations and researchers about who can legitimately have access to records and who safeguards them. Research management and governance staff at NHS Trusts should be able to guide researchers about current policies.

2.2.1 Interrogating local primary care systems
General practices use one of a range of electronic operating systems. The most common are EMIS and VISION (see below 2.2.4). Within current guidelines and circumstances only members of the clinical care team may interrogate local primary care electronic records to search for potentially suitable participants. Searches usually have to be undertaken at each primary care site, and the list generated by the search has then to be screened by a clinician before the practice sends out prepared letters on behalf of researchers, inviting participation in the study. There are organisations which can construct a search strategy for researchers for use locally. Searches are usually compatible with the different operating systems. Currently a project is under way to develop secure remote interrogation, which would enable researchers to generate numbers of potential participants at any given site, with the list of patient details only being visible to practice staff for screening. Researchers who are clinically trained and have a substantive or an honorary contract at the practice are allowed to interrogate the system(s).

2.2.2 Legal barriers and solutions
The Department of Health is committed to research. In 2008 Alan Johnson, Secretary of State for Health, speaking at the health research summit hosted by the Prime Minister, stated that every patient in the NHS should have the right to take part in approved medical research that is appropriate for them, and set out the measures that will be introduced to deliver this commitment. The Government’s commitment to research is in the proposed NHS Constitution which was published for consultation on 30 June. Part of the DH’s commitment will involve setting the legal framework for researchers to be able to access patient data appropriately.

2.2.3 Disease registers
Disease registers are held by many primary care organisations. These registers could help researchers to identify patients – as a searchable resource. Registers may include: age, gender, diabetes, asthma etc.

2.2.4 Systems guides (EMIS, VISION etc.)
In order to interrogate electronic systems, researchers may need help. Although practice staff members know their own systems they may not have used them for the type of searches which
Researchers wish to conduct. Some of the systems have online guides or advice lines. For example EMIS have an online FAQ: [http://www.emis-online.com/help/faq/?Searches](http://www.emis-online.com/help/faq/?Searches) which includes questions about searches and VISION run training courses – see: [http://www.training.inps.co.uk/](http://www.training.inps.co.uk/)

2.2.4.1 List generation
Once records have been searched a list of potentially suitable participants is generated. The patient details should only be viewed by those with a legitimate right to see them.

2.2.5 Engaging the services of local personnel in PC
Researchers may need the help of primary care staff for a range of tasks related to research. These include searching practice records, screening lists, undertaking mail-outs on the researchers’ behalf, fielding queries about the study, sending faxes to the researchers, filling in basic forms, explaining the study, consenting patients and so on. Researchers need to be clear about the tasks, who will do them, timelines and level of reimbursement to be paid.

2.2.6 Screening lists of eligible participants
It is usual for a member of the PC Team to assist researchers by screening the lists resulting from system interrogation. This is to avoid letters about research being sent out inappropriately, e.g. to a recently bereaved patient. Once screened staff will inform researchers about the numbers of patients who will be sent invitations to participate.

2.2.7 Mailing out to potential participants
Mailing out is usually undertaken on behalf of the researcher by a practice receptionist, secretary or clerical assistant. Researchers currently do not have the right to see patient identifiable information. Therefore they need to prepare as much of the mail-out material as possible for practice staff to send out, including information sheets, provision of envelopes, labels and stamps. Some researchers report that practice staff members are inexperienced in ‘mail-merge’, so it is worth considering whether they can offer training as an incentive.

2.3 Prospective electronic approaches
Patients may also be recruited prospectively. This occurs during consultation. Programmes can be installed onto computerised systems to create an electronic ‘pop-up’ or ‘flag’ in response to specific data entry codes, so that when a clinician enters a certain read-code or string, a reminder flashes on the screen to discuss possible study participation with this patient. Care is needed with the message content as some messages may be ignored or become an irritation. If used, clinicians may need brief training in how to broach the topic of research within the consultation. They will also need an appropriate supply of study material such as Patient Information Leaflets, consent and enrolment forms.

2.4 Direct approaches within primary care
Direct approaches within primary care can be considered as ways to produce participants. These direct approaches might include a researcher on site in a waiting area of the practice, posters on display, TV feeds or video-clips, or receptionists giving out leaflets to attendees.

2.4.1 Negotiating access
Whether it is for a researcher on site, a poster to be displayed or some other local form of direct approach, it is very important to negotiate access and be clear what needs to happen and who does what. At general practices the most important person to approach for access is the Practice Manager (or senior receptionist).
2.4.2 TV feeds on site for research awareness
Many waiting areas now have TVs or videos. It may be possible to ensure a short video is played at suitable times when there are patients in the waiting room.

2.4.3 Researcher on-site
Recruitment is often helped by the personal touch. Arrangements can be made with centres for a researcher to be present in the waiting area. The practice manager and GPs will need to agree to the role of a researcher being present in this way. For example, some prefer it if the reception staff alert patients by giving out information and pointing patients in the direction of the researcher, others may be happy for the researcher to approach patients initially.

2.4.3.1 In clinics
It may be possible for a researcher to attend clinics such as baby clinics or asthma clinics to recruit patients as they come in. Clinic staff will need to agree to the role of the researcher present in this way as in 2.4.3

2.4.4 Posters on site
Notice-boards can be a useful way of recruiting patients. An eye-catching poster with researcher contact information should be displayed in an area which patients can easily see it and take note of the information. Generally it is helpful if a researcher gains permission to place any poster, as if this is left to practice staff they may not place it in the best position to catch people’s attention. You might want to ask receptionists about which area they think patients are most likely to pass by and notice.

3. What patients think
As much as having lay input to the development of specific studies and information materials is vital, it can also be helpful for teams to be aware of the views of participants who have actually participated in studies. The following links to ‘Healthtalkonline’ take you to interviews with patients about participating in health research:

Difficulties finding a trial to join
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3634/topicList
Why people may not be eligible
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3639/topicList
Appointments, monitoring, questionnaires
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3646/topicList
Communication between different health professionals
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3647/topicList
Feedback of trial results
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3649/topicList
messages to professionals
http://www.healthtalkonline.org/medical_research/clinical_trials/Topic/3655/topicList
Chapter 6. ‘Selling’ the study to participants

There are many things we can learn from commercial marketing that are applicable in social marketing. Although we are not ‘selling’ trials, concepts from sales and marketing are relevant to the questions asked about customer needs and satisfaction when trying to maximise engagement in our studies. There are many things we can learn from commercial marketing that are applicable in social marketing. Although we are not ‘selling’ trials, concepts from sales and marketing are relevant to the questions asked about customer needs and satisfaction when trying to maximise engagement in our studies.

“When we took it to a professional marketing company, they said well, it’s actually not clear what your study is about, really. .....because academics are very good at research. I mean, that’s what we do. That’s our bread and butter. You don’t necessarily have to be very good at marketing. And I think, sometimes we have to accept where our roles are and our skills are, and get the extra support when we need it.” (Chief Investigator)

1. Why should participants be interested?
Whether at design or operational stage, it is important to think about the perspectives of the potential participants. Why should they be interested in being involved? What factors about them as a person or about their personal or work situation may affect their interest, decision, and commitment? This may be the first time they have ever really been confronted with an opportunity or invitation to get involved in research. It may be a difficult time due to their health status, which may affect their ability to take in information about the study and make a decision. These issues need to be considered in the context of ‘selling’ the study to participants.

1.1 Direct benefits
Direct benefits to participants could include health gains or improvements, learning more about their conditions, having more time and attention from the clinical team and research staff, increased monitoring of symptoms compared to usual care and possible speedier identification of problems, opportunities to try new medications or procedures prior to general availability.

1.2 Indirect benefits
Indirect benefits to participants could include being part of a ‘club’, opportunities to meet other participants, learn about research, or feel valued.

1.3 Altruism
Many people get involved in research for altruistic reasons, by being able to contribute to the greater good, feeling part of a community of people who have given up their time for a good cause, contributing to future health improvements for others.

“The surprising thing to me is that relatively few patients will say no. Even for ‘x’ study, you know, most people you ask will say yes. Obviously I’m used to asking people and it’s a study I’m interested in, so I take time to explain it. So I think the way you explain something is obviously going to be important and the time you take, and still show you care about somebody, you are not just levering them into the study for the study sake.” (Chief Investigator)
2. Honesty about costs and uncertainty

It is important that an honest explanation about the study is given, including the costs, such as
time, discomfort, pain, travel (burden), as well as potential benefits for future patients and carers.
In addition, although it may conflict with the need to ‘sell’ the study, it is important to be clear
about uncertainty regarding which treatment will be received and whether individual participants
will benefit. An interviewer who questioned over 40 people about their experiences of being
recruited into clinical trials (‘Healthalkonline’, personal communication) found that some of the
interviewee’s responses suggested they either hadn’t had uncertainty explained to them, or had
not, for whatever reason, taken this information on board (see Chapter 5 section 3 above). This
suggests researchers need to ensure explanations are given (about the principles of research
exploring new treatments because it is unknown which works better) and to double check
participants’ understanding about this uncertainty. See, for example the following paper:
http://www.ncghta.org/execsumm/summ908.shtml. Although honesty about costs and uncertainty
may be perceived as incompatible with ‘selling’ the study, some very experienced investigators
believe participants appreciate this as a form of trust (personal communication).

3. How to convey the study information

How to convey the study information should have been thought through at the study design stage,
but may also need to be considered at the operational level, for example who will convey this
information, how, what is the best time, location, format? It is also important to ensure patients
are approached in the right way, for example that patients understand who provided the
information that led to them being approached, and also who exactly is approaching them. This
links back to ethics and also to social marketing to understand the target group, their needs and
any special considerations.

“Ensuring that people have lay participation on the study design is very helpful. One thing in
particular that we always find is really helpful is on the recruitment part of it. So about how you
would approach people. What sort of, information do they want? What will and won’t engage
them. What’s patronising and what isn’t. That’s quite a lot of input that we would get that way.
And also thinking about the information that we present to people, that it’s done in a
professional way.” (Chief Investigator)

3.1 Information sheets

These will need to be carefully thought through in terms of the information needs of potential
participants, language(s), visual presentation, level of detail needed (to explain the study
sufficiently well in a way the patient can understand). User involvement in the development of
information sheets is recommended. Communications experts may be useful to help with
language and visual presentation. Will the target group need special modes of communication due
to literacy or limited capacity (related to age or physical abilities)? In a recent (2009) focus group
with a group of ten trial participants undertaken by the authors, attendees stated the most
important issue for them was to have the information in clear, unambiguous terms that they could
understand, without jargon.

3.2 Scripts

Getting people to participate in research requires researchers to address the needs and future
satisfaction of those they wish to involve (as mentioned above) thereby employing ‘selling’
techniques may be beneficial. Scripts are often used for ‘selling’. For research this can be an
important part of standardisation. A script should be written for the person(s) who have to explain
the study to potential participants. This will ensure the same language and information are used
for each person who is approached and will reduce individual bias, bearing in mind the need for flexibility as all patients/members of the public are individuals, and as such, may often require the 'script' to be adapted/personalised where appropriate.

3.3 Posters
Would it be helpful to prepare posters to publicise the study? What information would need to be on them? As with patient information leaflets, thought needs to go into the design and visual presentation. Where would they be displayed? When would they be displayed? Who would ensure they are on display? Is a health centre waiting room the right place? Could an alternative place be better to maximise publicity, for example a pharmacy, supermarket, library or health club?

3.4 Video clips, podcasts and web-casts
There may be other ways to publicise your study. Consider where your target group would be most likely to have time and interest to find out about the study. A short video played in practice waiting-rooms, a pod-cast or web-cast online might be options. Groups who may not be able to read information in leaflets or posters might be more effectively reached through multi-media methods such as community TV.

3.5 Support material
Support material for the study may be helpful, such as the inclusion of additional general information about taking part in research, how studies are approved, what it means to be involved (NIHR CRN leaflets) and also contact information for research teams, linked services and help-lines related to specific health conditions, if appropriate.

3.5.1 Information linked to the study topic
Information linked to the study topic, such as medical information could be helpful.

3.5.2 Information about patient support groups or resources
Researchers may find it appropriate to provide contact details of support groups or other resources relating to specific health conditions.

3.5.3 Study promotional material (e.g. mugs, pens etc)
Sometimes it can be useful to hand out promotional material to participants. They can act as reminders or help participants feel part of a special group but should not be used as an incitement to agree to participate.

“Usually - I have to say that for most studies - the thing we would be most anxious about is loss to follow-up and attrition bias which actually isn’t usually a big feature in primary care trials. The biggest problem is just difficulty in recruitment and therefore the fact that the confidence intervals around the result are a bit wider than you’d expect and that is a problem.” (Chief Investigator)