Procedure for recruitment and obtaining informed consent

If there are concerns with the following consent and recruitment process, please get in contact with Karen Jones from the Evaluation Team.

1. Overall recruitment process

In each pilot site PCT, participating health professionals (HPs) (for example, care planner, practice nurse or specialist nurse) will be offering personal health budgets to patients in each diagnosis group who meet the necessary criteria. Each pilot site will have a specified quota. Each patient will be asked if they are willing to participate in the evaluation.

In the same pilot PCTs, health professionals not offering personal health budgets will be identified and asked to recruit patients to form the comparison group. The identified health professional (for example, care planner, practice or specialist nurse) will be asked to recruit patients who have the same health condition to form the comparison group.

Ideally we want health professionals who can recruit to the comparison group to be working in different local operational settings (e.g. different practices) from those recruiting to the personal health budget group. If this is not possible, the evaluation team will ask that the selected patients are randomised into either the personal health budget group or to the comparison group. The randomisation process will need to be completed before the offer of the personal health budget. You can find the web-based tool on the PHBE website (www.phbe.org.uk).

How to use the randomiser

- Login to the PHBE website;
- Click on Randomiser (‘Randomise an ID’);
- Select the specific health condition;
- Enter the one unique ID;
- Click ‘randomise’;
- The randomiser will allocate the patient into either the PHB or Comparison Group;
- Patients who are allocated into the Personal Health Budget Group can be offered a budget and invited to participate in the evaluation;
Patients allocated into the Comparison Group will continue to receive conventional services and will be invited to participate in the evaluation.

2. Recruitment to the Personal Health Budget Group

If the same Health Professional offers the PHB and recruits to the evaluation

At the same time as offering a personal health budget, health professionals will invite patients to take part in the evaluation.

a) Recruitment process

A full description of the evaluation will need to be given to the patient by the Health Professional and any questions need to be answered.

The Health Professional will need to:

(a) explain the purpose of the study
(b) explain what participation involves for the patient or their representative— that is:
   - completing questionnaires with an interviewer who does not provide care to them soon after they have consented to participate in the research;
   - completing a questionnaire to be sent to them by post six months after they consented to participate in the research. Participants can have help completing the questionnaire if needed;
   - completing a questionnaire with an independent researcher about 12 months after they consent to participate in the research;
   - collecting information from their medical records using a specifically designed template;
   - collecting information about their use of secondary care services from a confidential Government database;
   - possibly being asked to take part in another part of the research, which would be an interview about their experiences of personal health budgets three and nine months after they have agreed to participate in the evaluation;
   - stress that all information collected will be used for the research only, will be kept confidential and will be made anonymous before reports are written;
   - explain that they can withdraw from the study if they change their mind – they will still receive their health care services as usual;
   - they can still be involved in the evaluation if they refuse the offer of the personal health budget;
   - ask if they have any questions and answer them as best you can;
(g) reassure the patient that whatever their decision about taking part in the study, their health care will not be affected in any way – they will continue to receive normal health services and/or PHB as appropriate;

(h) reassure the patient that the Health Professionals providing care to them will not know anything about the answers they give on the questionnaire or anything else they tell the research team.

An information pack will be given to the patient to take home with them containing:
- Invitation letter;
- Information sheet explaining the evaluation;
- Consent form;
- Baseline questionnaire.

The information sheet will include contact details of two members of the evaluation team, should patients wish to discuss the study in more detail.

All versions of the documents will be included in each pack (for example, the consent form has three different versions: a standard patient consent form; a simplified version of the consent form for people who may have difficulties reading or understanding English; and a consent form for a consultee who is giving consent on behalf of someone who lacks capacity). Before inviting the patient to participate in the evaluation please select the most appropriate documents. When you are taking consent, remove the baseline questionnaire from the pack and write the name of the study participant on the front page of the questionnaire. The unique ID on the consent form and the baseline questionnaire in each pack are identical and therefore it is essential that the correct questionnaire is used for the right participant. Please keep the questionnaire safe until the interview.

b) Consent process

Once happy that each patient understands what their participation in the study involves, an interview can be arranged.

If the patient agrees to participate in the evaluation, they will be asked to complete a consent form. The patient will need to read each statement, tick each box if they agree, write their name, and sign and date the forms at the bottom. The patient can choose not to consent for information from their medical records to be given, or data to be extracted from the Hospital Episodes Statistics.

The health professional or person identified as leading recruitment in each site may need to talk through and explain each statement if necessary.

If the patient does not agree to take part, thank them for taking the time to consider the project and continue with your usual tasks.
There are various ways that the consent form could be sent back to the University of Kent which will be negotiated with each site:

- Special delivery which requires a signature;
- Sent back to the University of Kent via a courier;
- Scanned and uploaded on to the secure PHBE website;
- A secure fax line.

A unique sequence number will be printed on the consent form and questionnaires by the University of Kent to ensure that all data can be matched to the relevant participant.

If one Health Professional offers the PHB but another person is recruiting to the evaluation

After the offer of the personal health budget, the patient will need to be told who will be contacting them to discuss the evaluation. Each site can decide who this person will be, but this must be decided before beginning the recruitment process.

The identified person taking the lead on recruitment in each site will need to arrange a face-to-face meeting with the patient to discuss the evaluation. The same recruitment and consent process outlined above will need to be followed.

Recruitment to the Comparison Group

The identified health professional will need to arrange a meeting with each patient to discuss the evaluation. The same recruitment and consenting process outlined in Sections 2 and 2b will need to be followed.

How to recruit to the comparison group

The person recruiting people to the comparison group needs to emphasise the following:

- Because we do not know what, if any, difference this new approach might make, it is important to find out the views and experiences of people like them, who have had services arranged in the usual way as well as those who have had a personal health budget.

- Their involvement in the evaluation will last for 12 months. After this time they could be offered a personal health budget if there is a national roll-out.

- As the initiative is new there may be a number of issues to be resolved related to delivering personal health budgets. As a result they may have a better experience with the personal health budget process once issues have been overcome.