Induction Pack for PPI Contributors on Trial Oversight Committees

This template Induction Pack provides the key information that should be given to new PPI members of trial oversight committees. All sections in grey are either guidance notes for study teams or text that should be amended by the study team to tailor the pack to suit their clinical trial. The notes should be deleted from the pack before distribution and any study specific text should be amended to black font.

NB: The term PPI Contributor has been used throughout this document for consistency and in line with MRC CTU at UCL standard practice. However, study teams should amend this to the most appropriate term for their study. Other common terms used include ‘PPI representative’, ‘public representative’, ‘lay contributor’ or ‘public contributor’. Advice should be sought from the PPI Group if teams are uncertain as to the term they should use.
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You can find an explanation of all the words written in orange in the Jargon Buster
Medical Research Council Clinical Trials Unit (MRC CTU) at University College London

What is the MRC CTU at UCL?
The MRC CTU at UCL is one of the UK’s leading not-for-profit centres for clinical trials. Our research helps to improve health care in the UK and around the world.

We specialise in research in cancer, HIV/AIDS and tuberculosis (TB). But we also do research in other areas.

We plan and run clinical trials that test treatments or interventions in healthcare.

We also bring together the results of a number of trials which look at the same illness or condition. Looking at the results of multiple studies helps improve estimates of the effects of these interventions. This is called a meta-analysis.

Some of our studies don’t test an intervention but only collect data. This type of research provides information on the natural progression of a disease. They can also report on patients’ experiences on the current standard treatment.

In addition, we carry out research to improve the design, conduct and analysis of clinical trials.

The CTU employs over 200 staff and is currently coordinating around 60 trials and other research studies. For more information see www.ctu.mrc.ac.uk
Clinical Trials

What is a clinical trial?
A **clinical trial** is a research study that involves patients. It compares a new or different type of **intervention** with the best **intervention** currently available (often called the **control intervention** or **standard care**).

It tests whether the new or different **intervention** is safe, effective and any better than standard care.

For example, the **intervention** could be a new drug. But it could also be a new scanning machine or surgical technique.

Why are clinical trials needed?
A **clinical trial** will test the safety and effectiveness of a new treatment or device. The **data** collected from a trial will show the benefits and risks of the new **intervention**.

Laboratory tests and computer simulations are useful. However, they cannot tell a **researcher** about side effects or how a drug makes a patient feel. A computer doesn’t know if a new device is more comfortable than what is currently used.

Feedback from trial **participants** is essential. This tells **researchers** if a new discovery is an improvement for patients.

Trials aim to find out if **interventions** used in health care:

- Are safe
- Have side effects (whether short or long term)
- Work better than the standard **intervention**
- Help make people better

A **clinical trial** that has been run properly is the best way to assess whether an **intervention** is safe and effective.

What is a trial oversight committee?
Trials often run in lots of different locations or clinics (called **study sites**) at the same time. There will be a **Principal Investigator** at each site. But they are only in charge of making sure their own team is running the trial properly. A **Chief Investigator** is assigned to lead the study from a national or global position.

Trial oversight committees look at all activity on a study from a ‘top-down’ perspective. They combine the **data** from all the **sites** and patients involved. This means they can see the whole picture of how a trial is progressing.
There are three main types of oversight committee:

<table>
<thead>
<tr>
<th>Trial Management Group (TMG)</th>
<th>Trial Steering Committee (TSC)</th>
<th>Independent Data Monitoring Committee (IDMC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focuses on study delivery</td>
<td>Focuses on study oversight</td>
<td>Focuses on patient safety</td>
</tr>
<tr>
<td>- Getting approvals from ethics committees and regulatory bodies to run the trial</td>
<td>- Monitoring how closely the protocol is being followed</td>
<td>- Analysing the patient data to check for any safety issues or serious side effects that differ between the intervention groups</td>
</tr>
<tr>
<td>- Making sure that the study sites are running the trial correctly, and that the plan for the study (the protocol) is followed</td>
<td>- Suggesting protocol amendments to the study Sponsor</td>
<td>- Monitoring whether one intervention is more effective than the other</td>
</tr>
<tr>
<td>- Dealing with any problems with recruitment or retention rates</td>
<td>- Reviewing safety recommendations from the IDMC</td>
<td>- Writing reports and recommendations for the TSC</td>
</tr>
<tr>
<td>- Checking the quality of the data being provided by the study sites</td>
<td>- Advising the TMG on delivery of the study</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Sharing the results of the study when it has been analysed</td>
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</tr>
</tbody>
</table>

**Why do you need Patient and Public Involvement (PPI) Contributors in clinical trials?**

Involving patients, carers and the public in research design helps run the trial. It makes sure that the study analysis is relevant to the people it is trying to help. It improves its quality.

It would be impossible to speak to everybody with a specific condition about every piece of research. Instead we work with people from those communities. They are often called PPI Contributors and are interested in supporting clinical research. They provide input from the point of view of someone who may need to receive the new intervention.

PPI Contributors can be involved in the design of a research protocol. They can advise funders on aspects of their condition that need to be researched. Another important task is to write or give feedback on draft versions of participant information sheets (PIS). A PIS should be written in plain English. This is so it can be understood by the target audience.

Doctors and researchers can often under or overestimate how attractive a clinical trial might be to a patient. PPI Contributors on oversight committees can give a different perspective. They can explain considerations patients may have before agreeing to join a trial. For example, how much risk or how many additional hospital visits a patient may be willing to take on.

We recommend that you have a look at the INVOLVE website. This organisation is the National Institute for Health Research’s advisory group for public involvement. Although a lot of the information on their website is for researchers wanting to involve the public, it also has details and guidance on how members of the public can get involved themselves.
Trial X

This section is to be completed by the Trial Manager/Lead for the study in question. The headings and prompts below are to provide guidance on what sort of information should be included; it is not a prescriptive list and should be adapted to best suit the individual study. A member of the PPI Group should review/moderate it before it is distributed to PPI Contributors. It should be no longer than two sides. The PIS should be used as a starting point for populating these sections as this will already have been written and reviewed to ensure it is in plain English.

What is Trial X?
Plain English summary of the trial including:

- Population and disease under study
- Interventions to be used (IMP and control)
- Geographic spread of study sites

What are the objectives of Trial X?
Plain English explanation of the primary objective(s)

What will happen during Trial X?
Plain English summary of trial design and key study visits to include:

- Study design (RCT, cross-over etc.)
- Randomisations
- Blinding
- Duration of intervention and/or follow-up
- Key study procedures (e.g. MRI scans, psychometric testing, x-rays)
- Additional study interventions/visits compared to standard of care
- Dissemination plan for results
- Level of expenses covered
- How patients will be identified/recruited and whether PPI Contributors will be involved in any recruitment activities

How are PPI Contributors involved in Trial X?
Details of whether PPI Contributors are involved in, or have been consulted in the study design, either in the past or future plans. This could include:

- TSC, TMG, IDMC membership
- Consultation of reference or advisory groups
- Co-creation of the protocol/study premise
- Dissemination plans for results and study updates
- Ethics approvals

How will the results of Trial X be shared?
Overview of the dissemination plan for the study. Consider referring to the plans given in any funding applications as well as:

- Planned study update newsletters/report for study teams and/or participants
- Projected end date for data collection and planned date for submission of manuscript
- Details of written materials or presentation of results for participants
- Whether the PPI Contributors on the committees will have the opportunity to feed into and/or be named authors or acknowledged on any publications
Trial Management Group (TMG)

What is the TMG?
The Trial Management Group (TMG) is responsible for the day-to-day running of Trial X. The TMG analyses the results of the study for publication.

The TMG usually includes the researchers who had the initial idea and gained funding for this study. This is to ensure that the study is conducted safely and scientifically. They work with representatives from the different specialties involved in the trial (e.g. doctors, nurses, trial and data managers, statisticians and PPI Contributors).

The group is chaired by the Chief Investigator (CI) of the study. The CI has overall responsibility for the design, conduct and reporting of a clinical trial and must be a health professional (i.e. a doctor, dentist, nurse or pharmacist).

What is my role on a TMG?
All committee members share many of the same roles, but members are not involved in all aspects of the TMG’s work. Each has their own specific experience and expertise.

Your specific role is to bring a patient/community perspective. You have expertise and experience through living with the condition being studied. You can bring valuable insights about this to the TMG.

Trial teams should add in any specific areas of expertise or experience they would like their PPI Contributors to contribute to the TMG. Trial teams must also state whether the PPI Contributor will have voting rights on the committee and if these will be of an equal weighting to other members.

How will I support the TMG?
Examples of how PPI Contributors can support the TMG include:

- Preparing the participant information sheet (PIS) and informed consent form (ICF)

  Helping to write and/or comment on these documents and other written information that is for all participants.

- Promoting the trial and helping to create recruitment materials

  Writing articles about the trial in partnership with the trial team. This could be for a voluntary organisation or patient group newsletter or website. Giving talks about the trial at a patient group meeting or a scientific conference, with input from the trial team. If the trial is struggling to recruit patients, you may be asked to assist with developing posters or adverts to attract more patients into the study.

- Quality of life issues

  Bringing a patient/community perspective to any discussion about quality of life. This can be measured by using patient reported outcome measures (PROMs).
• Helping to tell people about the results of the trial

Commenting on draft materials designed for participants and/or their families, patients’ organisations and members of the public. These may include:

- A results letter for participants
- Articles for websites/newsletters
- Giving talks at conferences or meetings
- Input to Twitter chats and/or other social media activity
- Involvement in any media activity.

Who sits on the TMG for Trial X?

Additional lines should be added for all members of the committee. Examples of key members and their roles have been given below.

<table>
<thead>
<tr>
<th>Title</th>
<th>First Name</th>
<th>Second Name</th>
<th>Committee role</th>
<th>Role description</th>
<th>Short biography e.g.:</th>
</tr>
</thead>
</table>
| Chair & Chief Investigator | <Title> | <First name> | <Second name> | Leads the TMG meetings to ensure all agenda points are covered and allocates actions to appropriate members | Job title
Amount of trials experience
Where they normally work |
| Trial Manager | <Title> | <First name> | <Second name> | Provides updates and information on how the study is performing overall | Job title
Amount of trials experience
Where they normally work |
| Lead Statistician | <Title> | <First name> | <Second name> | Analyses any study data to provide updates on the trial’s progress | Job title
Amount of trials experience
Where they normally work |
| <Committee role> | <Title> | <First name> | <Second name> | <Role description> | Job title
Amount of trials experience
Where they normally work |
Trial Steering Committee (TSC)

What is the TSC?
The role of the TSC is to provide overall supervision of Trial X. They agree the protocol and meet at least once every year to review the progress of the trial.

The TSC is made up of representatives from Trial Management Group as well as independent members.

The TSC provides advice on all aspects of the trial to the Trial Management Group and funders. The committee reviews safety and efficacy recommendations. It examines reports prepared by the Independent Data Monitoring Committee.

The ultimate decision about whether a trial continues lies with the TSC. They are the executive oversight group advising the study’s Sponsor on the trial’s conduct.

What is my role on a TSC?
All committee members share many of the same roles. But members are not involved in all aspects of the TSC’s work - each has their own specific experience and expertise.

Your specific role is to bring a patient/community perspective. You have expertise and experience through living with the condition being studied. You can bring valuable insights about this to the TSC.

Trial teams should add in any specific areas of expertise or experience they would like their PPI Contributors to contribute to the TSC. Trial teams must also state whether the PPI Contributor will have voting rights on the committee and if these will be of an equal weighting to other members.

How will I support the TSC?
Examples of how PPI Contributors can support the TSC include:

- Problem solving
  Suggesting new ways to identify potential participants and encourage them to join the study. Especially if the trial is facing recruitment or retention problems.

- Input into changes in the trial design
  Contributing to discussions around acceptable levels of risk if new safety data becomes available. Providing a patient’s perspective on protocol amendments.

- Create public trust in the research study
  The study protocol may only allow people under 60 to join the study because researchers think older patients wouldn’t want to join. You might suggest that actually people over 60 have more time to dedicate to joining a study and are just as keen to support research as younger patients.
As an independent member of the committee, your main interest will be the welfare of participants. You will help to balance any non-independent members who may be concerned about the financial or reputational effects of stopping a trial early.

When the study results are published, the public can be confident that there were people on the committee who were only concerned with the wellbeing of participants. They are not concerned about the success or failure of the study.

Who sits on the TSC for Trial X?
Additional lines should be added for all members of the committee. Examples of key members and their roles have been given below.

<table>
<thead>
<tr>
<th>Title</th>
<th>First name</th>
<th>Second name</th>
<th>Role</th>
<th>Biography</th>
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<tbody>
<tr>
<td>Chair &amp; Chief Investigator</td>
<td></td>
<td></td>
<td>Leads the TSC meetings to ensure all agenda points are covered, and allocates actions to appropriate members</td>
<td>Job title, Amount of trials experience, Where they normally work</td>
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<tr>
<td>Trial Manager</td>
<td></td>
<td></td>
<td>Provides updates and information on how the study is performing overall</td>
<td>Job title, Amount of trials experience, Where they normally work</td>
</tr>
<tr>
<td>Lead Statistician</td>
<td></td>
<td></td>
<td>Analyses any study data to provide updates on the trial's progress</td>
<td>Job title, Amount of trials experience, Where they normally work</td>
</tr>
<tr>
<td>Committee role</td>
<td></td>
<td></td>
<td>&lt;Role description&gt;</td>
<td>&lt;Short biography e.g.: Job title, Amount of trials experience, Where they normally work&gt;</td>
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Independent Data Monitoring Committee (IDMC)

What is the IDMC?
The IDMC looks at how the trial is progressing and assesses the safety of the intervention. To do this they look at the data collected from the study participants as well as new information from other trials or sources.

They also monitor for evidence of harm or differences in how effective the new intervention is compared to the control intervention.

Most of the committee members are independent of the trial.

They are the only people who see the confidential, live trial data split down by intervention group.

This means that only they know if the new intervention is working or not. They might run an interim analysis to see if a clear result has been reached earlier than expected. They can check if participants in one group have reported more side effects than the other.

If the IDMC thinks that a trial should not continue, the committee can suggest that it is stopped early. This could be because people are experiencing serious side effects that were not expected, or the results have shown better than expected outcomes. The IDMC will write a recommendation to the TSC who will make the final decision on whether to continue or not.

There are x number independent members of the IDMC for Trial X. There needs to be at least x number at a meeting for decisions to be made. This is to make sure that there is a suitable balance between members who are involved in the running or design of Trial X and independent voices.

What is my role on an IDMC?
All committee members share many of the same roles. But members are not involved in all aspects of the IDMC’s work - each has their own specific experience and expertise.

The Trial Management Group and Trial Steering Committee never see the data of an ongoing trial broken down into the different interventions.
Your specific role is to bring a patient/community perspective. You have expertise and experience through living with the condition being studied. You can bring valuable insights about this to the IDMC.

Trial teams should add in any specific areas of expertise or experience they would like their PPI Contributors to contribute to the IDMC. Trial teams must also state whether the PPI Contributor will have voting rights on the committee and if these will be of an equal weighting to other members.

**How will I support the IDMC?**

Examples of how PPI Contributors can support the IDMC include:

- **First-hand insight on patients’ views of risks**

  Drawing on personal experience of the level of risk that patients with “disease/condition under study” are willing to take in studies. You can provide a patient’s perspective on the trial’s benefits, burdens and potential risks. You can identify issues that may not have been thought of by the other members.

- **Quality of life issues**

  Bringing a patient/community perspective to discussion about how quality of life may be affected by the trial drug or procedures.

**Who sits on the IDMC for Trial X?**

Additional lines should be added for all members of the committee. Examples of key members and their roles have been given below.

<table>
<thead>
<tr>
<th>&lt;Title&gt;</th>
<th>&lt;First name&gt;</th>
<th>&lt;Second name&gt;</th>
<th><strong>Independent Chair</strong></th>
<th>Leads the IDMC meetings to ensure all agenda points are covered and allocates actions to appropriate members</th>
<th>&lt;Short biography e.g.: Job title Amount of trials experience Where they normally work&gt;</th>
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<tr>
<th>&lt;Title&gt;</th>
<th>&lt;First name&gt;</th>
<th>&lt;Second name&gt;</th>
<th><strong>Lead Independent Statistician</strong></th>
<th>Analyses any study data to provide updates on the trial’s progress</th>
<th>&lt;Short biography e.g.: Job title Amount of trials experience Where they normally work&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Independent Statistician</td>
<td>Analyses any study data to provide updates on the trial’s progress</td>
<td>&lt;Short biography e.g.: Job title Amount of trials experience Where they normally work&gt;</td>
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<thead>
<tr>
<th>&lt;Title&gt;</th>
<th>&lt;First name&gt;</th>
<th>&lt;Second name&gt;</th>
<th><strong>Independent Clinical Expert</strong></th>
<th>Provides advice on the medical aspects of the study as an independent expert in disease under study</th>
<th>&lt;Short biography e.g.: Job title Amount of trials experience Where they normally work&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent Clinical Expert</td>
<td>Provides advice on the medical aspects of the study as an independent expert in disease under study</td>
<td>&lt;Short biography e.g.: Job title Amount of trials experience Where they normally work&gt;</td>
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<tr>
<th>&lt;Title&gt;</th>
<th>&lt;First name&gt;</th>
<th>&lt;Second name&gt;</th>
<th><strong>Committee role</strong></th>
<th>&lt;Role description&gt;</th>
<th>&lt;Short biography e.g.: Job title Amount of trials experience Where they normally work&gt;</th>
</tr>
</thead>
</table>
# Training, Support and Key Study Contacts

**Who can I speak to if I need help fulfilling my role?**

The thought of joining a trial oversight committee can be quite intimidating but there are lots of people you can speak to for support and advice.

<table>
<thead>
<tr>
<th>Position</th>
<th>Contact</th>
<th>Role</th>
<th>Phone Number</th>
<th>Email Address</th>
<th>Biography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial X PPI Lead</td>
<td>&lt;First name&gt; &lt;Second name&gt;</td>
<td>Your primary contact for any questions you may have about your role. He/she will guide and support you in your role.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial X Trial Manager</td>
<td>&lt;First name&gt; &lt;Second name&gt;</td>
<td>Manages the day to day coordination and administration of Trial X at the CTU.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Trial X Chief Investigator</td>
<td>&lt;First name&gt; &lt;Second name&gt;</td>
<td>The lead investigator for Trial X. He/she has overall responsibility for its design, conduct and reporting.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPI Group at the MRC CTU at UCL</td>
<td>&lt;First name&gt; &lt;Second name&gt;</td>
<td>Oversees all the patient and public involvement work run by the MRC CTU at UCL.</td>
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</tr>
</tbody>
</table>

**Who should I speak to if I have a concern about Trial X?**

We really value your unique insight as a PPI Contributor. So please do let the trial team know if you are worried about any aspect of Trial X.

You can raise any concerns at your committee meeting for discussion with the whole group.

If you would prefer to speak more privately to begin with, your PPI Lead will normally be the best person to speak to first. He/she will let you know who else you should speak to, such as the Chief Investigator, if the issue needs to be discussed further.
Can I talk about Trial X outside of the meetings or is everything confidential?

As the PPI Contributor on your committee, you are encouraged to feedback ideas and thoughts from other members of the community.

You can discuss your involvement on Trial X with other people but must be careful to only talk about information that has been made public already.

Everything that is discussed at committee meetings should be treated as confidential. This is to protect

- The privacy of participants in the study
- The intellectual property of the study Sponsor.

If you are approached by the press or media to talk about Trial X, please direct them to the Trial Manager. You should not give any interviews or discuss the study unless the trial team are there to support you.

If you are unsure about what you can or can’t say, you should speak to the Trial Manager (<insert name and email address>) or Chief Investigator (<insert name and email address>).

Where can I find out more about clinical trials?

There are lots of resources, guides and training documents available online that have been written for members of the public interested in learning more about clinical trials. Here are some of our suggestions.

Improving Healthcare Through Clinical Research Online Course: This free online course was developed by the National Institute for Health Research Clinical Research Network and the University of Leeds. You can learn about how clinical research and discovery changes modern healthcare.

EUPATI Toolbox: EUPATI is a European collaboration of academic, not-for-profit and pharmaceutical industry representatives. They have a collection of videos and articles that cover all aspects of medical research and development.

Cancer Research UK – What are Clinical Trials?: This section of the Cancer Research UK website explains what clinical trials are, the different phases they go through and what you should consider before joining one. The focus is on cancer, but the way studies are designed and run is the same for any disease.

Where can I find out more about disease area under study?

The Trial Manager should insert a link to the most appropriate patient facing directory of information for the disease under study. The links below are examples of resources that could be used, and irrelevant links should be deleted.

Your PPI Lead (<insert name and email address>) has been assigned to answer any medical or scientific questions about Trial X. If you want to find out about disease
under study more generally and other research that is taking place, here are some suggestions on where to look:

Cancer:
   Cancer Research UK: www.cancerresearchuk.org/about-cancer
   National Cancer Institute: www.cancer.gov/about-cancer

HIV:
   Community Advisory Board: www.ukcab.net
   HIV i-Base: www.i-base.info
   Aidsmap: www.aidsmap.com

Tuberculosis:
   British Lung Foundation: www.blf.org.uk/support-for-you/tuberculosis
   TB Alert: www.tbalert.org
Committee Meetings

The Trial Manager should edit this page to make it trial specific.

Where do the meetings take place?
Face-to-face meetings held at the MRC CTU at UCL offices in London are usually the first choice for committee members.

It can, however, be difficult to find a time when all committee members can be in the same place at the same time. Because of this, sometimes meetings will take place over the phone on a teleconference.

The Trial Manager will send you a list of planned dates for meetings which will say whether they will be face-to-face or by teleconference.

How often will the committee meet?
This will depend on the stage of the trial and whether it is facing any difficulties that need to be addressed more frequently. Timings might, therefore, change during the study but typically the committees meet at the following times:

<table>
<thead>
<tr>
<th></th>
<th>TMG</th>
<th>TSC</th>
<th>IDMC</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMG</td>
<td>• Every (x) weeks/months when sites are opening and recruiting participants</td>
<td>• Every (x) months during study setup and recruitment</td>
<td>• Once the first (x) participants have been in the study for (x) weeks/months, the committee will meet every (x) weeks/months</td>
</tr>
<tr>
<td></td>
<td>• Then every (x) weeks/months when recruitment has finished, and all participants are in follow-up</td>
<td>• Then every (x) months when participants are in follow-up</td>
<td>• Face-to-face meetings usually last (x) minutes/hours</td>
</tr>
<tr>
<td></td>
<td>• Face-to-face meetings usually last (x) minutes/hours</td>
<td>• Face-to-face meetings usually last (x) minutes/hours</td>
<td>• Teleconferences normally last (x) minutes/hours</td>
</tr>
<tr>
<td></td>
<td>• Teleconferences normally last (x) minutes/hours</td>
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</tbody>
</table>

What happens at the meetings?
The Trial Manager or Coordinator will send you an agenda \(x\) days/weeks before the meeting. This will list all the topics to be discussed during the meeting and will name who is presenting or leading the discussion.

You will receive minutes (notes) from the last meeting so that you can remind yourself of what happened. If any documents or reports are going to be discussed, these will be provided too so that you have time to read them before the meeting.

Meetings will be led by the committee’s Chairperson. At the beginning of each meeting, attendees will introduce themselves and apologies will be given from members who cannot attend.
Everyone will be asked if they agree with the minutes from the previous meeting. This is your opportunity to request any changes if you feel that a discussion point or suggestion has been left out or needs re-wording. If any actions have been agreed, the Chairperson will ask for updates on this activity from the responsible committee member.

Depending on which committee you sit on, there will be some standard topics that are likely to come up at each meeting:

<table>
<thead>
<tr>
<th>TMG</th>
<th>TSC</th>
<th>IDMC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progress of trial set-up and sites opening</td>
<td>Progress of the trial</td>
<td>Looking at safety and side-effect data from sites</td>
</tr>
<tr>
<td>Recruitment rates of participants (actual vs. predicted)</td>
<td>Reviewing information about the study intervention that has been published by other researchers</td>
<td>Checking whether the new intervention is having a different effect to the previous one</td>
</tr>
<tr>
<td>Problems with the data being provided by sites</td>
<td>Discussing recommendations from the IDMC</td>
<td>Preparing reports and recommendations for the TSC</td>
</tr>
<tr>
<td>Reviewing reports and recommendations from the TSC</td>
<td>Suggesting protocol amendments</td>
<td>Reviewing information about the study intervention that has been published by other researchers</td>
</tr>
<tr>
<td>General trial difficulties or successes</td>
<td>Preparing reports and recommendations for the TMG</td>
<td></td>
</tr>
</tbody>
</table>

**What happens between meetings?**

You may be asked to read and comment on documents or reports between meetings. If your views are needed before the next meeting, you should be given $x$ days/weeks to provide this. If you are asked to provide comments in a shorter time-frame than this, you should feel confident to question the deadline or to ask the Trial Manager for more time.

As a PPI Contributor, you can provide a unique viewpoint on Trial X and it is important that your opinions are included in committee discussions. You should discuss any concerns you may have about meeting a deadline with the Trial Manager or your Mentor.

If you come across any new information about the interventions in Trial X or think of something that you feel should be discussed at the next meeting, you can let the Trial Manager know by email. This can then be added and you will be given the opportunity to lead the discussion.

**What should I do if I can’t attend a meeting?**

We will always try to hold meetings on dates that are suitable for all members of the committee and you should try to attend wherever possible. However, we understand that situations and plans do change at the last minute and can’t be avoided.

If you are not able to attend a meeting, please let the Trial Manager know as soon as possible. You can provide any comments by sending an email which can be read out.
at the meeting on your behalf. Your input is very valuable even if you can't attend on the day.
Honoraria and Expenses

The Trial Manager should amend and complete this table based on what PPI activity has been costed for. Any irrelevant sections should be deleted. The MRC CTU at UCL PPI cost calculator and PPI SOP should be referred to when completing this section.

How do I claim expenses?
If trial teams are able to arrange travel tickets or accommodation on behalf of PPI Contributors, details of the process to be followed should be provided here.

The Trial Manager or Coordinator will send you an expenses form by email after any meeting you attend. You can also ask for a paper copy at the end of any meeting you attend.

You can choose whether you would like to receive payment through a bank transfer or by cheque.

You must provide receipts for any travel, childcare or subsistence costs you wish to claim for. If you return your expenses form by email, you can attach a scanned copy of the receipts or you can post the originals with a paper copy of the form.

The contact details of the person you should return your form to will be included on the document. If these are missing, you should contact your Trial Manager or Coordinator.

What is covered?
We will offer you a payment (known as an honorarium) for preparation for, attendance at and participation in committee meetings. The level of honorarium will depend on the type of meeting and how much preparation work is needed.

No PPI Contributor should be out of pocket as a result of involvement in research. You can also claim for reasonable travel expenses and other expenses for attending face-to-face meetings and conferences. But you will be asked to provide a receipt to support any claim.

<table>
<thead>
<tr>
<th>Meeting Type</th>
<th>Payment</th>
<th>Additional Expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face-to-face meeting</td>
<td>&lt;insert amount e.g. £75 per meeting&gt;</td>
<td>Travel: standard/economy train ticket or car mileage at 45p per mile Childcare/carers: &lt;insert amount e.g. £40 per hour&gt; Accommodation: &lt;insert amount e.g. up to £150 in London, or £100 elsewhere&gt; Subsistence: &lt;insert amount e.g. £5 for lunch; £20 for dinner if staying overnight or travelling home after 8pm&gt;</td>
</tr>
<tr>
<td>Joining a teleconference</td>
<td>&lt;insert amount e.g. £40 per meeting&gt;</td>
<td>Childcare/carers: &lt;insert amount e.g. £40 per hour&gt;</td>
</tr>
<tr>
<td>Meeting Type</td>
<td>Payment</td>
<td>Additional Expenses</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>--------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Attending a conference/training as an observer</td>
<td>&lt;insert amount e.g. £30 per day&gt;</td>
<td>Travel: standard/economy train ticket, or car mileage at 45p per mile&lt;br&gt;Childcare/carers: &lt;insert amount e.g. £40 per hour&gt;&lt;br&gt;Accommodation: &lt;insert amount e.g. up to £150 in London, or £100 elsewhere&gt;&lt;br&gt;Subsistence: &lt;insert amount e.g. £5 for lunch; £20 for dinner if staying overnight or travelling home after 8pm&gt;</td>
</tr>
<tr>
<td>Attending a conference/training as a presenter</td>
<td>&lt;insert amount e.g. £150 per full day&gt;</td>
<td>Travel: standard/economy train ticket, or car mileage at 45p per mile&lt;br&gt;Childcare/carers: &lt;insert amount e.g. £40 per hour&gt;&lt;br&gt;Accommodation: &lt;insert amount e.g. up to £150 in London, or £100 elsewhere&gt;&lt;br&gt;Subsistence: &lt;insert amount e.g. £5 for lunch; £20 for dinner if staying overnight or travelling home after 8pm&gt;</td>
</tr>
<tr>
<td>Any other meeting type</td>
<td>&lt;insert amount e.g. £75 per meeting&gt;</td>
<td>Include options as appropriate</td>
</tr>
</tbody>
</table>

Are there any implications of accepting payments for my involvement?

Official guidance from INVOLVE, the National Institute for Health Research’s advisory group for public involvement says:

“Receiving payment of a fee for your involvement in research is likely to have implications for you whether you are currently employed, unemployed, receiving state benefits or retired. This is because the payment you receive will be treated as earnings.”

There are guides and advice sheets with information on how you can check if you will be affected by any payments on the INVOLVE website:

Top Tips for PPI Contributors

There are a lot of very experienced PPI Contributors who sit on oversight committees at the MRC CTU at UCL. We asked them for some of their ‘top tips’ to pass on to new members:

☆ Your opinion and thoughts are just as important as everyone else’s in the room: do not be afraid to speak up. There will be professors and statisticians with lots of experience in medicine and trials but usually only you can speak for what it is like for a patient on a trial.

☆ There’s no right or wrong amount of contribution to give. You don’t need to say something about every discussion point.

☆ It’s important to share feedback from other members of the community about the study. As long as you don’t share confidential information, you should talk to other people before the meetings to get more opinions to share. You could speak to members of a support group at community meetings or on online forums.

☆ You are there to hold the researchers accountable for patient safety and wellbeing. Question their decisions and plans if you do not think the patients’ rights or welfare are being put first.

☆ Some of the committee members might feel that they can’t question the Chief Investigator because he/she is more experienced or respected. Because you’re a member of the public and not a junior doctor, you don’t need to worry about hierarchy, so you can ask them to justify themselves or tell them if you disagree.

☆ As well as representing people with <insert condition under study>, you can bring in your skills and experiences from your working or family life too. For example, if you are an expert at Photoshop, why not suggest improvements to the study materials? If you’ve worked as a Project Manager you might be able to design a better activity plan for the committee to use.

☆ It can sometimes be difficult to make yourself heard on a teleconference if there are other committee members all in the same room. A good Chairperson will make sure you are asked for your opinion during each discussion. If this doesn’t happen, raise it with your mentor or Trial Manager after the meeting so that it doesn’t happen again. The Chairperson may need some training on good teleconference etiquette.

☆ Read through the minutes (notes) and other materials before joining a meeting. This will mean you have the opportunity to ask any questions or get clarification on something before the discussion starts.

☆ If something doesn’t make sense, ask for an explanation.

☆ You can help to ensure that the language used to discuss the trial is appropriate and supportive. For example, encouraging researchers to refer to “participants” not “subjects” or “patients”
Jargon Buster

The world of clinical trials is full of acronyms and jargon which can take a while to get used to. Below are explanations of some of the terms used in this induction pack.

You can find bigger jargon busters online. There is a comprehensive list on the INVOLVE website [www.invo.org.uk/resource-centre/jargon-buster](http://www.invo.org.uk/resource-centre/jargon-buster) from which most of these definitions have been taken.

**Analysis**: examining and processing research data to answer the questions that the project is trying to address

**Chief Investigator / CI**: the authorised health professional, whether or not he/she is a Principal Investigator at any study site, who takes primary responsibility for the conduct of the trial

**Clinical trial**: a research study involving people who use services which compares a new or different type of treatment with the best treatment currently available

**Control intervention / treatment**: the intervention that acts as a comparator for one or more experimental interventions. Controls may be placebo, no treatment, standard treatment or an active intervention such as a standard drug

**Data**: the information collected through research. It can include written information, numbers, sounds and pictures. It is usually stored on computer so that it can be analysed, interpreted and then communicated to others, for example in reports, graphs or diagrams

**Efficacy**: extent to which an intervention produces a beneficial result under ideal conditions

**Ethics committee**: a group of researchers, healthcare professions and public members who must give their approval for a research study to make sure that it respects the dignity, rights, safety and wellbeing of the people who take part

**Follow-up**: periodic contact with participants enrolled in the trial for administering the assigned intervention(s), modifying the course of intervention(s), observing the effects of the intervention(s), or for data collection

**Funder**: the organisation providing funding for a study through agreements, grants or donations

**Independent**: somebody with no direct involvement in the trial other than as part of an oversight committee. Involvement could include being part of the study team, working for the company/organisation that created the treatment/device being tested or having a financial link to the manufacturer of the product

**Informed consent form (ICF)**: a document that participants sign to show they have understood what the trial involves and are happy to participate

**Intellectual property (IP)**: the new or previously undescribed tangible output of any intellectual activity

**Interim analysis / results**: comparing intervention groups at any time before the formal completion of a trial, usually before recruitment is complete

**Intervention**: something that aims to make a change and is tested through research. For example, giving a drug, providing a counselling service, improving the environment or giving people information and training are all described as interventions
**Participant**: someone who takes part in a research project. In the past, the term 'subject' was used but this is no longer considered appropriate

**Patient and Public Involvement / PPI**: doing research ‘with’ or ‘by’ people who use services rather than ‘to’, ‘about’ or ‘for’ them

**Patient / Participant Information Sheet / Leaflet / PIS**: an information leaflet given to those who have been invited to participate in a research study. The sheet is designed to provide the potential participant with sufficient information to allow that person to make an informed decision on whether or not they want to take part

**Patient reported outcome measures / PROMs**: questionnaires that ask patients to give their views on their health status

**Principal Investigator / PI**: the individual or a leader of the researchers at a site who is responsible for the conduct of a study at that site

**Protocol amendment**: a change to the terms of the approval given for the trial protocol. A significant protocol amendment is put in place if the changes will affect the safety of participants, management of the study, scientific value of the data or safety or quality of the investigational product. Significant protocol amendments need to be re-approved by the regulatory body and ethics committee

**Protocol**: the plan for a piece of research. It describes in great detail what the researchers will do during the research

**Quality of life / QoL**: a person’s own view of their life situation

**Regulatory body**: organisation responsible for ensuring the safety, quality and effectiveness of medicines and medical devices. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK’s regulatory body

**Researcher**: the people who do the research. They may do research for a living and be based in a university, hospital or other institution and/or they may be a service user or carer

**SAE / Serious Adverse Event**: any event that results in death, is life-threatening, requires hospitalisation or extended hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. An SAE does not have to be related to the clinical trial

**SAR / Serious Adverse Reaction**: any event that results in death, is life-threatening, requires hospitalisation or extended hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect and is at least possibly related to the participant's involvement in the clinical trial

**(Study / Trial) Site**: A hospital, clinic, health centre, surgery or other establishment or facility from which any part of a trial is conducted

**Sponsor**: the individual(s) or organisation(s) that take on responsibility for confirming that there are proper arrangements in place to initiate, manage and monitor, and finance a study

**SUSAR / Suspected Unexpected Serious Adverse Reaction**: an adverse reaction that is both unexpected (has not been previously linked to the intervention) and also meets the definition of a Serious Adverse Event/Reaction
Acknowledgements
This induction pack was created by Emily McGinn-Summers. I would like to acknowledge and thank the following for their support and input: Conor Tweed, Bec Hanley, Alfred Oliver, Christine Allmark, Michael Phillips, Diana Robinson, Philip Bell, Danielle Horton Taylor, Jacqui Gath, Jennifer Bostock, Lindy Berkman, Susan Mannix, Damian Kelly, Robin Millman, Roy Trevelion, Richard Stephens, Pat Hanlon, the PPI Group at the MRC CTU at UCL, PPI leads from the UK CRC CTU Network and the Shared Learning Group for Involvement in Research.