MRC CTU AT UCL PATIENT INFORMATION SHEET TEMPLATE: GUIDANCE DOCUMENT

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1 PURPOSE

This guidance document has been put together to assist study teams as they begin to adapt the Patient Information Sheet (PIS) template to their studies.

It includes detailed guidance on how to use the template, and also examples from two MRC CTU at UCL patient information sheets (Add-Aspirin and SHINE, in red text throughout) that have received ethical approval using this format.
2 GENERAL GUIDANCE

- **Use plain English throughout**
  Write as if you are explaining the project to someone who does not have a research or medical background. Use simple words and avoid jargon, acronyms and technical terms. If you must use them, explain what they are. Keep your sentences short. If you feel you need to use more than one comma or connecting word, think about using more than one sentence. Or use a list of bullet points. Make sure your main point is in the first part of a sentence and/or paragraph. Use “study” rather than “trial” where possible. It may be advisable to explain that the type of study is a “clinical trial”.

- **Use the active voice**
  This means talking to people directly. Say things like, “in this study, you will have a blood test”. Say “we will look at quality of life” NOT “quality of life will be observed.”

- **Involve patient representatives, or talk to someone from a relevant voluntary organisation**
  If possible, have one or more patient representatives on your trial management group (TMG) or trials steering committee (TSC). If not possible, seek help from the MRC CTU at UCL’s Patient and Public Involvement (PPI) Group, or a voluntary organisation that works with people with the condition you are dealing with. A patient’s input to the PIS is valuable; this can be either by helping to write the PIS or at the very least by commenting on a draft.

2.1 FORMATTING AND LAYOUT

- **Aim for plenty of white space.**
- **Number all of the sections, and leave gaps between a question and the answer then a bigger gap to the next question.**
- **The template document has been set up with suitable Styles, and, for consistency, you should try to use these rather than amending formatting yourself. Most body text you need to add uses the ‘Normal’ Style.**
- **Use bullet points where you can.**
- **Make sure all headings are clear and in **bold** type**
- **If you use any colour, ensure it still looks fine printed black and white, in case people choose not to, or cannot, print in colour**
- **Number all pages and include the total number of pages (e.g. 1 of 6).**
- **Aim for a total length of no more than 8 pages. This should be about 3000 – 3500 words (including headings)**
- **Page 1 should be a summary sheet and should only contain the following sections:**
  - study title
  - contents
  - invitation to join the study
  - important things you need to know
  - contacts
- **Left-hand justify the text but do not right-hand justify it.**
• Depending on the population you wish to recruit, consider printing the information sheet as an A5 booklet, as some of Peter Knapp’s work suggests that this size is preferable. But remember that if your target population includes older people and/or people with a visual impairment, you should use a 12-point font size or larger. This means you will need to print on A4 paper.

• Depending on the level of responsibility MRC CTU at UCL has for the trial, you may need to consult MRC branding guidelines during PIS development.

2.2 FINALISATION

Before you use the template for your trial, it will be useful to ask someone who has never seen your trial’s copy to review. Ask them in particular to look for things like typos, punctuation, over-complex language, document length and general suitability for your trial.

2.3 NEED MORE INFORMATION?

For more guidance, see the free advice available from the Plain English Campaign at: www.plainenglish.co.uk/ and guidance produced by the HRA: http://www.hra-decisiontools.org.uk/consent/examples.html.
In general, the front page is intended to provide all the crucial information in one glance. Keep the information on this first page, and don’t spill over onto the second.

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>(top left) Patient information sheet for [name of study or acronym] and MRC CTU and UCL logos</td>
<td>Add logo for other sponsors, collaborating groups, funder and research network, as required.</td>
</tr>
<tr>
<td>[Name of study and/or acronym]</td>
<td>Add name of study and or acronym (e.g. Add-Aspirin or SHINE) Add one sentence summary of the study in plain English – around 8 words. This would normally be the same as the headline you use for the summary on the MRC CTU study page for your study.</td>
</tr>
</tbody>
</table>

**Contents**

1. Why are we doing this study?
2. Why am I being asked to take part?
3. What do I need to know about the medicines [or procedures] used in this study?
4. What will happen if I take part?
5. What are the possible side-effects?
6. What are the possible benefits and disadvantages of taking part?

**We are inviting you to take part in a research study called [insert name]**

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can stop taking part in the study.

It is not expected that you will need to change this text, but do review to check it all applies to your trial or study.
**Suggested text**

- at any time, without giving a reason.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and asked to sign a consent form. You’ll get to keep a copy of that as well.

**Important things you need to know**

- We want to find out [insert text]
- We are testing [insert text]
- This study has [add number] different groups or treatment options
- Like all medicines used to treat [name of condition], the medicines used in this study can have unwanted side-effects. The most common side-effect of [add treatment] is...
- The study fits into your normal treatment, so there are no extra hospital visits. [OR This study will require you to visit the hospital X more times than if you were being treated in the usual way for [add condition]]

**Example 1 – Add-Aspirin:**

- We are testing whether taking aspirin regularly after treatment for early stage cancer stops or delays the cancer coming back.
- We are testing different doses of aspirin. Some people will receive a dummy drug (placebo).
- Like all medicines, aspirin can have side-effects. The most common side-effects of aspirin are:
  - irritation of the stomach
  - indigestion
  - bleeding - this a serious side-effect of aspirin but it is uncommon.
- We expect that most people who take part in this study will need to visit the hospital approximately 12 times over 5 years depending on your cancer type. Whenever possible, this will be at the same time as your regular check-up visit.
- We will also ask if you would like to donate a small amount of blood, urine and tissue from your cancer for future research.

**Guidance**

This section is a list of the key information someone needs to know – it should contain a maximum of 6 bullet points.

When including the most common side-effects, do not list all here; perhaps choose around three of the most important.

When addressing the issue of how many extra visits (if any) will be required, mention the amount of time for each. A 20-minute appointment is quite different to an overnight stay.

If you are paying people to take part in the trial, or are covering expenses for additional hospital visits, you should tell people about this here.

See examples in following rows.
Example 2: SHINE
- We want to find out the best way to treat children who have TB. The usual treatment is to take several medicines for 6 months
- We are testing whether taking medicines for 4 months would work as well as taking them for 6 months
- If your child takes part in this study, we will ask that your child is brought to the clinic regularly (every month while they are on treatment, and every 3 months after they finish treatment) for 18 months. We will give you money to cover the cost of these visits

<table>
<thead>
<tr>
<th>Suggested text</th>
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</thead>
<tbody>
<tr>
<td><strong>How to contact us</strong>&lt;br&gt;If you have any questions about this study, please talk to your study doctor or nurse at:</td>
<td>This is a space for participating centres to add their own contact details. Make sure it is still clear, when the document is circulated to sites, that sites themselves have to make this change. The highlighting on the template should help with this.</td>
</tr>
</tbody>
</table>
### 3.1 SECTION 1: WHY WE ARE DOING THIS STUDY?

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
</table>
| **1. Why are we doing this study?**  
This study is for [insert name of condition]. | Add in the name of the condition the study involves.  
Consider including the rationale for the study, if it can be summarised. For example, are outcomes not good for the potential participants?  
**Example (SHINE)**  
This study is for children with TB. |
| **What is [add name of condition]?**  
[Insert two or three sentences about the condition.]  
If you want to know more about [add name of condition], talk to the doctor or nurse who is treating you. | Explain the condition in plain English.  
**Example (SHINE)**  
**What is TB?**  
TB is a bacterial infection spread through inhaling tiny droplets from the coughs or sneezes of an infected person. It is a serious condition, but it can be cured with proper treatment.  
TB mainly affects the lungs. However, it can affect any part of the body, including the bones and nervous system. |
| **How is [insert name of condition] usually treated?** | Describe how the condition is normally treated – one paragraph per standard treatment.  
**Example (SHINE)**  
**How is TB usually treated?**  
Usually children with TB are given tablets which contain several anti-TB medicines. The treatment usually lasts for 6 months. |
| **What are we trying to find out?** | Summarise the trial question(s) in plain English.  
**Example (Add-Aspirin)**  
We are aiming to find out whether taking aspirin regularly after treatment for cancers that have not spread widely (early stage cancer), stops or delays the cancer coming back. This study will compare groups of people who take aspirin and those who take placebo tablets.  
**Example (SHINE)**  
We are testing whether giving children anti-TB tablets for 4 months will work as well as giving them for 6 months. |
### 3.2  SECTION 2: WHY AM I BEING ASKED TO TAKE PART?

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Why am I being asked to take part?</strong>&lt;br&gt;You are being asked to take part in the [add name] study because [explain...](it is about the person that makes them eligible for the study).</td>
<td><strong>Example (Add-Aspirin)</strong>&lt;br&gt;You are being asked to take part in the Add-Aspirin study because you have had or are having treatment for cancer of the breast, stomach, oesophagus, prostate or bowel. Although your doctors believe that they are able to successfully treat your cancer, some cancers unfortunately may come back. This study will find out whether or not taking aspirin regularly after treatment can stop or delay this happening. <strong>Example (SHINE)</strong>&lt;br&gt;Your child is being invited to join this study because he or she has been diagnosed with TB.</td>
</tr>
</tbody>
</table>
### 3.3 SECTION 3: WHAT DO I NEED TO KNOW ABOUT THE MEDICINES USED IN THIS STUDY?

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. <strong>What do I need to know about the medicines/procedures/other [choose one] used in this study?</strong></td>
<td>Building on the information on the front page and in section one, briefly describe the medicines/procedures used in this study. If any part of the usual treatment will be withheld as part of the study, explain this here. If the study is testing a new drug, give one or two sentences of information about it here. See examples in following rows.</td>
</tr>
</tbody>
</table>

**Example (Add-Aspirin):**
Aspirin is a common drug that is used as a painkiller and to prevent further heart attacks and strokes in some people. Some studies have suggested that people who regularly take aspirin may be less likely to be diagnosed with cancer than those who don’t take aspirin. Also, in studies testing the beneficial effect of aspirin on heart disease, aspirin appeared to reduce the number of people who developed cancer, and if people did develop cancer, it appeared to be less likely to spread. So researchers believe that aspirin may stop cancer coming back in people who have had treatment for early stage cancer. But, importantly, there is not any reliable evidence yet since previous studies were not specifically designed to answer this question.

**Example (SHINE):**
If your child takes part in this study, he or she will be given the medicines that are usually used to treat children with TB.

For the first 8 weeks, your child will take a number of tablets each day which will include the following medicines:
- Rifampicin, Isoniazid and Pyrazinamide

In addition your child may also take
- Ethambutol

After 8 weeks, you child’s medicine will be changed to one tablet per day. This tablet contains Rifampicin and Isoniazid.
### 3.4 SECTION 4: WHAT WILL I NEED TO DO IF I TAKE PART?

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4. What will I need to do if I take part?</strong></td>
<td>This is a heading only, but do add in text between this heading and the subheading if need be.</td>
</tr>
<tr>
<td><strong>Can I definitely take part?</strong> Not everyone may be able to take part in this study. We need to do some tests first to see whether you are able to take part.</td>
<td>Explain any screening that will take place before the study starts. If any of these procedures have a risk associated with them, please state this. Consider also adding which of these procedures are extra compared to standard, and how many people are expected to be ineligible at screening. See examples in following rows.</td>
</tr>
</tbody>
</table>

**Example (Add-Aspirin)**

If you agree to take part in this study, you will have a blood test and be asked questions about your medical history to check your suitability to take part. In the study, you will be asked to take the study medicines for at least 5 years. We know that it can be difficult to take medicines every day over a long period so everyone will be asked to take 100mg of aspirin for about 8 weeks at the beginning of the study. This is called the “run-in” period and will help us to identify people who may have problems taking aspirin. If you find it difficult to take aspirin regularly, it may not be recommended that you continue.

**Example (SHINE)**

If you agree that your child can take part in the SHINE study, the study doctor will examine your child and do some routine TB tests to check which type of TB your child has and to make sure it is safe for your child to take part. These tests are:

- **A TB skin test** A doctor will give your child an injection into the skin of their forearm. Your child’s skin will be checked after 2 or 3 days.
- **A chest X-ray** We will take an X-ray of your child’s chest, as TB can cause the lungs to have scars, which can be seen on an X-ray.
- **A sputum test** For small children this might involve putting a tube through the child’s nose and into the throat or the stomach to get the sputum. Older children may be asked to cough up sputum. To help them cough up sputum we may ask them to inhale a spray of saline. This method is safe and works well. The sputum is tested in a laboratory to see if it shows TB germs.
- **Blood tests** We will take a small amount of blood, up to 3 teaspoons, depending upon the age and size of your child. We will use it to check that the anti-TB medicines given to them are safe. We will also use it to test your child for HIV if their HIV status is unknown.

The results of these tests are ready in about one week. A doctor or nurse will discuss the results of these tests with you.

A trained counsellor will tell you the results of the HIV test. We will refer you to the local HIV centre for treatment if your child needs medicines to fight HIV.

If we find that your child is sick from any other illnesses or infections (at the beginning of the study and during the study), we will help to make sure that your child receives the right treatment.

If the results show that your child is not able to join the SHINE study, the clinic team will talk to you about whether he or she needs to start TB treatment here or in another clinic.
**Suggested text**

<table>
<thead>
<tr>
<th>What if the tests show I can take part?</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>If these tests show you can take part and you agree to join the [name] study, we will ask you to sign a consent form.</td>
<td>Describe each of the different arms. Include:</td>
</tr>
<tr>
<td></td>
<td>- How long the participant will be involved in the research</td>
</tr>
<tr>
<td></td>
<td>- How long the research will last</td>
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<tr>
<td></td>
<td>- How often they will need to attend the hospital/clinic</td>
</tr>
<tr>
<td></td>
<td>- What will happen during these visits</td>
</tr>
<tr>
<td></td>
<td>- How much of the trial treatment is different to or instead of the normal treatment.</td>
</tr>
<tr>
<td></td>
<td>- Information about long-term monitoring or follow-up</td>
</tr>
<tr>
<td></td>
<td>- Information about the use of video/audio taping/photography and additional consent related to this.</td>
</tr>
<tr>
<td></td>
<td>Use the most appropriate format. This might include a picture, diagram, time-line or flow chart. Ensure the diagram is appropriate to the audience, and that it can be edited or translated if need be.</td>
</tr>
<tr>
<td></td>
<td>See examples in following rows.</td>
</tr>
</tbody>
</table>

**Example (Add-Aspirin)**

After 8 weeks, if taking aspirin every day hasn’t caused you any problems, you will then be randomly allocated by computer to one of the three treatments:

1. 300mg of aspirin every day (one tablet per day) or
2. 100mg of aspirin every day (one tablet per day) or
3. A placebo tablet every day (one tablet per day).

![Diagram of study flow](image-url)
If you are 75 years old or over, you will only be allocated to 100mg of aspirin or placebo. This is because you may be more likely to have side-effects from aspirin.

To make sure the results of this study are as reliable as possible, neither you, nor your doctor, will know which treatment you get. If your doctor needs to find out which treatment you are taking at some point during the study, they will be able to do so.

Whichever treatment you get, we will ask you to take one tablet a day for at least 5 years. It is very important that you take your tablet daily. It is usually easier to remember to do this if you take the tablet at the same time each day. If you forget to take a tablet or number of tablets do not take additional tablets to catch up, you should only take one tablet a day. Please let your study doctor or nurse know if you have missed any tablets next time you see them.

**Example (SHINE)**

If the results show that your child can take the TB medicines, and you agree to them joining the SHINE study, we will ask you to complete a consent form.

We will weigh your child, measure his/her height/length and the distance around his/her upper arm.

We will give you anti-TB tablets for your child to take every day until your next visit to the clinic. The doctor and nurses will tell you all about these tablets and how to give them to your child.

One group of children will be given tablets for 4 months. Another group will be given tablets for 6 months.

A home visitor may come to your home with you when your child joins the SHINE study, so that they can help remind you about clinic appointments, and make sure that you and your child are alright if you are not able to bring your child for a study appointment as planned.

**Suggested text**

<table>
<thead>
<tr>
<th>Which group will I be in?</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is important that the groups receiving each treatment/procedure/other are as similar as possible at the start of the study. To ensure that this happens, a process called randomisation is used to allocate people to each group.</td>
<td>The sample text here is a minimum; if you’d like to say more about the process of randomisation, add it in. However, be aware that it is a clinical trial-specific term and detailed explanations may not be needed here. Also amend as required if your study does not use randomisation. See example in following row.</td>
</tr>
</tbody>
</table>

**Example: SHINE**

A computer will choose whether your child will get treatment for 4 months or 6 months, using a process called ‘randomisation’. It means your child will have an equal chance of being treated for 4 months or 6 months. This ensures that the groups of children being compared in the SHINE study are as similar as possible to start with, except for the duration of the treatment they take. It also ensures that any differences between these groups are only due to the duration of treatments in the study.
<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What will happen to me during the study?</strong></td>
<td>Explain what will happen during the study, including any drugs or activities that should be avoided during the study. See examples in following rows.</td>
</tr>
<tr>
<td><strong>Example (Add-Aspirin)</strong>&lt;br&gt;&lt;br&gt;<strong>Other medicines</strong>&lt;br&gt;It is extremely important that you do not take any other medication that contains aspirin regularly and you should not buy aspirin from a chemist or shop while taking part in the study. You should also not take drugs such as ibuprofen or Nurofen (non-steroidal anti-inflammatory drugs) on a regular basis but they can be used occasionally where absolutely necessary for no more than two weeks at a time. If you need to use a painkiller for more than two weeks, please discuss an alternative with your doctor e.g. paracetamol. They will also give you more information about this if you decide to take part in this study.</td>
<td></td>
</tr>
<tr>
<td><strong>Example (SHINE)</strong>&lt;br&gt;You should bring your child to the clinic every month for evaluation and to be given more tablets. The clinic nurse will help you to ensure you do not run out of tablets. We know that it can be difficult giving medicines to your child every day. We want to know how well children take their medicines and if there are any particular problems taking them. From time to time during the study we will ask you and your child some questions about their experiences of taking these medicines. The study home visitors may also visit your home from time to time and ask to count the anti-TB tablets you have. This is to check that you have been giving the tablets to your child correctly. After 4 months (16 weeks) or 6 months (24 weeks) your child will stop taking the anti-TB tablets, but will continue to come to the clinic every 3 months until your child completes 18 months from when they started to take the anti-TB tablets. &lt;br&gt;&lt;br&gt;<strong>Taking TB medicines regularly</strong>&lt;br&gt;It is very important that: &lt;br&gt;- your child does not miss any doses of the anti-TB tablets &lt;br&gt;- the tablets are not shared with anyone else&lt;br&gt;If your child does not take the anti-TB tablets as the clinic team tells you, they may not work properly. You should ask the study staff’s advice before your child takes any other medicines. If you do not bring your child for their appointment, we may send a home visitor to your home to find out how your child is.</td>
<td></td>
</tr>
<tr>
<td><strong>What checks and tests will be done?</strong></td>
<td>Describe any checks or tests that will be undertaken as part of the trial, and when and how often they will happen. Explain whether any additional consent will be sought for this, and whether they can stay in the study if they do not give this additional consent.</td>
</tr>
</tbody>
</table>
Explain what will happen to any samples – include whether they will be kept and if so where, and whether they will be destroyed at the end of the study or retained. If they are to be retained, explain why.
See examples in following rows.

Example (Add-Aspirin)
Everybody that participates in this study will be asked to donate samples which may include small samples of blood, urine and tissue from their cancer. We would like to collect samples from everybody participating in the study, even if their study medication is stopped because it allows us to study the side-effects of aspirin.
If you choose not to give permission for this you can still take part in the study.

**What samples will I be asked to donate?**
Cancer samples: samples of your cancer may have been stored in the hospital pathology laboratory. If you decide to take part in this study, we will ask your permission to retrieve your samples. You will not be asked to have any additional samples taken for this to happen.

Blood samples: we will ask your permission to take a small amount of blood when you register for the study. You may also be asked to donate additional blood samples at the end of the run-in period (approximately 8 weeks after starting the study). Some participants will be asked to have an additional blood test every six months. Wherever possible, this will be done at the same time as your regular scheduled blood tests. We will ask your permission now to do this. This part of the study is optional and if you do not give your permission for this, you can still take part in the main study.

Urine samples: Some participants will be asked to donate a sample of urine when you register for the study, at the end of the run-in period and after one year. We will ask your permission now to do this. This part of the study is optional and if you do not give your permission for this, you can still take part in the main study.

**What will happen to samples I give?**
Your donated samples will be stored in a laboratory for future research on the anti-cancer effects of aspirin and other projects aimed at improving outcomes for cancer patients.

Any research using your donated samples would only be carried out after an independent research ethics committee has approved it.

**Will any genetic tests be done?**
Depending on your cancer type and your hospital, you may have routine genetic tests done. You will receive personal results from these tests. Your study doctor can tell you more about these tests.

In the future, cancer researchers would like to use the blood and cancer samples that you donate (including your DNA) for separately approved research to help find out how genetics influence the risk of cancer and responses to treatments (including aspirin). You will not receive any personal results from these non-routine genetic tests unless we discover genetic information which has significant implications for your ongoing care, your future health or for that of your family. If this happens, we will contact you or the doctors looking after you with this information.
Example: (SHINE)

**Blood samples**

At some of the visits to the clinic we will ask you if we can collect a small amount of blood (up to 3 teaspoons, depending upon the age and size of your child). This blood will be stored in a laboratory, so that tests can be done later. This means that we may not give you the results of these tests.

New tests to diagnose TB are being developed all the time, so we shall ask for your permission to use your child’s blood samples in future for any tests that are relevant to TB. This might be during this study or after it ends. These tests would be decided by a group of experts. The blood samples taken from your child would never be identified by his or her name.

Your study nurse or doctor will be able to give you more information about this.

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will I get back any travel costs?</td>
<td>If you are paying people to take part in the study, and/or if you are covering expenses, you should give further information here, or in section 8. If you are not paying people or covering expenses, you should not include this question.</td>
</tr>
</tbody>
</table>

**Example (SHINE)**

We will give you some money to pay for transport to get you and your child to the study clinic and back to your home for these visits.
### 3.5 SECTION 5: WHAT ARE THE POSSIBLE SIDE-EFFECTS?

<table>
<thead>
<tr>
<th>Suggested text</th>
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<tbody>
<tr>
<td>5. <strong>What are the possible side-effects?</strong></td>
<td>This is a heading only, but do add in text between this heading and the subheading if need be.</td>
</tr>
<tr>
<td>All treatments/procedures/other can have unwanted side-effects. The most common side-effects of this treatment are:</td>
<td>Describe the side-effects for each treatment, grouping them if you can and listing them by seriousness, severity or frequency. You do not need to list every possible side-effect – the GCP Guidance states you should describe “reasonably foreseeable risks”. See examples in following rows.</td>
</tr>
<tr>
<td>If you become concerned about any side-effects, please tell the study staff as soon as possible.</td>
<td>For new drugs, you should explain there may be unknown side-effects. For example: Although [name] and [name] have been used in many patients across the world, they are still quite new treatments. There may be other side-effects which we do not know about yet.</td>
</tr>
</tbody>
</table>

#### Example (Add-Aspirin)
Aspirin is a common, frequently used drug and most people take it without experiencing any side-effects. We will ask you some questions about your medical history to check that aspirin is a suitable treatment for you but some people might experience some side-effects. Most side-effects are mild but, for a very small number of people, they can be serious.

**Common side-effects**
The most common side-effects of aspirin include indigestion and irritation of the stomach. Between 1 in 10 and 1 in 100 people will experience these side-effects. Aspirin can also make you more prone to bruising.

**Un-common side-effects**
Aspirin can cause minor bleeding from the stomach or bowel. It is very important to tell your study doctor or nurse or GP if you have any dark or black stools or any vomiting of blood. This is uncommon (between 1 in 100 and 1 in 1000 people will experience it). Aspirin can also cause severe bleeding, but this is rare and will affect between 1 in 1000 and 1 in 10,000 people.

**Rare side-effects**
Irritation of the stomach or bowel can cause a small break in the lining called an ulcer. It is very important to tell your study doctor or nurse or GP if you have any dark or black stools or any vomiting of blood. Rarely, bleeding in the brain occurs. It is important to have your blood pressure checked regularly while you are taking part in the study and this will be done at each visit. Aspirin can rarely cause other areas of bleeding for example, nose bleeds or bleeding gums. Hypersensitivity reaction (allergic reaction) is also a rare side-effect. Rare side-effects will affect between 1 in 1000 and 1 in 10,000 people.

**Very rare side-effects**
Kidney and liver impairment are very rare side-effects of aspirin. Very rare side-effects affect less than 1 in 10,000 people.
**Other side-effects**
Some people have experienced tinnitus (ringing sound in ears) when taking aspirin. Some recent evidence has suggested that a condition called macular degeneration (age related loss of sight) may be more common in people taking aspirin.

Please tell your GP or study doctor as soon as possible if you become concerned about any potential side-effects at any stage, or if you are concerned about any medical problems you are experiencing. For a more detailed list of possible side-effects, please see the patient information leaflet provided with your medication.

If you become pregnant or decide you want to during the study, please inform your study doctor or nurse as there are risks associated with taking aspirin during pregnancy.

**Example (SHINE)**
The medicines being used in the SHINE study are all recommended by the World Health Organisation (WHO) and are routinely used in our country’s national TB treatment programme. Although the TB medicines in the SHINE study are usually safe in children, side-effects may very rarely occur.

The most common side-effects caused by anti TB drugs are:

- Red tears
- Red urine
- Joint pains
- Injury to the liver

Please tell the study staff as soon as possible if you become concerned about any side-effects. It may be necessary to stop the medicine until the problem goes away or it is safe to resume the medicine. We will look for side-effects carefully and replace anti-TB tablets that cause problems.

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there other side-effects?</td>
<td>Add in details as necessary.</td>
</tr>
<tr>
<td>Radiation</td>
<td>If the study involves the use of ionising radiation, (e.g. X-rays, mammograms, CT scans, radiotherapy), you must give information on the radiation involved and dosage.</td>
</tr>
</tbody>
</table>
### 3.6 SECTION 6: WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6. What are the possible benefits and disadvantages of taking part?</strong></td>
<td>This is a heading only, but do add in text between this heading and the subheading if need be.</td>
</tr>
<tr>
<td><strong>What are the possible benefits of taking part in the [insert name] study?</strong></td>
<td>Outline any specific benefits here.</td>
</tr>
<tr>
<td>We hope that you will be helped by having any of the [treatments/procedures/other] in this study, but this cannot be guaranteed.</td>
<td><strong>Example (Add-Aspirin)</strong></td>
</tr>
<tr>
<td>The information we get from this study will help us to improve treatment for future patients with [name of condition].</td>
<td>We hope that you will be helped by taking part in this study, but we can’t guarantee this. However, the information we get from this study will help us to improve future treatments for people like you who have had treatment for cancer and help us find out more about the overall healthcare benefits that aspirin might provide such as preventing heart disease.</td>
</tr>
<tr>
<td><strong>Example (SHINE)</strong></td>
<td></td>
</tr>
<tr>
<td>There may not be a direct benefit to your child from taking part in this study. However, the information we get from this study will help us to improve future treatments for children with TB.</td>
<td></td>
</tr>
</tbody>
</table>
### 3.7 SECTION 7: WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. What are the possible disadvantages and risks of taking part in the [insert name] study?</td>
<td>Outline any disadvantages or risks here. Where appropriate you should include information about any potential harm to unborn children or any potential risks for breastfeeding. If appropriate, add information about whether private health insurance cover or travel insurance may be affected and what to do about this. See examples in following rows.</td>
</tr>
</tbody>
</table>

**Example (Add-Aspirin)**

You might experience side-effects from the treatment that you take in this study. Side-effects of aspirin are listed in section 5.

You will be asked to have a blood test before joining the study and then asked for your permission to have additional blood tests during the study.

You may also be asked to have some extra appointments at the hospital if you take part in the study.

During the study, you will not be able to take non-steroidal anti-inflammatory drugs such as ibuprofen or Nurofen on a regular basis.

If you have private medical insurance or require travel insurance, your policy may be affected. You should check this with your insurance provider.

**Example (SHINE)**

Your child needs to be treated for TB regardless of whether or not they participate in the SHINE study. Your child might experience side-effects from the tablets that he or she takes in this study. Common side-effects of the anti-TB medicines being used in the SHINE study are listed in section 5.

Your child will need to attend the clinic more often than he or she would do if they were treated for TB outside the SHINE study. He or she will also need to have some extra blood tests.

*What about risks to pregnancy?*

For girls who have started to menstruate (started their monthly periods), a pregnancy test will be carried out before entry to the study and at regular intervals during the study. If girls do become pregnant, they can continue to be part of the SHINE study and receive anti-TB medicines.

*What if my child is HIV infected?*

Your child can still join the SHINE study if he or she is HIV infected.
## 3.8 SECTION 7: MORE INFORMATION ABOUT TAKING PART

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8. More information about taking part</strong></td>
<td>This is a heading only, but do add in text between this heading and the subheading if need be.</td>
</tr>
</tbody>
</table>
| **Do I have to take part in the [insert name] study?**  
No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form.  
If you decide not to take part in this study, you are likely to receive the standard treatment, which is [insert sentence about standard treatment]. A decision to not take part at any time will not affect the standard of care you receive. | It is not expected that this suggested text would need to be changed much, but do amend as required to suit your study. |
| **Will I get back any travel costs?** | If you are paying people to take part in the study, and/or if you are covering expenses, you should give further information here, or in section 4. If you are not paying people or covering expenses, you should not include this question.  
**Example (SHINE)**  
We will give you some money to pay for transport to get you and your child to the study clinic and back to your home for these visits. |
| **Can I stop taking part after I’ve joined the study?**  
You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. But you must talk to your study doctor or nurse first. They can advise you about any concerns you may have.  
If you decide to stop taking your study treatment, we will need to continue collecting information about you. This is important, because it helps us to ensure that the results of the study are reliable.  
If you stop taking part in this study, you are likely to receive the standard treatment. A decision to stop taking part at any time will not affect the standard of care you receive. | Explain here what arrangements will be made if someone withdraws from a study – e.g.  
- Whether any samples taken will be retained/destroyed  
- Whether any data already collected will be retained/destroyed  
  
Explain whether people can withdraw from parts of the trial without having to withdraw from the whole trial.  
**Example:**  
If you stop taking part, we will destroy all your identifiable samples. But we will need to use the information we collected about you up to the time you decided to stop taking part. |
<table>
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<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What will happen to information about me collected during the study?</strong></td>
<td>If appropriate, you should explain that information will be passed to the participant's GP. If appropriate, you should also add information about links with other parts of the NHS. Leave the last paragraph in if you intend to collect information on databases like the one mentioned. Be sure to add the statement to the consent form as well. The HRA has guidance and suggested text for this: see <a href="http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html">http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html</a> for more information. See examples in following rows.</td>
</tr>
</tbody>
</table>

If you agree to take part in this study, your doctor will send information about you, your [name of condition] and your progress to the Medical Research Council Clinical Trials Unit at University College London (MRC CTU at UCL). The information will be analysed by [name of trial] researchers. Your hospital notes may also be looked at by MRC CTU at UCL staff if necessary. The information we collect about you will be useful in future research. Other researchers, including some who may be working outside the UK [change to name of country if this PIS is used outside the UK], may ask to use your information. If they do, this will be considered very carefully by [study name] researchers, the MRC CTU at UCL and independent scientists. We will follow all legal requirements to make sure that all information about you is treated appropriately and ensure that other researchers do so too. Information held, for example by the NHS, may be used to provide information about your health status after participation in the trial. The MRC CTU at UCL is registered under the UK Data Protection Act (DPA) to store this information. There is a question about this on the consent form that we will ask you to sign before you begin the study. We would keep this information separate from other information we collect about you.

**Example (Add-Aspirin)**

If you agree to take part in the study, your doctor will send information about you, your cancer and your progress to the MRC CTU. This information will be put into a computer and analysed by Add-Aspirin researchers. With your permission, we will also link to your details at the NHS Central Register (NHSCR), so we can check your health status if you lose touch with your study doctor or stop visiting the hospital. To do this, we will need to keep your name and NHS number on file, but these will be kept separately from other information about you. Some participants may be asked to send a health update directly to the MRC CTU. You do not have to take part in this aspect of the study if you do not wish.
**Suggested text**

Also, if you agree to take part in the study, your medical records may be looked at by selected hospital staff or the lead doctor for the study (or his/her nominee).

Results from the study and any future research will be published but will be anonymous.

We will follow all legal requirements to make sure that all information about you is treated in confidence.

If you take part in this study, we will also tell your GP that you are taking part in this study so that s/he is aware that you might be taking aspirin.

We would also like to keep you updated with information about the study. If you would like us to send you information, we will take your contact details and keep them separately from other information about you. You do not have to give us your contact details if you do not want us to send you updates.

**Example (SHINE)**

If your child takes part in the SHINE study, the doctors and nurses will collect information whenever they see your child. The information will be put into a computer and sent to MRC CTU and will be analysed by SHINE researchers.

We will follow all the laws as required to make sure that all information, including your child’s identity and any personal details, will be kept confidential. No named information about you or your child will be published in any report of this study.

<table>
<thead>
<tr>
<th>What will happen to the results of the [insert name] study?</th>
<th>Give any information about other ways that study results will be shared.</th>
</tr>
</thead>
<tbody>
<tr>
<td>When the study is completed, we will publish a summary of the results on the website of the Medical Research Council Clinical Trials Unit - <a href="http://www.ctu.mrc.ac.uk/">http://www.ctu.mrc.ac.uk/</a>.</td>
<td><strong>Example (Add-Aspirin)</strong></td>
</tr>
<tr>
<td>We will also publish the results in a medical journal, so that other doctors can see them. You can ask your doctor for a copy of any publication. Your identity and any personal details will be kept confidential. Your name will not be used in any report of this study.</td>
<td>If you give us permission, we will contact you to tell you the results of this study when it is completed. We will also publish a summary of the results on the study website: <a href="http://www.AddAspirinTrial.org">www.AddAspirinTrial.org</a> and in a medical journal, so that other doctors can see them. You can ask your doctor for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.</td>
</tr>
</tbody>
</table>

**Example (SHINE)**

We will publish a summary of the results on the MRC CTU website: www.ctu.mrc.ac.uk and in a medical journal. You can ask the study staff for a copy of any publication.

Results will also be discussed in community meetings and with TB and HIV programme personnel.

**Who is organising and funding the study?**

This study is organised by the [insert name of organisations] and the Medical Research Council Clinical Trials Unit at University College London (MRC CTU at UCL), which has run trials for many years.

Adapt as necessary for your trial.

If appropriate, add: “A patient representative has been involved in the design/management of this study and/or in writing this information.”
<table>
<thead>
<tr>
<th><strong>Suggested text</strong></th>
<th><strong>Guidance</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The study co-ordination, data collection and analysis, and administration will be provided by the MRC CTU at UCL. You can find out more about us at <a href="http://www.mrc.ctu.ac.uk">www.mrc.ctu.ac.uk</a></td>
<td></td>
</tr>
<tr>
<td>Your doctor is not receiving any money or other payment for asking you to be part of the study. The [name of sponsoring organisation] has overall responsibility for the conduct of the study.</td>
<td></td>
</tr>
</tbody>
</table>
| **Who has reviewed the [insert name] study?**  
The study has been reviewed by international scientists. It has been approved by [add any organisations that have approved the study – e.g. NCRI].  
It has been authorised by the Medicines and Healthcare Products Regulatory Agency (MHRA), as well as by [insert name of NHS Research Ethics Committee] and the hospital’s Research and Development Office. | Adapt as required for your study. |
| **What if new information becomes available during the course of the study?**  
Sometimes during a study, new information becomes available about the [medicines/treatments/procedures] that are being studied. If this happens, your doctor will tell you about it and talk with you about whether you want to continue in the study. If you decide to stop taking part in the study, your doctor will arrange for your care to continue outside of the study.  
Your doctor might also suggest that it is in your best interests to stop taking part in the study. Your doctor will explain the reasons and arrange for your care to continue outside the study. | It is not expected that this text would need to change much to be trial-specific, but do review just in case. |
| **What happens if the [insert name] study stops early?**  
Very occasionally a study is stopped early. If this happens, we will explain reasons for this to you and your doctor will arrange for your care to continue outside of the study. | Consider adding in an example (or more) of why your study might end early. |
<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
</table>
| **What if something goes wrong for me?**  
If you have any concerns about the way you have been approached or treated during the study, please talk to your study doctor or nurse. If you are still unhappy, or if you wish to complain, please use the normal NHS complaints process.  
If you are harmed by taking part in this study, or if you are harmed because of someone’s negligence, then you may be able to take legal action. | Make sure you check the exact insurance and indemnity requirements for your trial, including arrangements in different countries. |
### 3.9 SECTION 8: CONTACTS FOR FURTHER INFORMATION

<table>
<thead>
<tr>
<th>Suggested text</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9. Contacts for further information</strong></td>
<td>Amend as necessary. Make sure that, in the final version, it is still clear what information sites need to add to this section.</td>
</tr>
<tr>
<td>If you want further information about the [name] study, contact your study doctor or nurse (see below).</td>
<td></td>
</tr>
<tr>
<td>[Insert address and telephone number of recruiting centre]</td>
<td></td>
</tr>
<tr>
<td>More information is also available on our website [insert study website or email address for study page on MRC CTU at UCL website]</td>
<td></td>
</tr>
<tr>
<td>Thank you for taking the time to consider taking part in this study.</td>
<td></td>
</tr>
<tr>
<td>At the bottom of the last page, insert:</td>
<td>You can also add PIS version and date, though note that in the template these are set to appear in the footer on every page. All these details should appear somewhere on your final document.</td>
</tr>
<tr>
<td>- Protocol version</td>
<td></td>
</tr>
<tr>
<td>- Protocol date</td>
<td></td>
</tr>
</tbody>
</table>