GUIDANCE ON PROVIDING LAY SUMMARIES FOR ALL RESEARCHERS REGISTERING OR RUNNING CLINICAL TRIALS SPONSORED BY OUH NHSFT, OXFORD UNIVERSITY AND OH NHSFT

Poor lay summaries of clinical trials can leave patients unwilling to join them, and they may fail to recruit to time and target. Ensuring patient and public involvement (PPI) in writing or reviewing these summaries, and that these summaries are correctly placed on the trial registers, can address this. This guidance sets out how.

The NIHR UKCTG, promoted as a patient-friendly trials database, currently contains much highly technical information which patients say would stop them wanting to participate. This is because UKCTG is populated directly from the trial registers, and what is posted there is often not written for patients.

We are working with UKCTG and the registers to improve processes as much as possible, but we need you to take steps to ensure that your register entry contains your lay summary written in the best way possible and posted into the correct section of the register so that it is drawn down correctly into UKCTG. UKCTG may invite patients to rank the quality of lay summaries. If they remain poor in the registers and hence on UKCTG this will both hinder recruitment and reflect badly on the sponsors.

The recommended way to ensure that what gets onto UKCTG is useful to patients is to:

- follow the guidelines on page 2 for writing a lay summary (we recommend using the same lay summary for the HRA IRAS; the HRA tells us that the quality of these is often poor)
- follow the guidance on page 3 which explains how to provide your lay summary to the register (ISRCTN requests a lay/plain English summary, clinicaltrials.gov does not, but it still provides "lay" summaries to UKCTG – it is very important that your summary is therefore entered into the correct register field on ct.gov as explained)
- send the link to your register entry to the PPI working group (**sandra.regan@ouh.nhs.uk**) for review. If we have suggestions for change we will send these back to you and you can then amend the register entry by following the above step again. UKCTG downloads from these registers weekly, so any changes you make to summaries will be reflected in UKCTG within a week. We aim to review entries within two weeks; when we send the summary to the PPI rep for review we will copy you so you can have direct contact-dialogue is often very helpful.

Researchers are requested to follow the above steps for all new trials and to review their register content for all trials that will recruit beyond the end of 2016. Ideally you will have had PPI input during your study development and when writing your lay summary. But we recognise not all research teams do this yet, which is where we can help.

If you are in doubt as to why this matters, try searching UKCTG for information on clinical trials in Oxford, and imagine you are a patient: www.**ukctg**.nihr.ac.uk

Writing a good lay summary

General points:

- The audience for trial summaries is educationally very varied, and often under great stress

- Avoid long words, use short sentences and bullet point lists where these aid clarity

- Avoid acronyms or use only after the full term has been used and explained

- Use analogies and metaphors, e.g. 'nerves are like cables and are covered in an insulating material called the myelin sheath'

- Address patients directly as 'you', not 'the patient'

- Explain medical terms simply: 'your prostate will be removed (prostatectomy)'

- Use active speech: 'you will have radiotherapy', not 'radiotherapy will be used'

Structure:

- Start with eligibility, e.g: 'this trial is recruiting patients aged 18-45 who have diabetes'

- Continue with a sentence explaining what the trial will do/test

- Explain how the trial will do this/over how long/with what number of clinic visits etc.

- Do not use 'death' as an outcome: where possible refer to quality of life

- Lay summaries often do not have lay titles – make sure yours does

Words & phrases:

Use simple words/cut out unnecessary ones, e.g:

- efficacy of X – how well X works
- probability – how likely X is to happen
- participate in – take part
- prior to – before
- discontinue – stop
- in the event of – if
- inform – tell
- scheduled to undergo – due to have
- accordingly, consequently – so
- with reference to, with regard to – about
- if this is the case – if so

Writing or updating lay information for the registers, ISRCTN and clinicaltrials.gov

It is very likely that you will register your trial on the UK-based register, ISRCTN, or the US clinicaltrials.gov.

Which register should I use? Registering on clinicaltrials.gov is free, while ISRCTN charges a fee (£214+VAT). However, we urge you to register here as it is supported by the Department of Health, Medical Research Council and the Wellcome Trust and provides intensive support to create high quality lay summaries.

Data entered onto these registers are fed directly to the UK Clinical Trials Gateway (UKCTG), on a weekly basis. Because UKCTG aims to display trial data that is accessible to potential participants, it is important that your lay summary is entered into the correct data fields of the registers so that this is in turn drawn down into the "summary" field of UKCTG. This field may be renamed "lay summary" if a point is reached where the register information is sufficiently good that what appears in this section of UKCTG is truly lay.

ISRCTN: If registering a new trial here, you will be asked to supply a "Plain English Summary" (see: http://www.isrctn.com/page/definitions). This summary will be further reviewed by a team of writers and you may be asked for clarification. Because the ISRCTN team work with you in this way, trials registered here tend to have good lay information on UKCTG. However, if your trial is already registered and you do not feel that what is in the "Plain English Summary" section (and hence what appears in the "summary" in UKCTG) is easy to understand, you can contact the ISRCTN editorial team (info@isrctn.com) and they will amend the details as you request.

Clinicaltrials.gov: For this register, you will not be asked for a plain English or lay summary. The automatic drawdown into the UKCTG summary field is from the field called "Brief Summary." The information you enter here when you register a new trial thus needs to be lay friendly. If your trial is already registered and appears on UKCTG, but the information in this field is too technical, you can correct it by following the instructions in 'How to Edit Your Study Record' here: https://clinicaltrials.gov/ct2/manage-recs/how-edit and the new information will automatically replace what is on UKCTG.

Please contact Sophie Petit-Zeman if you have any queries: Sophie.petit-zeman@ouh.nhs.uk

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