Plain language summaries: Guidance for NIHR Bioresource Applications

Provision of a plain-language summary (PLS) is a condition of ethical approval for access to NIHR (National Institute for Health Research) BioResource resources. A well written PLS is an essential part of the application and approval process. One of the main reasons that approval of applications is delayed is a poor PLS that does not meet the requirements below.

Following application approval, the study title, lead applicant name, institution and PLS **will be published on the NIHR BioResource website** where it is available to study participants, the public, media, other researchers, and funders.

What is a plain language summary?

The plain language summary is a stand-alone summary of the proposed research project. It should not simply be copied from other project descriptions but needs to be written afresh.

The PLS should use plain English suitable for a reading age of 9. You may want to consider using a readability checker such as https://readable.io/.

In the PLS you should minimise the use of technical terms and jargon. Any technical or scientific terms including acronyms used should be clearly explained. Examples of jargon are clinical and methodological terms, as well as words that can have different meanings in science than in common use (e.g. local, blind, control). Consider using a plain language glossary such as https://www.lib.umich.edu/taubman-health-sciences-library/plain-language-medical-dictionary.

The PLS should clearly convey the key questions and purpose of the project. The goal of writing in plain language is to enable readers to understand the content the first time they read it.

You must make sure the plain language summary is consistent with the scientific project description submitted for approval.

What should the summary include?

The summary should clearly state what the specific purpose of the research is, who is conducting the research (organizations rather than individual names), what will happen to the data generated, the expected outputs and benefits to patients. Please include any potential disclosure risks and how these will be addressed. Your summary needs to contain the following **4 sections**:

- 1. Problem set out the problem, explain why the research is necessary
- 2. Methods explain in simplistic terms what methods you will use
- 3. Relevance of requested data/samples/recall of volunteers describe how NIHR BioResource contributes to the work
- 4. Benefit to patients and impact describe the impact that the research could have to the patients and public

What should I include in the 4 sections?

Problem. Evoke the problem first. There are some questions which help to do this: What is the essence of the problem and what are the consequences of the problem? Which research question are you trying to answer to solve the problem? Why is it important?

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Methods. What is the method, in plain language?

Relevance of requested data. How will the participants' data or samples be used to investigate the research question?

Benefit to patients and impact. What are the potential benefits or implications of your proposed research? This may include short term outcomes or longer-term impact. This section is also important to show Bioresource volunteers their valuable role in participation in health research.

Example of a good plain language summary

Changes in our DNA, called "mutations", cause some people to get Inflammatory Bowel Diseases (IBD). The specific mutations responsible for this disease and how they lead to diseases are unknown. We are studying a region of DNA that has been linked to Crohn's disease and ulcerative colitis, two types of IBD. Which genetic region controls inflammation in Crohn's disease and ulcerative colitis? Which exact mutation is responsible for it? To answer these questions may help us find better treatments.

To answer these questions, we would like to do an experiment with a mutation which we hypothesize is associated with IBD. We will test whether IBD patients with this mutation get worse than those without it by checking the difference in inflammation factors. We hope to learn what goes wrong to cause these diseases.

Through the NIHR BioResource, we can select participants for this study based on their genetic makeup and their disease. NIHR BioResource offers a unique opportunity to study the link between genetics and Inflammatory Bowel disease in a large group of individuals from the general population and patients.

The proposed research has the potential to improve treatment options for IBD patients.

Who is the plain language summary for?

- The NIHR BioResource Data Access Committee (DAC) and/or NIHR BioResource Steering Committee. The summary explains the project for the Committee members. Our committees have a diverse range of expertise and may not be familiar with your area of research.
- The funders of the NIHR BioResource. The funders want to know the scope and potential impact of the work that is being proposed.
- The Research Ethics Committee. The NIHR BioResource provides an annual summary of all research done, as condition of being permitted to release samples and data as a Research Tissue Bank.
- Researchers. The PLS for approved projects can be viewed online by other researchers. The
 research themes and broad methodology show what areas of research are already under
 investigation.
- NIHR BioResource participants. Participants can see how they have contributed to current knowledge. They need to understand what questions are being researched, how they have contributed to this, and the potential benefits of the work – without getting bogged down in technicalities

Tips for writing in plain language

• Limit sentences to one key point.

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- Use short sentences and short paragraphs.
- Be careful with words or phrases with dual or nuanced meanings (e.g. drugs; diet).
- Avoid technical words, jargon or words that are long or have many syllables. Consider those who do not have English as a first language.
- Avoid unnecessary technical details if you can make the same point in plain language.
- If you must use technical vocabulary, provide a short definition of your term when it is first introduced and do not use too many technical words together in one sentence.
- Do not include citations to research literature.
- Consider introducing an acronym or shorter term for repeated use.
- Write for an international audience. Avoid words or terms that are region-specific (A&E versusER).
- Use the active voice (For example, use "previous research showed that..." rather than "it was shown in previous research that...").
- Keep it concise (within the word limit of 300 words).

Sources

The NIHR BioResource gratefully acknowledges the work of METADAC study participant members and the METADAC Secretariat to generate these guidelines, which have been adapted here. The guidelines are based on (but not limited to) the following resources:

- METADAC guidelines https://cpb-eu-w2.wpmucdn.com/blogs.bristol.ac.uk/dist/7/314/files/2017/06/v1.0-Plain-language-guidance-for-METADAC-applications.pdf
- Cochrane Reviews Guidance -guidance-writing-cochrane-plain-language-summary.pdf
- National Institute for Health Research (INVOLVE)-http://www.invo.org.uk/resource-centre/plainhttp://www.invo.org.uk/resource-centre/plain-english-summaries/english-summaries/
- The Plain Language Campaign http://www.plainenglish.co.uk/free-guides.html