

Summary Patient Information Sheets

Background

Patient Information Sheets (PISs) are needed for people to give informed consent to take part in research. They're often the first thing people see when a research study is introduced. They give key information to help people decide whether to take part. To meet ethical rules, PISs need to include a lot of detail. This creates two main problems.

1. People who want to take part may not always read or understand everything. This can create unnecessary barriers to giving informed consent.
2. PISs may also put people off signing up for a study. We often hear that this affects people from groups who are already less likely to be heard. This makes it harder to recruit large and diverse groups of people into research.

The Depression Therapeutics PPIEP group noticed this was a common problem across many studies. Similar issues have also been recognised through national projects, such as [work by the MHRA to make medicines information more accessible](#).

What we did

We wanted to raise awareness of these issues. As a practical solution, we suggested using summary Participant Information Sheets (sPISs). We set up an sPIS project co-led by a public contributor.

We created examples of simple, well-designed sPISs. These explained what taking part in a study would involve and any risks. We wanted them to be 1–2 pages long, visually appealing, and written in plain English. sPISs can't replace full PISs. Instead, they act as a helpful addition and signpost people to more detailed information in the full PIS.

We paired researchers with public contributors to co-produce:

- Three example sPISs. One for an NHS study on dance and mood and two for university studies involving antidepressants, MRI scans, and cognitive tests.
- Guidance and practical tips on writing sPISs.

We shared these examples and guidance within our research theme, at a BRC PPI Pairs meeting, and with researchers across Oxford Health BRC. As this is a wider issue in research, we also shared the resources more broadly, including the Health Research Authority. All materials are available on the BRC [website](#).

What difference did it make?

Over 10 studies within the research theme now use an sPIS. Our contact with researchers at University of Cambridge led to them creating an sPIS for their AGILITY study. All sPISs submitted to ethics boards have been approved.

Researchers using sPISs report that fewer ineligible people have applied. Applicants are also better informed about what participation involves. It's too early to know whether this has improved participant diversity, but we will continue to monitor this and are optimistic.

This summary was drafted by the public contributor co-lead, with researcher contributions. It has a [readability](#) score of 60.12, where >60 is regarded as plain English.