DEPRESSION THERAPEUTICS GUIDANCE ON SUMMARY PARTICIPANT INFORMATION SHEETS

OVERVIEW

This pack contains:

- **Guidance and tips on writing a summary participant information sheet**, co-produced with the Depression Therapeutics PPI Group
- **Examples of three summary participant information sheets**, co-produced with the Depression Therapeutics PPI Group, including:
    - A drug study – *Selegiline* study
    - An MRI study – *Citalopram* study
    - A dance intervention study – *AMISTAD*

Response from ethics committees

So far, ethics committees have responded favourably – NHS ethics committees have specifically encouraged condensing earlier drafts further. The latter two above have been approved by university and NHS ethics boards (the first was developed after recruitment ended, purely to create an example). You can find more examples of approved summary Participant Information Sheets from across the theme here – these have been kindly shared by researchers, and we welcome additional examples being shared.

Sometimes ethics committees are unfamiliar with the concept and may raise queries or not understand the purpose. **It is important to be clear with ethics committees that these information sheets are supplementary and not intended to replace the full Participant Information Sheet. Alternatively, you can label them as additional adverts.**

Thank you to the PPI contributors and researchers who helped develop this pack!

For more information, or to work with the Depression Therapeutics PPI group, please contact Dr Amy Gillespie amy.gillespie@psych.ox.ac.uk (*Project Manager and PPI lead for Oxford Health Depression Therapeutics theme*)

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Writing a summary Participant Information Sheet (PIS)

Co-produced guidance from Depression Therapeutics PPI Group

Why write a summary PIS?

Because you want to make participating in your research accessible to a wider range of people – including those facing greater health inequalities.

- 54.3% of adults (aged 18-65) in Oxford local authority have low literacy, indicating they would likely have difficulties in understanding or interpreting health information England tool/geodata, Soton Uni for NHSE
- DfE's Survey of Adult Skills 2023 showed proficiency in literacy and numeracy is associated with particular ethnicities, employment, and level of parental education.

"A simple summary isn't dumbing down, it's reaching out" – PPI volunteer.

Because it will increase recruitment, and make screening/consent run more smoothly, if people can quickly understand what the study involves.

Because everyone is busy, and we're asking for more of their time, so we should do the initial work to make things easy to understand!

What should I include?

Think from the perspective of a potential participant, who knows nothing about your research, and what they will truly want to know –

- Why should I get involved?
- What will I have to do?
- Where and when will I have to do anything?
- What are the benefits (for me + to society/fellow sufferers)?
- What are risks or important practical considerations for me?

It might help the research feel more welcoming and personal if you include a photo of the research team members they'll be communicating with.

A lot of the other information in a full PIS – detailed data management plans, every detail of the visit, insurance details, dissemination plans at the end etc – overwhelms people and isn't needed at the first stage.

Don't make these decisions alone! This guidance should help you make a great first draft – but involve a PPI group/contact before finalising it.

But I'll have to leave important stuff out!

Yes and no. This isn't designed to replace the full information sheet. This is part advert/PIS/signposting – it's designed to get people interested, summarise what involvement means to them, and signpost to more information. The safeguards are:

a) Anyone can still access the whole PIS
b) You can answer any questions they have – and a short summary pointing to the key issues might be more likely to elicit questions
c) You can talk them through the details when appropriate. (e.g. full visit details are more likely to be read and absorbed the week before a visit)

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TEN TOP TIPS

❶ Try not to start with the text of your long information sheet, or chunks of protocol. These are likely to be dense, formal and full of jargon - start afresh.

❷ Less is more – if you focus on just the key messages, it's much more likely participants will read and absorb the information. So keep it short:

- short overall (keep it to 1 page ideally - but not by using 10pt font!)
- short blocks of text (most people don't typically read solid blocks of text)
- short sentences.

❸ There might be specific concerns for a population you're hoping to recruit, or ways you've made your research more accessible that are worth briefly mentioning e.g. having female medics on request, offering weekend or evening availability, providing a telephone number as well as an email address.

❹ It is worth pre-empting common concerns, and offering some reassurance/solutions e.g. if they won't be able to drive, say you'll cover a taxi. FAQ sections can be helpful.

❺ Think about how you'd explain things to a friend or relative who asked you about taking part, ideally one who has little knowledge of research.

- use everyday words - "the majority of" x, "most" ✓
- if essential to use technical words, explain them – "blood clot (thrombus)"
- be straightforward - "nonadherence to antihypertensives is prevalent" x, "patients often don't take their high blood pressure medicines" ✓
- Keep it human and use kind language over clinical language – "struggling with intense emotions" ✓ "emotion regulation deficits" x

❻ Communicating risk isn't straightforward. There's plenty of literature online – eg Winton Centre Cambridge - but start by remembering that expressing things in percentages or x in 100 may not resonate for some. Visuals can help.

❼ Check what you've written afterwards by reading it out loud. Does it sound like how you'd actually speak to a member of the public?

❽ You can also test your text for readability using Word online (tabs *Review>Spelling & Grammar>Insights)* or copying text into a site like https://www.thefirstword.co.uk/readabilitytest. It's an algorithm, so not a guarantee of a readable text, but if the score is <50 it should trigger you to review your text.

❾ Use visual design elements – boxes, titles, bold, colour, bullet points, pictures - to make the text less overwhelming. This can be particularly helpful for complex studies with multiple visits.

❿ Check out our three examples to give you some inspiration! There is no one right way to do this, so they differ in style, length and structure. These should give you a head start – but do still discuss your individual study needs with a PPI group!

HELPING US UNDERSTAND DOPAMINE

SELEGILINE STUDY

I'm Esther Teo, a researcher at Oxford University. **I'm looking for members of the public to take part in a research project which is led by Professor Catherine Harmer.**

We're researching depression. We are trying to understand the role of the brain chemical 'dopamine' in people losing their motivation and interest in hobbies. This is part of a wider project looking at drug treatment options for depression and anxiety.

What we are doing

We want to test the effects of giving healthy adults one dose of a drug called 'selegiline'. This drug blocks the breakdown of dopamine. It is used for treating Parkinson's.

We are aiming to recruit 62 people, aged between 18-40. For safety, we won't be able to take people in the categories listed in paragraph xx on the attached sheet. If you're interested but not sure if you're eligible, please contact us – details below.

What taking part involves

If you agree to take part:

1. One of our research team will arrange a call with you on Microsoft Teams to check your suitability. This call will last 60-90 minutes. We will ask you questions about your mental health and your medical history. This conversation can be done in-person if you prefer.
2. We'll then invite you to the Warneford Hospital for an in-person visit.

At the in-person visit, we will finish checking your suitability, by measuring your heart rate and blood pressure and taking a urine sample to check for drug use and pregnancy.

Then, if suitable, we'll do a 3 hour testing session. This includes:

- questions about your mood, personality and intelligence
- giving you one dose of selegiline or a dummy pill (placebo) – you won't know which
- doing psychological tests

Please note: We don't want you drinking alcohol, eating a big meal or taking certain medications just before the testing session. We advise you don't drive yourself home, so we can organise and pay for a taxi.

Payment: If you attend both the screening and testing sessions, we'll pay £80 (£15 just for screening). We will also pay your reasonable travel costs.

Risks

Selegiline is generally well tolerated and you'll only be getting a single dose. We've listed possible side effects in paragraph xx on the attached sheet.

Your information

We'll keep all your information securely. We have procedures to ensure no-one can identify you from the medical information you give us or the results of the tests.

Next steps

There is a longer Information Sheet available. We encourage you to read this in full.

For more information, please email us: selegiline.project@psych.ox.ac.uk

Ethics Approval Reference: [R64689/RE010]

Oxford 7T FACES study

The effects of citalopram on the brain's response to faces

Research into antidepressants: Would you like to take part?

Everyone's brain reacts to emotional information. We want to see how a medication for depression (citalopram) affects this reaction.

We hope this will help us in two ways:

- improve our predictions of which patients may benefit from different antidepressants
- develop new antidepressants.

We are looking for people aged 18-40 without a history of mental health disorders (like depression). You must have good English, not be pregnant, and meet the other criteria on pages 1 and 2 of the attached sheet.

What taking part involves

If you are OK to take part, we'll ask you to come to two visits at the Warneford Hospital.

First visit (about 1.5 hour): we will double-check your suitability for the research, including taking a urine sample.

Second visit (about 5 hours): we will give you one (20mg) dose of an antidepressant called citalopram or a dummy tablet. We'll then drive you to the John Radcliffe Hospital for a one-hour MRI scan. During the scan we'll ask you to do some simple computer-based tasks. Inside the scanner, you'll have easy access to a call button if you wish to stop the scan.

We'll pay you £12.50 for the first visit and £100 for the second, plus up to £20 travel costs each time.

Who are we?

Dr. Marieke Martens
Lead researcher on this project

Lena Beckers
Assisting with this project

Things to think about

Possible side effects: the effects of taking citalopram are normally mild. These commonly include: sweating, nausea, headache, and insomnia. Since you're only having one dose, they shouldn't last more than a couple of days.

Driving after the second visit: Because of possible side effects, we advise you don't drive yourself back from your second appointment. We can organise and pay for a taxi.

Personal questions: It's possible you'll be upset by some of our questions, as they are personal and ask about your mental health. You can always tell us you don't want to answer.

MRI scan: MRIs are safe and don't use x-rays, though they're not suitable for everyone. Our questions beforehand will ensure no-one unsuitable takes part.

Your data: All the information you provide will be kept securely. We have procedures to ensure no-one can identify you from the medical information you give us or the results of the scan.

There is a full Participant Information Sheet attached. We encourage you to read this in full. For more information, you can contact us at **01865 618338** or by emailing **amygdala.study@psych.ox.ac.uk**.

OXFORD AMISTAD

SOCIAL DANCE STUDY

WHO ARE WE?

We are a team of mental health researchers from the University of Oxford and University College London. Our research focuses on new approaches to treating and preventing depression.

Brennan Delattre (PhD Student)

Brennan is leading this project, supported by Professor Catherine Harmer, Associate Professor Susie Murphy, and Dr. Joshua Buckman.

WOULD YOU LIKE TO HELP US?

Our study is about how **salsa dancing** can affect **mood** and **well being.**

We're looking for about 30 volunteers who are taking part in **NHS Talking Therapies** and are okay with some mild physical activity and social interaction.

You've previously agreed to be contacted for research so are inviting you to take part. **Participation is entirely voluntary,**

WHY IS THIS RESEARCH BEING DONE?

More than 60% of people using public mental health services have said they want **creative therapy options**. We are especially interested in **physical activity** that are also **social.** Specifically, we want to see how salsa dancing affects mood and behaviour over time.

BENEFITS OF PARTICIPATING

- **Free salsa classes** taught by a professional instructor.
- **£70** for completing all online questionnaires.
- Potentially improving your **mental health** through social dancing.
- **Help us understand** whether salsa is useful for people seeking help with their mental health.

RISKS OF PARTICIPATING

- **Minor physical activity** and social interactions which might be **uncomfortable** for some.
- **Answering personal** mental health **questions** which could be **distressing**.

For more information, contact:
brennan.delattre@psych.ox.ac.uk

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WHAT HAPPENS IF I TAKE PART?

Screening

Eligibility Check (Online)

- You'll fill out a form to check if you qualify. Questions will ask about your health history, medications, and if mild exercise is suitable for you.
- If you qualify, we'll ask for your contact details for further steps.

~10 minutes

Phone Screening

- If there is still space in the study, a researcher will call to confirm your details and answer your questions.
- If not, you'll be on a waitlist and we'll call you if a place becomes available.

~10-15 minutes

Salsa Classes

Salsa Classes

- You will attend **weekly hour-long salsa** classes.
- Classes will be in Camden/Islington.
- You need to attend at least 6 out of 8 classes to complete the study.
- You will complete short (**5-10mins**) online **questionnaires** about your mood at **four** different times.

Optional Tasks

(**Optional**) **Online Tasks**

You can choose to do extra online tasks like memory and word games for additional payment (£30).

~25-40 minutes

Oxford AMISTAD Social Dance Study

PRIVACY AND DATA PROTECTION

- Your personal data will be kept secure and confidential.
- Only the research team will access your information.
- Data will be stored securely and may be shared anonymously in future research.

STUDY RESULTS

- Findings will be shared in a PhD student thesis, conferences, and journals without revealing your identity.
- If interested, you can receive a summary of the study results.

There is a full Patient Information Sheet attached. We encourage you to read this in full.

For more information, please contact:
brennan.delattre@psych.ox.ac.uk

This study is approved by the University Research Ethics Committee (Reference: [To Be Assigned]).

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