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CONSENT FORM (Phase 5 Focus Group)

Title of Project: Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK
Name of Researcher: Dr Gail Gilchrist

Please initial all boxes

1. I confirm that the researcher has explained and that I understand the information sheet dated 20/10/15 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving any reason, without my care or legal rights being affected. ☐

3. The procedures regarding confidentiality have been clearly explained to me (e.g. anonymization of data, use of pseudonyms in reports etc.). I understand that if I express current or future intention to harm myself or someone else that the researcher will inform my key worker or a duty worker at the drug treatment service where the interview has taken place and the worker will conduct a risk assessment. ☐

4. I agree to the focus group being audio recorded. ☐

5. I understand that the data will be published at the end of the study and that completely anonymous quotations from the focus group may be used in the report/publication. ☐

6. I agree to my anonymous interview data being shared with researchers at the five institutions where the research is being carried out – King's College London, University of the West of Scotland, University of York, NHS Wales and the University of Huddersfield. ☐

7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

[Organisational logos and headers]

CONSENT FORM (Phase 5 Focus Group)

Title of Project: Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK
Name of Researcher: Dr Davina Swan

Please initial all boxes

1. I confirm that the researcher has explained and that I understand the information sheet dated 26/01/16 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving any reason, without my care or legal rights being affected. ☐

3. The procedures regarding confidentiality have been clearly explained to me (e.g. anonymization of data, use of pseudonyms in reports etc.). I understand that if I express current or future intention to harm myself or someone else that the researcher will inform my key worker or a duty worker at the drug treatment service where the interview has taken place and the worker will conduct a risk assessment. ☐

4. I agree to the focus group being audio recorded. ☐

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7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

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Participant information sheet (Phase 5. Focus group)

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

Thank you once again for taking part in the study. We would now like to invite you to take part in a focus group about your experiences of taking part in the group programme. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. This should take about 5 minutes. Do feel free to talk to others about the study if you wish. We appreciate you taking the time to decide whether or not to participate.

Why are we doing this study?

People who inject drugs are at risk of blood borne viruses (e.g. HIV, Hepatitis C and Hepatitis B) as a result of sharing injecting equipment (needles and syringes, water, spoons, cotton etc.) and unsafe sex. Preventing people who inject drugs from getting or passing on these viruses is an important health issue. Opiate substitution therapy (methadone or buprenorphine) and needle exchanges have reduced blood borne viruses but programmes that give people the skills and knowledge to be able to reduce these risks could further prevent the spread of these viruses.

You took part in a study to see whether it was feasible to deliver the programme in drug treatment settings, whether people who inject drugs would come to the programme and what they thought about taking part in the programme. Therefore, we would like to ask you to participate in a focus group with other people who attended the programme to find out what you thought about it.

Why have I been chosen?

You recently took part in a 3-session group programme to help people who inject to be able to reduce sexual and drug related blood borne virus risk behaviours. Even if you only attended one session, we would like to hear about your experiences so that we can improve the programme if necessary.

If you decide to take part

If you agree to take part in the focus group you will be asked to complete and sign the consent form. If you consent to take part in the study, we will invite you to take part in a focus group that will last about 60 minutes. There will be about 8 people in the focus group with you so you can discuss your participation together as a group.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice **and all information about you will be handled in confidence**. The focus group will be audio-recorded with your consent. We cannot guarantee that others participating in the research will keep what you say confidential but we will encourage people to do so, so that people feel comfortable discussing their experiences. The focus group will be analysed as a whole and participants' names will not be used in any analysis of the discussion. The transcript and audio recording will be stored on a secure computer and the audio recording will be deleted from the recording device. What you say in the focus group will be typed out word for word. Only the researchers conducting the study will have access to these typed copies. The researcher will check them to make sure that neither you nor any other person is identifiable from what you have said. Any references to names or addresses will be removed. The data will be kept on a computer and will be stored separately from your contact details. Data will be kept securely for 7 years after publication of the findings and then destroyed.

Limitations to confidentiality

- **If you express current or future intention to harm yourself or someone who is specifically identified, there would be no grounds for maintaining confidentiality**. Your key worker or a duty worker at the drug treatment service where the interview has taken place will be told by the researcher of your intentions and the worker will conduct a risk assessment.

What are the possible benefits of taking part?

Your feedback on taking part in this programme will help us improve the programme that will potentially help people who inject drugs reduce the risk of blood borne viruses transmission.

What are the possible disadvantages and risks of taking part?

There is low risk of harm by taking part. However, talking about sensitive topics including potential risks for the transmission of blood borne viruses may make you feel worried or anxious. If you are worried or anxious or wish to find out more about blood borne viruses, you will be given the opportunity to speak to a member of staff at a local drug treatment service if you want to. We have also provided you with a range of contact numbers and websites that will be able to help.

Do I have to take part?

No. It is up to you to decide whether or not you want to take part in the focus group. If you agree to take part, we will then ask you to sign a consent form. This study is independent of your treatment. You are free to withdraw at any time without giving a reason. This will not affect the care that you are receiving.

Expenses

This study is funded by the National Institute for Health Research. You will receive a shopping voucher for participating in the focus group.

Results of the research study

The results of this research study will be available after we have analysed the data. Summaries of the results will be made available in the drug treatment settings involved in this study in June 2016. You will not be identifiable from any of the results presented.

What happens if something goes wrong?

If you're not happy with the care or treatment you've received as part of this study, you have the right to complain. Your local Patient Advice and Liaison Service (PALS) will be able to help you make a complaint. Phone NHS 111 for details of your nearest PALS.

Who reviewed the study

All research in the NHS is looked at by an independent group called a Research Ethics Committee. They make sure that the research is fair. The study has been reviewed by the East Midlands – Leicester South Research Ethics Committee (reference: 15/EM/0413).

Who is organising and funding the research?

The research is being led by Dr Gail Gilchrist, from the National Addiction Centre at King's College London, and is funded by the National Institute for Health Research. If you wish to talk to someone about the research please contact Dr Gilchrist on [telephone number]

Useful contact numbers

For information about **local drug treatment services** call the Frank drugs helpline on [redacted] or visit the Frank website http://www.talktofrank.com/need-support?ID=108

The Hepatitis C Trust Helpline [redacted] or [redacted] http://www.hepctrust.org.uk/
Open 10.30am to 4.30pm Monday to Friday (except Bank Holidays and the Christmas break, when dates and times may vary).Helpline is staffed solely by people with hepatitis C, some of whom have been through/or are currently undergoing treatment.

British Liver Trust [redacted]
www.britishlivertrust.org.uk (Free helpline, Mon-Fri 09.00-17.00) *The British Liver Trust is the national charity working to reduce the impact of liver disease in the UK through support, information and research.*

National Hepatitis Support Line [redacted]
http://www.hepbpositive.org.uk/ *Help the public and patients overcome hepatitis B. They clarify and reassure patients that hepatitis B is both easy to vaccinate against and caught early on an easy to manage common child acquired condition.*

National Sexual Health Line [redacted] **(24 hours)**
The National Sexual Health Line is UK-wide and provides confidential advice and information on all aspects of HIV, AIDS and sexual health. The Helpline can also provide UK wide referrals to specialist services. Open 24 hours a day, seven days a week. All calls are taken by trained and paid staff. It is not a counselling service, but gives you details of local helplines & services if needed.

Terrence Higgins Trust Direct Helpline [redacted]
(open 10am - 10pm Monday - Friday, and 12 noon - 6pm on Saturday and Sunday). Terrence Higgins Trust Direct Helpline can give you HIV information, advice and support over the phone.

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Participant information sheet (Phase 5. Focus group)

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Thank you once again for taking part in the study. We would now like to invite you to take part in a focus group about your experiences of taking part in the group programme. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. This should take about 5 minutes. Do feel free to talk to others about the study if you wish. We appreciate you taking the time to decide whether or not to participate.

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Expenses

This study is funded by the National Institute for Health Research. You will receive a small sum of money for participating in the focus group.

Results of the research study

The results of this research study will be available after we have analysed the data. Summaries of the results will be made available in the drug treatment settings involved in this study in June 2016. You will not be identifiable from any of the results presented.

What happens if something goes wrong?

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