The Queen's Anniversary Prizes
For Higher and Further Education
2017

HSRU
Promoting Excellence in Health Services Research

Whose Participant Information Leaflet is it anyway? Do we tell potential trial participants what they want to know or what we want to tell them?

Lynn Laidlaw

Public Partner (@lynn_laidlaw)

Shaun Treweek

Researcher, University of Aberdeen (@shauntreweek)

HSRU is core funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. The author accepts full responsibility for this talk.

CHIEF SCIENTIST OFFICE

UNIVERSITY OF ABERDEEN

www.abdn.ac.uk/hsru

Follow us on @hsru_aberdeen

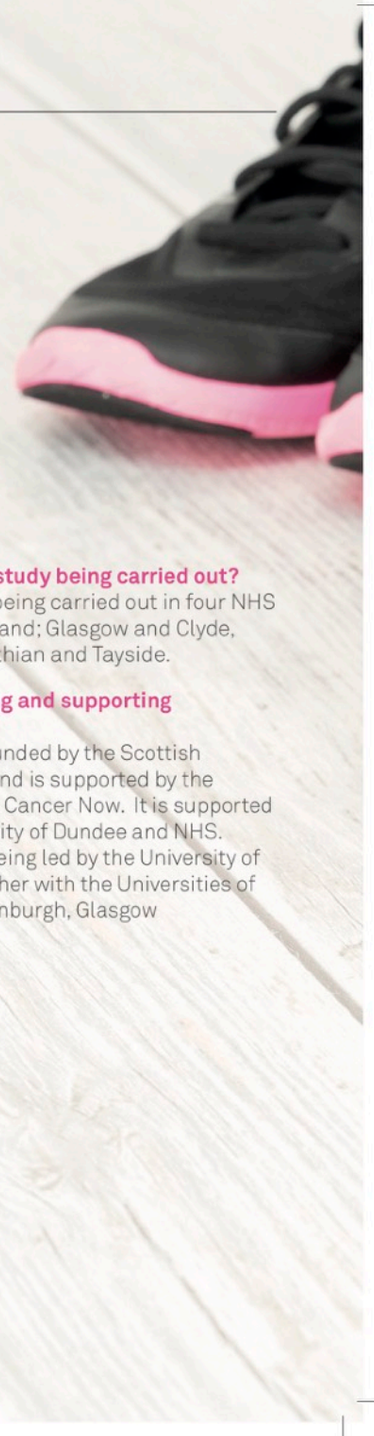
Background

HSRU

What is a Participant Information Leaflet and what is consent? And why do we have them?

Background

HSRU



PART 1: BACKGROUND TO THE STUDY

Around 75% of Scottish women aged 50 to 70 years attend the NHS breast screening programme with over 160,000 women being seen every year.

We believe that the breast screening clinic provides an excellent opportunity to provide information about how to reduce lifestyle related breast cancer risks. This study will recruit 552 women and aims to test the success of the ActWELL lifestyle programme. We will do this by comparing two groups of women to see whether our programme helps them change their diet, physical activity levels and body weight.

Why am I being given information about this study?

We are letting ALL women who attend for breast cancer screening know about the study.

Why should I read this leaflet?

Before you decide whether to take part, it is important that you understand why we are doing it, and what it involves. You may also want to discuss it with your family and friends. You do not have to make an immediate decision about taking part in the study.

Where is the study being carried out?

This study is being carried out in four NHS areas in Scotland; Glasgow and Clyde, Grampian, Lothian and Tayside.

Who is funding and supporting the study?

The study is funded by the Scottish Government and is supported by the charity Breast Cancer Now. It is supported by the University of Dundee and NHS. The study is being led by the University of Dundee, together with the Universities of Aberdeen, Edinburgh, Glasgow and Stirling.

ActWELL

INFORMED CONSENT FORM Participant Identification Number:

Title of Study: **A randomised control trial to assess the impact of a lifestyle intervention (ActWELL) in women invited to NHS breast screening**

Name of the Researcher: Professor Annie S Anderson, Centre for Public Health Nutrition Research

Sponsors: University of Dundee and NHS Tayside Please initial box

1. I confirm that I have read the information sheet dated ....., V..., 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 at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by the Researcher and/or research team, the Sponsors or regulatory authorities where it is relevant to my taking part in this research. I give permission for the Researcher and/or research team, the Sponsors and regulators to have access to my records. ☐
4. I agree to provide a blood sample for research purposes (change in diabetes and cardiovascular risk) and that I will not be informed of any results. ☐
5. I understand any coaching sessions or interviews I participate in during or at the end of the study might be digitally recorded, typed up, anonymised and then the recording will be erased. ☐
6. I understand that if I am interviewed during or at the end of the study, the comments I make may be quoted in any reports, papers or presentations that are produced as a result of the research, but that they will be kept anonymous. ☐
7. I agree to my General Practitioner being informed of my participation in the study. ☐
8. I agree to relevant information and my contact details being given to the charity Breast Cancer Now to allow a lifestyle coach to facilitate my coaching session. ☐
9. I agree to be contacted by the Researcher and/or research team in the event that I may be suitable for further research projects in the future. ☐
10. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
11. I agree to take part in the above study. ☐

PLEASE TURN OVER..

The PIL– the HRA view

HSRU

‘The [PIL] should support the consent process by helping to ensure that all those who are invited to take part in a research study have been adequately informed.

In most circumstances it should be used to support conversations with potential participants, rather than being the sole source of information being made available to them.’

The PIL– the HRA view

‘The [PIL] should support the
to ensure that all those who a
research study have been ade

In most circumstances it shou
conversations with potential p
being the sole source of infor
to them.’

Template released by HRA (version 2)

Participant Information Sheet (PIS) Template

This is not offered as a rigid template, but rather a flexible framework.

We have ***suggested*** sub-headings which you may decide are appropriate to use or not, depending on the type of study you are planning and what is involved.

Remember the aim of a PIS is to provide sufficient information, in an understandable format to support potential participants in making the right decision for them: to take part in your study, or to decline participation.

For an illustration of how thinking about layout can improve your PIS, see the Newland Hill example available from our online guidance.

We would suggest that you visit the full guidance which provides more detail on the content of a PIS, and importantly also discusses appropriate styles / formats and covers some of the principles underpinning consent to take part in research.

Study title

Remember: I.P.O.C - Intervention, Population, Outcome, Comparator (if appropriate) is a rule that helps produce a meaningful study title.

Invitation and brief summary

Potential participants should be given very brief information about your study: just enough to decide if they wish to read further.

There may be specific issues to address here when you are inviting someone else to give consent on behalf of another, or you are consulting someone to give their opinion on the inclusion of another (e.g. adults not able to consent for themselves)

What’s involved? (Full guidance covering what’s involved)

Explanation: purpose of and background to the research and invitation

What is the nature of what you are proposing? Why are you doing this research? What is already known? How many will be involved in the study? What alternatives are available to potential participants’? Etc.

You should try to keep this brief and avoiding cutting and pasting directly from a protocol; keep your language understandable.

Please check HRA PIS and consent guidance for updates (this version was released on Feb 10th 2017)

Consent– the HRA view

HSRU

‘The function of a consent form is to record the participant's decision, and to indicate that the process was conducted appropriately and with suitable discussion.’

Consent– the HRA view

‘The function of a consent for
participant's decision, and to
conducted appropriately and

(Form to be on headed paper)

IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) 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 at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. (If appropriate) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
5. (If appropriate) I agree to my General Practitioner being informed of my participation in the study. / I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my GP and the research team. ☐
6. (If appropriate) I understand that the information held and maintained by _____ [*(enter name of organisation(s) that will be providing you with data, including any NHS/HSC organisations)*] may be used to help contact me or provide information about my health status. ☐
7. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

Do PILs do what they should?

HSRU

2014: test of 60 PILs against a International Patient Decision Aid Standards*

‘PILs did not meet current standards of information to support good quality decision making.’

*Gillies et al. Trials 2014, 15:62

Do PILs do what they should?

HSRU

2018: What is most important (20 people)?*

Table 2 Potential trial participants: ranking of statements (from most to least important)

Statement	Rank	Median	IQR	Range
What are the possible side effects of trial treatment?	**1 (most important)**	2	1.5–3.5	1–5
What are the possible disadvantages and risks of taking part?	**2**	2	2–3	1–4
What will I have to do?	**3**	2.5	2–4	2–5
What are the possible advantages of taking part?	**4**	3	2–4	2–5
What is the treatment that is being tested?	**5**	3	2–4	1–7

*Innes et al. BMJ Open 2018;8:e023303

Consent form..

Who should decide what's on it?

NHS Grampian

UNIVERSITY OF ABERDEEN

Consent form

Centre Number (if applicable):
Participant ID Number:
IRAS reference:
Name of CI:

Study Number (if applicable):
Title of Study:
EudraCT number (if CTIMP):

		Please initial
1.	I confirm that I have read and understand the information sheet Version No: *<Current version No>* Date: *<Current version date>* 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 at any time, without giving any reason, without my medical care or legal rights being affected. Data collected up until the point of withdrawal may still be used in analysis.	
3.	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Aberdeen, from regulatory authorities if appropriate, or from the NHS Board/Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ***OR FOR A PROJECT WITH NO NHS INVOLVEMENT (e.g. healthy volunteers).*** *I understand that data collected during the study, may be looked at by individuals from the University of Aberdeen, the regulatory authorities if appropriate, or from the NHS Board/Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.*	
4.	I agree to my GP being informed of my participation in the study.	
5.	I agree to my interview being audio/video recorded. ***IF USING ANONYMOUS QUOTES FOR PUBLICATION*** *(remove if not required). I agree to my interview being audio/video recorded. I understand that anonymised quotations from this interview may be used for presentations and publications.* ***IF USING A THIRD PARTY TRANSCRIPTION SERVICE*** *(remove if not required)I agree that my interview may be transcribed by an external company contracted by (the University of Aberdeen/NHS Grampian delete as appropriate)*	
6.	I agree to the storage and use of my samples for ethically reviewed and approved future studies.	
7.	I agree that I may be contacted by the study team for future ethically approved studies. I understand identifiable contact information will be kept after the end of this study and this information will be held in accordance with the data protection act.	
8.	I agree to give a tissue/biopsy sample for this study.	
9.	I agree for my information to be stored on (*please insert whether UoA or NHSG servers*).	
10.	I agree to take part in the above study.	

Name of participant	**Date**	**Signature**
Name of researcher	**Date**	**Signature**

RECOVERY RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

Hospital Name:
(use CAPITALS)

Patient Name:
(use CAPITALS)

Study ID:
(enter after randomisation)

1. Information about the study has been provided to me: I confirm that I have read (or had read to me) and understood the Participant Information Leaflet (V3.0 07-Apr-2020) and I have had the opportunity to consider the information and ask questions. These have been answered satisfactorily.

2. Voluntary participation: I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.

3. Access to study data about me: I give permission for relevant sections of my medical notes and information collected during the study to be looked at, in confidence, by authorised individuals from this hospital, the University of Oxford, and regulatory authorities to check that the study is being carried out correctly.

4. Access to my medical information: I agree that medical information collected by the doctors and hospitals which provide me with care and which may be located in local or national health and research organizations (including hospital admission, civil registration, audit and research data) may be provided to the study coordinating centre both during and for up to 10 years after the scheduled follow-up period. I understand that information that identifies me will be passed securely to such bodies to make this possible and that I can opt out of this at any time by writing to the coordinating centre team.

5. Data stored on computer: I understand that information about my progress in the study will be recorded on a computer database, and that this data will be stored on computers supervised by the University of Oxford. I understand that this information will be kept securely and confidentially.

6. Agreement to take part: I have read the information (or had it read to me), had an opportunity to ask questions and agree to take part in the above study.

.....	.....	...../...../.....
PRINTED name of participant	Signature	Today's date
.....	.....	...../...../.....
PRINTED name of person taking consent	Signature	Today's date

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes*

UNIVERSITY OF ABERDEEN

Consent form

Study Number (if applicable):

Title of Study:

EudraCT number (if CTIMP):

Please initial

nderstand the information sheet Version No: *<Current version* > for the above study. I have had the opportunity to consider the have had these answered satisfactorily.

on is voluntary and that I am free to withdraw at any time, ut my medical care or legal rights being affected. Data collected may still be used in analysis.

ons of my medical notes and data collected during the study may the University of Aberdeen, from regulatory authorities if oard/Trust, where it is relevant to my taking part in this research. iduals to have access to my records.
HS INVOLVEMENT (e.g. healthy volunteers). *I understand that may be looked at by individuals from the University of Aberdeen, ropriate, or from the NHS Board/Trust, where it is relevant to my e permission for these individuals to have access to my data.*

l of my participation in the study.

dio/video recorded.
S FOR PUBLICATION *(remove if not required).*
dio/video recorded. I understand that anonymised ay be used for presentations and publications. ***IF USING A THIRD*** *E (remove if not required)I agree that my interview may be any contracted by (the University of Aberdeen/NHS Grampian*

f my samples for ethically reviewed and approved future studies.

by the study team for future ethically approved studies. I information will be kept after the end of this study and this dance with the data protection act.

ample for this study.

e stored on (*please insert whether UoA or NHSG servers*).

e study.

Date **Signature**

Date **Signature**

Trust and practicalities

HSRU

- Are PILs and consent fit for purpose?
- What do I want from a PIL and consent process?
- What are the issues with what we have now?

Questions and discussion

HSRU

- What does good look like and for whom (might it be different for different groups)?
- What stops us doing what looks good? What are the key challenges?
- How can we challenge and question what we do now? Why don't we?

HSRU
Promoting Excellence in Health Services Research

TRIAL FORGE

www.trialforge.org

If you have any further questions please contact:

Lynn Laidlaw

Public Partner (@lynn_laidlaw)

Shaun Treweek

Researcher, University of Aberdeen (@shauntreweek)

HSRU is core funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. The author accepts full responsibility for this talk.

CHIEF SCIENTIST OFFICE

UNIVERSITY OF ABERDEEN

www.abdn.ac.uk/hsru

Follow us on @hsru_aberdeen