UK Data Service

Consent issues in data sharing

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Overview

- Why, how and when to seek consent?
- Special considerations and challenges.
- Consent in practice: wording used in real example consent forms, information sheet and in UKDS model consent form.
- Further resources & future training events.

Why to seek consent?

To ensure:

- Participants understand what they’re signing up to making participation and research more effective.
- Research conducted is ethical.
- Compliance with data protection regulation.

Consent in research

- Consent for **research ethics.**
- Consent for **processing of personal data.**

Legal Frameworks

- The common law duty of confidentiality.

- Data protection legislation (the UK General Data Protection Regulation (UK GDPR) within the Data Protection Act (DPA) 2018).

Duty of confidentiality and data sharing

- Exists in UK common law and may apply to research data.

- Disclosure of confidential information is lawful when:
    - The individual to whom the information relates has consented.
    - Disclosure is necessary to safeguard the individual, or others, or is in the public interest.
    - There is a legal duty to do so, for example a court order.

- Best practice is to avoid very specific promises in consent forms.

Data protection considerations

- If personal information about people is collected or used in research, then the data protection regulations applies.

- **Personal information or data** is any information relating to an identified or identifiable natural person.

- **Anonymised data is NOT personal data so the GDPR does NOT apply.**

cont…Data protection considerations

- Data protection act 2018 (DPA), General data protection regulation 2018 (GDPR) & the UK GDPR 2021.

- DPA (2018) & the UK GDPR (2021) applies when
  - ✓a researcher based in the UK collects personal data about people anywhere in the world.
  - ✓a researcher outside the UK collects personal data on UK citizens.

- DPA (2018), EU GDPR (2018) & the UK GDPR (2021) applies when
  - ✓a researcher based in the UK collects personal data about people across Europe.

Legal basis to process personal data (UK GDPR)

- consent
- public interest
- legitimate interest
- protect vital interest
- legal obligation
- performance of a contract.

Conditions of consent when used as a legal base for processing personal data

- Must **be freely given, informed, unambiguous, specific (granular).**
- A **clear affirmative** action.
- **Cannot be inferred from silence, pre-ticked boxes or inactivity.**
- Participants can **withdraw** consent to process their personal data at any time.
- Must be **documented**, i.e. recorded, written or oral.
- An **explicit consent** is required to process special categories data (e.g. a person's race, ethnic origin, politics, religion, genetics, sex life, health).

  explicit = express statement of consent, e.g. written statement.

Legal basis to process personal data

- Research conducted in the UK:
  - **Task in public interest** (for all public bodies (NHS / HSC, Universities, UKRI, etc).
  - **Legitimate interest** (for all non-public bodies (charities, commercial companies, etc).
- If you are processing special category data::
    - Legal basis.
    - Additional condition.
    - Data protection impact assessment (DPIA) for any type of processing which is likely to be high risk.

Explicit consent

- Explicit consent is informed consent which is recorded or documented
- In order for consent to be valid, it must be:
  - freely given, Specific, Informed, Unambiguous.
- Explicit consent statement should specifically refer to:
  - the particular data set that is to be processed
  - the precise purpose of processing
  - any risks/implications as a result of the data processing
  - any relevant and specific information that might influence the decision of a data subject to give or not give their consent.

Explicit consent checklist (University of Dublin)

Checklist to determine whether consent in is line with the GDPR and Health Research Regulations

GDPR Explicit Consent Requirements – Processing of Personal Data	Yes/No
1. Has the consent been freely given? Have you informed the data subject that they have the option to withdraw their consent at any time if they so wish? - The element "free" implies real choice and control for data subjects. - If the data subject has no real choice, feels compelled or coerced to consent in any way or if the data subject feels that if they do not consent their medical care or treatment may be affected in some way, then their consent will not be valid. - We understand that given the relationship between a data subject and the medical/research team, this can be a difficult balance. If your data subject is fully informed (see item 3), it will be easier to assess whether their consent is freely given. - The data subject must be informed that they can withdraw their consent at any time without detriment. This should be highlighted from the outset so that the data subject does not feel under any obligation to continue against their wishes.	

Cont..Explicit consent checklist (University of Dublin)

2. Is the consent specific? - The data subject should not be surprised by any use of their personal data, health data or any other sensitive data by the research team. - Have all of the data controllers been clearly identified?	
3. Is the consent informed? - In order to be informed, the data subject should have enough information to be able to make their decision to consent or not. - Have you clearly stated what (type of) personal data will be collected and used? (e.g. names, addresses, blood type, medical condition, etc.).	
4. The consent must be unambiguous - Consent requires a statement from the data subject or a clear affirmative act, which means that the data subject must have taken a deliberate action to specifically consent to the particular processing of the personal data. Is it obvious that the data subject has consented to the particular processing? - You must demonstrate that consent has been given to a particular processing activity. Have you maintained a written record of the consent? - The consent form should be signed by the data subject in order to remove all possible doubt.	

Explicit consent checklist (University of Dublin) cont..

5. Automated decision-making

- *If applicable* Have you included information about the use of the data for automated decision-making in accordance with Article 22 (2)(c) GDPR? Processing is 'automated' where it is carried out without human intervention, and where it produces legal effects or significantly affects a data subject. Automated processing includes profiling.

6. International data transfers

- *If applicable* Have you included information on the possible risks of data transfers outside the EEA due to absence of an adequacy decision and of appropriate safeguards as described in Article 46? See: https://gdpr-info.eu/art-46-gdpr/

Health Research Authority guidance on Consent

European diversity in informed consent

Country	Consent required
Czech Republic	Yes, if personal data are collected
Croatia	Yes, if personal data are collected
Germany	Yes, if personal data are collected, processed and stored
Netherlands	Yes, if personal data are collected, processed and stored
Norway	Yes, but exceptions for research
North Macedonia	Yes
Serbia	Yes
Sweden	Yes, if research is carried out on humans, biological material, or sensitive personal data
Switzerland	Yes, for any processing of personal data
United Kingdom	No

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How to seek consent?

Format of consent

- Consent can be gained in **written** or **oral** form.
- Format depends on the kind of research.
- Important to document how it has been gained, what information has been provided to the participants and what they have agreed to.

Forms of consent

	Advantages	Disadvantages
Written consent	• More solid legal ground. • Often required by Ethics Committees. • Offers more protection for researcher.	• Not possible for some cases: infirm. • May scare people from participating.
Verbal consent	• Best if recorded.	• Can be difficult to make all issues clear verbally. • Possibly greater risks for researcher.

Consent documentation: Information sheet

An information sheet should cover the following topics:

- **Purpose** of the research.
- What is **involved** in participating.
- **Benefits** and **risks** of participating.
- Procedures for **withdrawal.**
- **Usage of the data** during research, dissemination, storage, publishing and archiving.
- **Details of the research:** funding source, sponsoring institution, name of project, contact details for researchers, how to file a complaint.

Cont…

Consent documentation: Consent form

Consent form should:

- Use simple language and free from jargon.
- Allow the participant to clearly respond to points such as:
    - The participant has **read and understood information** about the project.
    - The participant has been given the **opportunity to ask questions.**
    - The participant **voluntarily agrees to participate** in the project.
    - The participant understands that they can **withdraw at any time** without giving reasons and without penalty.
    - **Future uses** (e.g. publications, share and reuse).
    - Signatures and dates of **signing** for the participant and the researcher.

Cont…

cont…Consent documentation

If **personal information** is collected:

- How personal information will be processed and stored and for how long.
- Procedures for maintaining confidentiality.
- Procedures for ensuring ethical use of the data.

If the **GDPR applies**:

- The contact details of the data controller (DPO, REO, Researcher).
- Who will receive or have access to the personal data.
- A clear statement on the right of the participant (right to access, correction or removal).

Methods used to obtain consent

- **Signing** a consent statement on a paper form.
- **Ticking** an opt-in box on paper or electronically.
- **Clicking** an opt-in button or link online.
- **Selecting** from equally prominent yes/no options.
- **Choosing** technical settings or preference dashboard settings.
- **Responding** to an email requesting consent.
- **Answering** yes to a clear oral consent request.

Record keeping when processing personal data

Good record keeping should include the following:

- **Who consented**: name or other identifier.
- **When they consented**: dated document for written or oral consent and a time stamp for online records.
- **What they were told at the time**: for written consent, a copy of the consent form used to demonstrate the consent statement and for an oral consent a document with the script that was used at the time of data collection.
- **How they consented**: written, online, oral.
- **Have the consent withdrawn**: if so, when?

When consent becomes invalid

- If there are **doubts** over whether someone has consented.
- If a **person doesn't realise** they have consented.
- There are **no clear records** to demonstrate participants had consented.
- **No genuine free choice** over whether to opt in was given.
- There was a clear **imbalance of power** between a researcher and the individual.

cont…

cont…When consent becomes invalid

- The consent request was **vague or unclear.**
- **Pre-ticked opt-in boxes** or other **methods of default consent** were used.
- The researcher’s organisation was not specifically **named.**
- Subjects were not informed about their **right to withdraw.**
- Subjects cannot **easily withdraw consent.**
- The **research purposes or activities have evolved** since the original consent.

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When to seek consent?

One-off consent or process consent?

	Advantages	Disadvantages
One-off consent	Simple lease hassle to the participants	Research outputs not known in advance Participants may not know all info they contribute to
Process consent	Ensures active consent	May not get all consent needed before losing contact, repetitive, may annoy participants

Special considerations when seeking consent

- medical research
- internet research
- twitter
- consent for linking to administrative data
- children and young adults
- people with learning difficulties
- research within organisations or in the workplace
- crime.

Further information: consent in special cases.

Challenges

- Retrospective consent - could be obtained when consent was not sought at the point of data collection.
- Right to withdraw – what to do with already collected data?
- Research without consent (Further details: Research without consent).
- Participant perception and expectations.
- Children & vulnerable people.
- Participant's poor awareness of their rights.
- Failure to provide adequate information.
- Absence of consideration of participant's background such education, culture.
- Use of jargon.
- Sceptical of confidentiality issues.

UKDS Model Consent Form and examples from real research

Three key areas to be addressed

Wording in consent forms and information sheets could be broken down in **three** key areas:

- Taking part in the study.
- Use of the information in the study.
- Future use and reuse of the information by other.

UKDS Model Consent Form template: Section on taking part in the study

Please tick the appropriate boxes	Yes	No
1. Taking part in the study.		
I have read and understood the study information dated [DD/MM/YYYY], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	☐	☐
I understand that taking part in the study involves [.....] (Guidance) • Describe in a few words how information is captured, using the same terms as you used in the information sheet, for example: an audio-recorded interview, a video-recorded focus group, a survey questionnaire completed by the enumerator, an experiment, etc.]. • For interviews, focus groups and observations, specify how the information is recorded (audio, video, written notes). • For questionnaires, specify whether participant or enumerator completes the form. • For audio or video recordings, indicate whether these will be transcribed as text, and whether the recording will be destroyed.	☐	☐
(Optional) If there is a potential risk of participating in the study, then provide an additional statement: I understand that taking part in the study has [.....] as potential risk.	☐	☐

UKDS Model Consent Form Template: Section on use of information in the study

2. Use of the information in the study.		
I understand that information I provide will be used for [.....] (Guidance) • List the planned outputs, e.g. reports, publications, website, video channel etc., using the same terms as you used in the study information sheet. • Consider whether knowledge sharing and benefits sharing needs to be considered, e.g. for indigenous knowledge.	☐	☐
I understand that personal information collected about me that can identify me, such as my name or where I live, will not be shared beyond the study team. • At times this should be restricted to the researcher only.	☐	☐
(Optional) If you want to use quotes in research outputs, add: I agree that my information can be quoted in research outputs.	☐	☐
(Optional) If you want to use named quotes, add: I agree that my real name can be used for quotes.	☐	☐
(Optional) If written information is provided by the participant (e.g. diary), add: I agree to joint copyright of the [specify the data] to [name of researcher].	☐	☐

UKDS Model Consent Form template: Section on future use and reuse of the information

3. Future use and reuse of the information by others.		
I give permission for the [specify the data] that I provide to be deposited in [name of data repository] so it can be used for future research and learning. (Guidance) • Specify in which form the data will be deposited, e.g. de-identified, anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit. • Specify whether deposited data will be de-identified or anonymised, and how. Make sure to describe this in detail in the information sheet. • Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.	☐	☐

In practise: wording in consent form information sheet 1

The interviews will be archived at ……. and disseminated so other researchers can reuse this information for research and learning purposes:

- ❑ I agree for the audio recording of my interview to be archived and disseminated for reuse
- ❑ I agree for the transcript of my interview to be archived and disseminated for reuse
- ❑ I agree for any photographs of me taken during interview to be archived and disseminated for reuse

We expect to use your contributed information in various outputs, including a report and content for a website. Extracts of interviews and some photographs may both be used. We will get your permission before using a quote from you or a photograph of you.

After the project has ended, we intend to archive the interviews at …. Then the interview data can be disseminated for reuse by other researchers, for research and learning purposes.

In practise: wording in consent form/information sheet 2

Use of information I provide beyond this project	Yes	No
I agree for the data I provide to be archived at UK Data Archive.		
I understand that other genuine researchers will have access to the data only if they agree to preserve the confidentiality of the information as requested in this form.		
I understand that other genuine researchers may use my words in publications, reports, web pages, research outputs only if they agree to preserve the confidentiality of the information as requested in this form.		

In practise: wording in consent form/information sheet 3

We ask you to consider the following points before agreeing to participate.

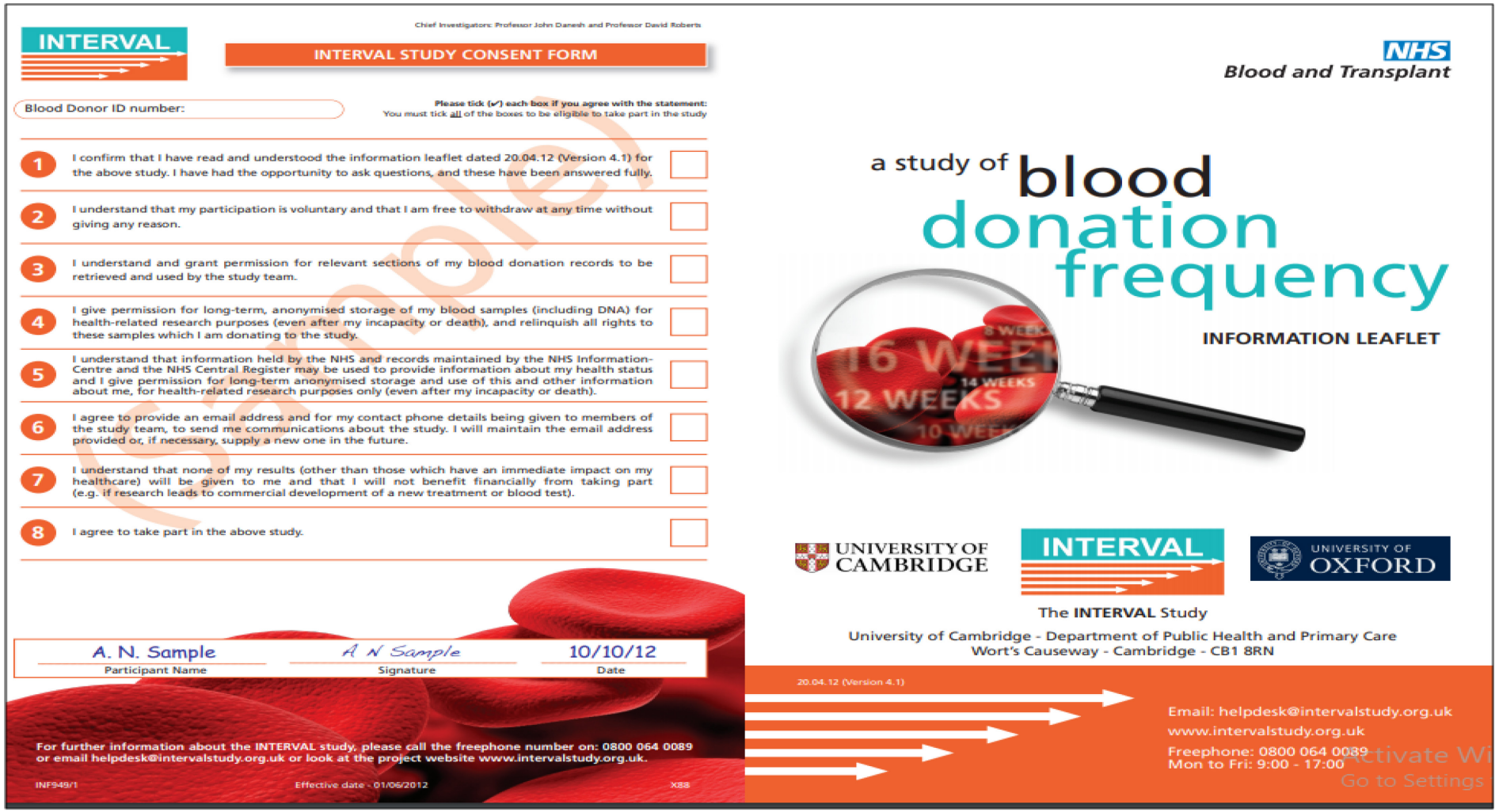
- Your contribution to the research will take the form of a focus group participant. This will be digitally video recorded and transcribed.
- **Your name and any information which may directly or indirectly identify you will be altered to protect your anonymity**.
- Any recordings of the discussions will be kept securely, and only authorised to other researchers on the condition they preserve your anonymity.
- The transcriptions (*excluding* names and other identifying details) will be retained by the researcher and analysed as part of the study. They will also be deposited with the UK Data Archive which has strict regulations about accessing data for research and protecting participant confidentiality.

Any personal information that could identify you will be **removed or changed** before files are shared with other researchers or results are made public.

Statements to avoid

1. Any information that I give will be used for research only and will not be used for any other purpose.
2. I understand that only the research team will have access to the information I provide.
3. Data will be destroyed after xxx years.

Example from Health Research Authority (HRA)



Chief Investigators: Professor John Danesh and Professor David Roberts

INTERVAL

INTERVAL STUDY CONSENT FORM

Blood Donor ID number:

Please tick (✓) each box if you agree with the statement:
You must tick all of the boxes to be eligible to take part in the study

1. I confirm that I have read and understood the information leaflet dated 20.04.12 (Version 4.1) for the above study. I have had the opportunity to ask questions, and these have been answered fully. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
3. I understand and grant permission for relevant sections of my blood donation records to be retrieved and used by the study team. ☐
4. I give permission for long-term, anonymised storage of my blood samples (including DNA) for health-related research purposes (even after my incapacity or death), and relinquish all rights to these samples which I am donating to the study. ☐
5. I understand that information held by the NHS and records maintained by the NHS Information Centre and the NHS Central Register may be used to provide information about my health status and I give permission for long-term anonymised storage and use of this and other information about me, for health-related research purposes only (even after my incapacity or death). ☐
6. I agree to provide an email address and for my contact phone details being given to members of the study team, to send me communications about the study. I will maintain the email address provided or, if necessary, supply a new one in the future. ☐
7. I understand that none of my results (other than those which have an immediate impact on my healthcare) will be given to me and that I will not benefit financially from taking part (e.g. if research leads to commercial development of a new treatment or blood test). ☐
8. I agree to take part in the above study. ☐

A. N. Sample	A N Sample	10/10/12
Participant Name	Signature	Date

For further information about the INTERVAL study, please call the freephone number on: 0800 064 0089 or email helpdesk@intervalstudy.org.uk or look at the project website www.intervalstudy.org.uk.

INF949/1 Effective date - 01/06/2012 X88

NHS Blood and Transplant

a study of **blood donation frequency**

INFORMATION LEAFLET

UNIVERSITY OF CAMBRIDGE

INTERVAL

UNIVERSITY OF OXFORD

The **INTERVAL** Study

University of Cambridge - Department of Public Health and Primary Care
Wort's Causeway - Cambridge - CB1 8RN

20.04.12 (Version 4.1)

Email: helpdesk@intervalstudy.org.uk
www.intervalstudy.org.uk
Freephone: 0800 064 0089
Mon to Fri: 9:00 - 17:00

Example from Health Research Authority (HRA): 1

INTERVAL

a study of blood donation frequency

We would like to invite you to join the INTERVAL study which has been set up by the Universities of Cambridge and Oxford in collaboration with NHS Blood and Transplant (NHSBT).

We are carrying out a study of 50,000 blood donors to compare different intervals between blood donations. Our goal is to find the optimum interval for which it is safe for different donors to give blood. We will want to look at whether intervals should be tailored to donors by age, gender, genetic profile and other characteristics. The study's findings should help to improve the well-being of future blood donors in England and enhance the country's blood supplies.

Before you decide whether to participate, it is important for you to understand why the study is being conducted and what is involved. Please take the time to read the following information carefully, and discuss it with others if you wish.

If anything is not clear, or if you would like more information, please call the freephone number on **0800 064 0089** to talk to a member of our study team or email **helpdesk@intervalstudy.org.uk**. More information about the study is also available at:

www.intervalstudy.org.uk

At your next donation visit, there will be a further opportunity to ask any questions that you might have.

Thank you for taking the time to consider taking part in the INTERVAL study.

1

Why is the study needed?

Because shortages in the blood supply are projected for England, NHSBT is exploring different approaches to ensure adequate blood supplies for the future.

One way to increase the blood supply is to ask blood donors to give blood more frequently. However, some time is required between blood donations to allow the body to replace its iron stores.

Because no one knows what is the optimum interval between donations, blood donation services in different countries have developed varying customs. In England, NHSBT invites men to donate every 12 weeks and women to donate every 16 weeks. By comparison, some European countries invite people to donate blood as frequently as every 8 weeks.

The INTERVAL study aims to recruit about 25,000 men and about 25,000 women from NHSBT blood donation centres across England. If you choose to join this study, you will take part for a period of two years. During this time we will invite you to give blood either at your usual donation interval or more frequently. Men will be invited to donate every 8, 10 or 12 weeks and women every 12, 14 or 16 weeks. The donation interval you are allocated to will be decided by a process called 'randomisation', which is like a coin toss **(see box below)**. As usual, you will be able to give blood only if you pass the screening haemoglobin finger-prick test.

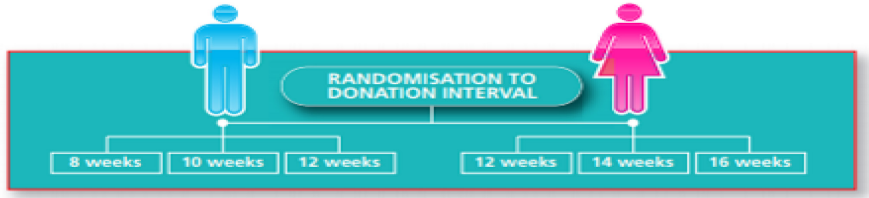
At the end of the study, we will compare the amount of blood donated and measures of well-being in people asked to give blood at standard intervals versus those asked to give blood more frequently.

To find out whether certain people have capacity to give blood more frequently, we will be collecting an additional small blood sample at the beginning and end of the study to look at iron levels and DNA for relevant genes. Not all of the blood sample will be used immediately and some will be stored so that it can be used to assist future studies about the health of blood donors.

Randomisation: means you will have an equal chance of being allocated to any one of three donation interval groups.
You will not be able to choose the interval you would prefer.
So before you agree to join the study, **it is important you are willing to be invited to donate at any of the three intervals.**

2

Example from Health Research Authority (HRA): 2



What does taking part in the study involve?

Taking part in the INTERVAL study would involve you:

- Being asked to attend donation appointments either at standard intervals between donations (i.e. 12 weeks for men and 16 weeks for women) or reduced intervals (i.e. either 10 or 8 weeks for men and 14 or 12 weeks for women) over a two-year period.
- Giving a small sample of blood for research purposes on your enrolment to the study and after two years. For some participants, further small samples of blood for research will be taken at additional time-points during the two-year period. This will not involve any additional needles.
- Completing online questionnaires and assessments every six-months during the study.
- Agreeing to give the INTERVAL study team permission to access your medical and other health-related records and for long-term anonymised storage and use of this information for future ethically-approved health-related research purposes only.
- Agreeing to have your samples, questionnaire data, health-related and other information stored by the INTERVAL study team and used, for many years, in an anonymous form by researchers for a broad range of ethically-approved scientific health studies.
- Being contacted, no more than three times a year, by the INTERVAL study team about further studies organised by NHSBT and/or Universities of Cambridge and Oxford. These studies will build on results and samples generated from the INTERVAL study to further understand the links between lifestyle, genes, traits and diseases. It is completely up to you if you would like to take part in further studies or not.

3

Why have I been invited and am I eligible?

We are inviting all blood donors who usually give blood at one of the permanent donation centres across England.

You <u>are eligible</u> to take part in the study if you:

- Are aged 18 or over.
- Are a whole-blood donor who usually gives blood at one of the permanent donation centres across England.
- Fulfil all normal criteria for blood donation.
- Are willing to be assigned to any of the study's donation intervals relevant to your gender.

You <u>are not eligible</u> to take part in the study if you:

- Do not have internet access or are unable to provide an email address for study correspondence.

Do I have to take part?

No, it is completely up to you. If you decide to take part you will be asked to sign a consent form at your next donation visit (see a sample copy of the consent form at the end of this leaflet). You are free to withdraw at any time, without giving a reason. Your decision has no influence on your blood donation or your choice to donate in the future.

What should I do if I want to take part?

If you would like to join the study, then all you need to do is to take this information leaflet and the accompanying invitation letter to your next donation appointment. Here you will be asked if you would like to take part and you will have the opportunity to ask any further questions.

4

Example from Health Research Authority (HRA): 3

What happens DURING my next donation visit?

Regular NHSBT staff at your donation centre will:

- Ask if you have received and understood this information leaflet and whether you would like to take part in the study. You will also have the chance to ask any questions that you might have before deciding whether to join.
- Assess whether you are eligible to join the study and, if you are, ask you to sign a study consent form. An example of this consent form is included at the back of this leaflet. As part of the consent process we will ask you to provide an email address and contact mobile phone number at which the study team may contact you.
- Collect about 15 ml of extra blood (approximately 3 teaspoons) for research from the sample pouch of the routine donation pack. No additional needles will be used.

What will happen to my blood samples?

Blood samples collected for the purposes of the research will either be used immediately, i.e. to perform a full blood count and measure substances related to your body's iron stores (e.g. ferritin) or will be frozen for use in future research. Stored samples will include separate components of your blood (e.g. plasma, serum and DNA) which will be:

- Kept securely at central laboratories. They will not be labelled with your name or contact details, but only with a unique study number.
- Used by the study investigators for medical and health-related studies which have relevant scientific and ethics approval.
- Used to measure biomarkers, which are substances in the body (e.g. haemoglobin) that can easily be measured and give a clue to health (e.g. iron deficiency).

5

- Used to study your DNA and related substances. In particular, we want to know how genes regulate blood cells. Variations in genes influence the behaviour of the blood cells and so we need to analyse your DNA in detail. As part of this study, we will test your DNA for many genes and we may determine the sequence of part of or your entire DNA code.

What happens immediately after I enrol?

A few days after enrolling in the study, we will send you an email containing a link to an online questionnaire. We would like you to complete this questionnaire within 7 days of receiving the email. The questionnaire will take about 15 minutes to complete and will ask you questions about your general health and lifestyle (e.g. smoking and diet). The data we collect will be stored securely and will contain no personal identifiers.

Once we have received your completed questionnaire, we will send you a further email. This will let you know the donation interval to which you have been randomly assigned. This information will also be given to NHSBT so they know you are taking part in the study and can make appointments at the required intervals.

6

Example from Health Research Authority (HRA): 4

What happens next?

Every six months we will send you an email requesting you to:

- Complete a very brief online questionnaire (taking less than 5 minutes) which will ask you to rate your general health.
- Report any medical events and/or any symptoms while you are taking part in the study.

At the end of the study we will also ask you to complete an online:

- Questionnaire about your general health which will take about 10 minutes to complete.
- Questionnaire about your views on donation and taking part in the research. We estimate that this questionnaire will take about 5 minutes for you to complete.
- Assessment including memory and attention-related tasks. We estimate this assessment will take about 10 minutes for you to complete.

At the end of the study there will also be the option for some blood donors, attending pre-selected donor sessions, to:

- Take part in one-to-one interviews to obtain views on giving blood and participation in the research.
- Take home and wear devices to measure physical activity over a period of 7 days.

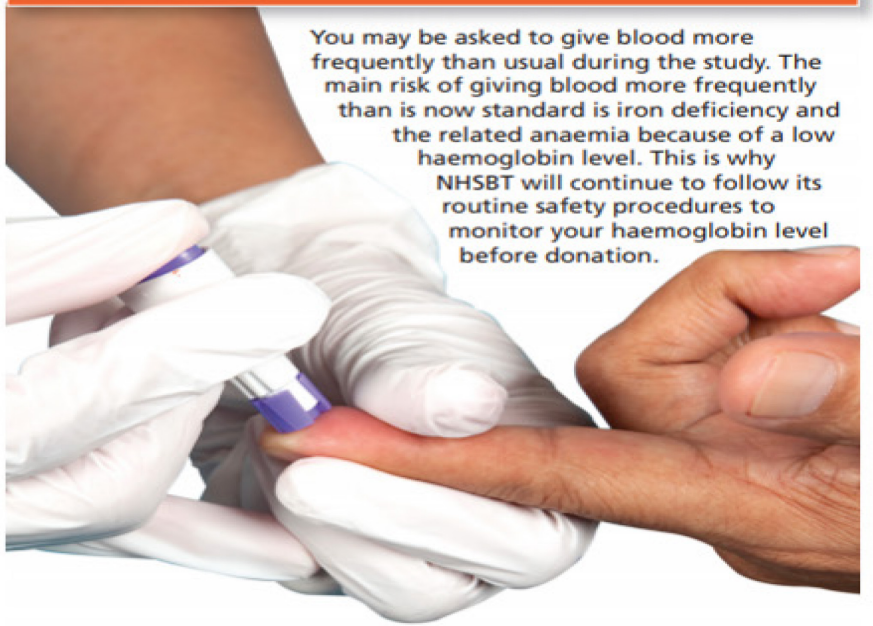
Information on your future health will be accessed by INTERVAL researchers from your routine medical and other health-related records at the time of joining the study and from time to time thereafter.

To be able to retrieve relevant health information we use your NHS number.

Are there any benefits for me in joining the study?

There will be no immediate direct benefit to you should you participate. However, there should be benefits to future blood donors and to the country's future blood supply because the results of the study are likely to influence how NHSBT collects blood donations.

Are there any risks for me in joining the study?



You may be asked to give blood more frequently than usual during the study. The main risk of giving blood more frequently than is now standard is iron deficiency and the related anaemia because of a low haemoglobin level. This is why NHSBT will continue to follow its routine safety procedures to monitor your haemoglobin level before donation.

It is important to stress that your safety will be looked after by NHSBT in the same way as before. That is, you will receive the usual 'finger-prick' screening test for haemoglobin levels and you will need to be within the safe range to be eligible to donate. If you fall outside this range you will be invited to return again at your allocated interval.

Example from Health Research Authority (HRA): 5

How do I withdraw if I want to do so?

The study will be most valuable if few people withdraw from it, so it is important to discuss any concerns you may have with a member of the study team before you agree to participate. However, you can withdraw from the study at any time and without giving a reason but we hope that you will continue to give blood as a regular donor.
You can withdraw by telephoning us on **freephone 0800 064 0089** Mon to Fri: 9:00 - 17:00 or by emailing helpdesk@intervalstudy.org.uk or by writing to the coordinating centre (see front of leaflet). This will allow us to discuss your concerns with you and determine the desired level of withdrawal from the following options.

"No further contact": This means that the INTERVAL team would no longer contact you directly, but would still have your permission to retain and use information and samples provided previously and to obtain and use further information from your health records.

"No further use": This means that, in addition to no longer contacting you or obtaining further information about you, any information and samples collected previously would no longer be available to researchers. Please note that we will not be able to remove results of any tests already performed with your samples from the study database but we will prevent your records from being used in any future research. We can also assure you that your blood samples will be removed from the central study repository after we have received your written notification. It will, however, not be possible to remove small volumes of your samples which already have been distributed to research laboratories but results which are generated after you have withdrawn will not be uploaded to the study database. Your signed consent and withdrawal forms will be kept as a record of your wishes.

If, having discussed the options and your concerns, you did decide to withdraw then we would send you a withdrawal form to confirm your wishes in writing. Examples of this form can be viewed on our website www.intervalstudy.org.uk. This form can be completed by you or, if you are not able to do so for some reason (such as illness), by someone able to act on your behalf. In the unlikely event of a loss of capacity to decide on continued participation in the study, the study team would retain blood samples and personal data collected and continue to use it confidentially in connection with the purposes for which consent has been granted.

11

Who will be able to use my information and samples?

Your anonymous information and samples will be available only to researchers who have relevant scientific and ethics approvals for their planned research. This could include researchers who are working in other countries and in commercial companies who are looking for new treatments or laboratory tests.

Insurance companies and employers will not be given any individual's information, samples or test results, and we will not allow access to the police, security services, relatives or lawyers, unless forced to do so by the courts.

There will be a requirement to publish the results of the research arising out of the samples and data collected during the study so that people can benefit from it.

The results will also be made available to participants and anyone else who might be interested at www.intervalstudy.org.uk.

Can I know the results obtained from my blood samples?

It is not planned to feedback any results from genetic tests. The only scenario where any other blood-based test results would be communicated back to you would be if we discover anything that has an immediate impact on your healthcare (e.g. in case cells are present in your blood that may point to leukaemia or a very high count of platelets). In this case, the researcher will inform a medical professional about the nature of the problem, and about who you are. The NHSBT medical professional would then use the routine procedures applicable in the NHS to get in touch with you and offer advice which may involve contacting your GP.

12

Example from Health Research Authority (HRA): 6

Who is organising and funding the study?

NHS Blood and Transplant

UNIVERSITY OF OXFORD

UNIVERSITY OF CAMBRIDGE

The INTERVAL study has been set up by the Universities of Cambridge and Oxford in collaboration with NHSBT. Your involvement in the study will be for a period of two years; however, the study will extend beyond this as we intend to look at participants' health over many years to assist future studies about the health of blood donors.

Funding has been provided by NHSBT. If the 1-year initial phase of the study is concluded satisfactorily, then further funding is expected from NHSBT to complete the study. Once funding stops, data and samples collected during the study will be maintained, as a national collection, by the lead academic institution, the University of Cambridge, in partnership with NHSBT.

Who has approved the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee which is there to protect your safety, rights, wellbeing and dignity. This project has been reviewed and was given a favourable review by the Cambridge (East) Research Ethics Committee.

What will happen if an invention is made using my sample?

You are giving your sample as an absolute gift, i.e., without receiving a payment and without attaching conditions. The INTERVAL study is operating on a non-commercial basis, meaning it does not sell your sample to make a profit and will not allow anyone else who is working with the sample to do so either. However, if samples are made available to other research institutions or to private-sector research partners, a fee may be charged to cover the operational costs.

13

In the future, your sample may help researchers in the public and private sector to make an invention, e.g. develop a new product to diagnose, prevent or treat disease. If an invention results from the research undertaken with your sample you will not receive any compensation or payment. INTERVAL partners in the public sector may work together with commercial companies to develop inventions for the benefit of patient and donor care; and we hope that such products are brought into use by the NHS to improve health care in the future.

What happens if something goes wrong?

The risk of participants suffering harm as a result of taking part is minimal, and INTERVAL has insurance in place to provide compensation for any negligent harm caused by participation.

Who do I contact if I have any concerns?

If you have any concerns or complaints about anything to do with the INTERVAL study then you can telephone the freephone number on:

0800 064 0089 Mon to Fri: 9:00 - 17:00 or

email us at: **helpdesk@intervalstudy.org.uk**

Alternatively, if you would like to write to the person in charge, please send your letter to:

Professors John Danesh and David Roberts
The INTERVAL Study
University of Cambridge
Department of Public Health and Primary Care
Wort's Causeway, Cambridge CB1 8RN

We will reply to your letter promptly in writing, unless you enclose your telephone number and wish to discuss your concerns with us.

14

Take away message

- Do not collect personal data if it is not essential.
- Indicate clearly in a consent form where the participant's consent is being asked for processing their personal data and where consent is being asked for taking part in the research.
- Keep consent forms under constant review.
- Indicate the future uses of data (publishing, archiving).

Further resources

- UK Data Service
- UKDS Model Consent Form
- Example Information Sheet
- Consent for data sharing
- DARIAH ELDAH Consent Form Wizard | CFW
- HRA Example Consent Form
- Regulating access to data
- Managing and sharing research data: A guide to good practice.

Thank you.

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