Consent issues in data sharing

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UK Data Service Introductory Training Series
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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?
Why to seek consent?

Consent is the process by which a researcher discloses appropriate information about the research so that a participant may make a voluntary, informed choice to accept or refuse to cooperate.

Why to seek consent?

- 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: provide information regarding study purpose, risks, benefits, voluntary participation

• Consent can also be used as a legal basis for the processing of personal data under GDPR
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 apply.

• **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.

• 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.
Principles of processing personal data - GDPR

All data must be:

- be processed lawfully, fairly and transparently
- be kept to the original purpose
- be minimised (only the personal data that is necessary is collected)
- be removed if they are not necessary
- have the accuracy upheld
- be kept confidential and their integrity maintained
## Legal bases to process personal data (the UK GDPR)

<table>
<thead>
<tr>
<th>Legal base</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent</td>
<td>Survey to capture public opinion, whereby email addresses are collected to contact respondents at a later stage.</td>
</tr>
<tr>
<td></td>
<td>Qualitative study on a sensitive topic, e.g. violence against women, where respondents may be identifiable from the collected information.</td>
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<tr>
<td></td>
<td>Oral history project where people's real names are used.</td>
</tr>
<tr>
<td>Public interest / public task</td>
<td>Longitudinal study of people living with dementia and their carers, to identify how people would like to be supported. Findings inform and support the caring strategy and public advocacy.</td>
</tr>
<tr>
<td>Legitimate interest</td>
<td>Research project funded and undertaken by a private corporation to look at the effects of smoking on car passengers.</td>
</tr>
<tr>
<td>Protect vital interests</td>
<td>Unlikely in research.</td>
</tr>
<tr>
<td></td>
<td>Hospital treating a patient after a serious road accident can search for his/her ID to find previous medical history or to contact his next of kin.</td>
</tr>
<tr>
<td>Legal obligation</td>
<td>Unlikely in research.</td>
</tr>
<tr>
<td></td>
<td>Processing personal data as part of a health and safety report or incident.</td>
</tr>
<tr>
<td>Performance of a contract</td>
<td>Unlikely in research.</td>
</tr>
<tr>
<td></td>
<td>Processing personal data as part of an employment contract.</td>
</tr>
</tbody>
</table>
Conditions for 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
How to seek consent?
How to seek 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
# Formats of consent

<table>
<thead>
<tr>
<th>Written consent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
|                 | • 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 |

- **Written consent**
  - **Advantages**
    - More solid legal ground
    - Often required by Ethics Committees
    - Offers more protection for researcher
  - **Disadvantages**
    - 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

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
Consent documentation

Consent form should:

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

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...
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
When to seek consent?
When to seek consent?

<table>
<thead>
<tr>
<th><strong>One-off consent</strong></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used for taking part in the research project only once</td>
<td>Simple</td>
<td>Least hassle to participants</td>
</tr>
<tr>
<td></td>
<td>Ensures ‘active’ consent</td>
<td>Participants will not know all info they will contribute</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Process consent</strong></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent is requested continuously throughout the research project</td>
<td>Ensures ‘active’ consent</td>
<td>May not get all consent needed before losing contact</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repetitive, can annoy participants</td>
</tr>
</tbody>
</table>
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](#))
UKDS model consent form & real examples from the consent form
In practice: wording in consent form / information sheet

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.
## Use of the information I provide beyond this project

<table>
<thead>
<tr>
<th>Statement</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>I agree for the data I provide to be archived at the UK Data Archive?</td>
<td>☐ ☑</td>
</tr>
<tr>
<td>I understand that other genuine researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.</td>
<td>☐ ☑</td>
</tr>
<tr>
<td>I understand that other genuine researchers may use my words in publications, reports, web pages, and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.</td>
<td>☐ ☑</td>
</tr>
</tbody>
</table>
In practice: wording in consent form / information sheet

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.
Example information sheet outline

- What is the **purpose** of the study?
- Why have I been invited to take part in the study?
- Do I have to take part?
- What will happen if I take part?
- What will I have to do?
  - Walking interview and questionnaire
  - Living with sensors
  - Time use diary
  - Final interview and questionnaire
- What are the **possible disadvantages or risks** of taking part?
- What are the **possible benefits** of taking part?
- What happens when the research study stops?
- What if there is a problem?
- Will my taking part in the study be kept **confidential**?
- Who is organising and funding the research?
- Who has reviewed the project?
Example from Health Research Authority (HRA)
HRA example… contd

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.

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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.
HRA example… contd
HRA example… contd
HRA example… contd

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.
HRA example… contd

How will information about me be kept confidential?

We will protect your privacy at all times. The steps taken to ensure confidentiality are detailed below.

- At the donation session, your consent to take part in the study will be recorded on a form that will contain identifiers including your name, email address and mobile phone number. These forms will be stored in a secure location and separately from the study data.
- Your samples and data will not include any personal identifying details: researchers working with your samples and data will, therefore, never know your identity. Your data will be stored using a unique, anonymous study identification number.
- A single table linking your anonymous study identification number to your NHSBT Donor Number and your NHS number identity will be stored on a separate password protected location which may be accessed by the study data manager only.
- The link table will be used to retrieve only relevant health information from your medical and other health-related records. The retrieved information will be anonymous as any personal identifying details will have been removed and replaced by the unique anonymous study identification number.
- All study data will be stored in a restricted-access study database. This study database will not be connected to the NHSBT database containing your personal details. The study data will be linked to your study identification number, but your personal details (surname, first name, date of birth, address) will never appear in this database. Access to the study database will be password protected and will be used only by named researchers working on this study under the direct supervision of the senior scientific investigators.

What will be stored on the INTERVAL research database?

Your anonymised data will be stored in the INTERVAL study database and will be used by the study investigators to, for example, understand characteristics (e.g. age and gender) that influence the frequency with which people can donate safely. Stored anonymised data may also be used for future medical and health-related studies which have relevant scientific and ethics approval. Information that will be stored on the database will be anonymised and will include:

- Relevant information from your NHSBT donor record, e.g. gender, month and year of birth, details of your donation history and blood group.
- Data from the online questionnaires, forms and assessments (described above).
- Results from all laboratory measurements using your blood components. This will include your genetic information.
- Information on health outcomes collected from routine medical and other health-related records at the time of joining the study and from time to time thereafter.
HRA example… contd
HRA example... contd

Who is organising and funding the study?
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.

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.
UKDS Model Consent Form

Informed Consent for [name of study]

Please tick the appropriate boxes

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 [......................................................].

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.

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.
2. Use of the information in the study

I understand that information I provide will be used for [.................................].

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.

If you want to use quotes in research outputs, add: I agree that my information can be quoted in research outputs.

If you want to use named quotes, add: I agree that my real name can be used for quotes.

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

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.

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 (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.
Consent checklist (ICO)

Checklist

**Asking for consent**

- We have checked that consent is the most appropriate lawful basis for processing.
- We have made the request for consent prominent and separate from our terms and conditions.
- We ask people to positively opt in.
- We don’t use pre-ticked boxes, or any other type of consent by default.
- We use clear, plain language that is easy to understand.
- We specify why we want the data and what we’re going to do with it.
- We give granular options to consent to independent processing operations.
- We have named our organisation and any third parties.
- We tell individuals they can withdraw their consent.
- We ensure that the individual can refuse to consent without detriment.
- We don’t make consent a precondition of a service.
- If we offer online services directly to children, we only seek consent if we have age-verification and parental-consent measures in place.
## Informed consent checklist

<table>
<thead>
<tr>
<th>Informed consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for consent is independent of other obligations or any other terms and conditions</td>
</tr>
<tr>
<td>Pre-ticked boxes or any other type of consent by default is not used</td>
</tr>
<tr>
<td>Language used is easy and clear to understand</td>
</tr>
<tr>
<td>Data subjects are being informed why the data is being collected and how it will be processed</td>
</tr>
<tr>
<td>Named organisation and any third parties</td>
</tr>
<tr>
<td>Included an affirmative statement indicating the right to voluntary participation</td>
</tr>
<tr>
<td>Included an affirmative statement indicating the right to withdraw</td>
</tr>
<tr>
<td>Included an affirmative statement indicating any potential risks</td>
</tr>
<tr>
<td>Included an affirmative statement indicating any potential benefits</td>
</tr>
<tr>
<td>Included an affirmative statement indicating information about data sharing and archiving</td>
</tr>
</tbody>
</table>
Take away message for the best practice!

• 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

• Different forms of consent for different materials, e.g. audio recordings vs transcripts

Cont…
Take away message for the best practice!

• As simple as possible and in easy language
• Avoid excessive warnings
• Indicate the future uses of data (publishing, archiving)

• Indicate the steps that will be taken to safeguard anonymity and confidentiality
• Remember, consent is NOT the only ground to process personal data
Take away message for the best practice!

• Indicate the steps that will be taken to safeguard anonymity and confidentiality

• GDPR does not apply if data is anonymised

• Different data sharing consent agreements for different types of research data, e.g. less sensitive (survey) vs. highly sensitive (medical)
Further Resources

- UK Data Service
- UKDS Model Consent Form
- Example Consent Forms
- 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 practise
Questions

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