Guidance notes for the preparation of Participant Information Sheets for Research

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Guidance for Participation Information Sheets

Contents

1. Who is this guidance for?

Before research activity takes place with potential participants they should be fully informed of why it's happening, what will happen to them, their data/samples, of their rights, and any limitations to their rights. This document aims to describe the process for attaining this informed consent (when necessary). This document will describe the process for creating a participant information sheet for internal ethics committee and external ethics committees. Instructions for use, as most sections are pertinent to participant information sheets for both University ethical review and NHS ethical review. This guidance document should be used for the preparation of participant information sheets for research participants, using the templates available from RIGO and should be used by staff and students at the University of Surrey..

1.1. Will I need a consent form too?

Consent documentation usually comprises an information sheet and signed consent form, but in some circumstances, the method of obtaining consent can be different (e.g. verbal consent or online consent). If obtaining consent with a signed form, use the 'Consent Form Template' and remember to do the following:

- get participants to initial boxes (NOT tick),
- get the participants to sign the bottom,
- refer to the latest version of the Information sheet.

2. What makes a good Participant Information Sheet?

In this guidance you will find information on the recommended content, design and style of an effective Participant Information Sheet. The guidance should be considered as a framework, where researchers are encouraged to think carefully about how best to inform potential participants. The best way to make sure consent documentation is fit for purpose, is to test it with other researchers or members of the public (without collecting the actual data).

2.1. University requirements

- If the researcher is a student, the supervisor must check the Participant Information Sheet is fit for purpose.
- All information sheets and consent forms (and other study documents) should have a version number and/or date. This allows changes or amendments to be more easily tracked and implemented.
- The first draft of the document should be labelled 'Version 0.1' and dated. Further draft versions should be labelled 'Version 0.2, 0.3' etc. and dated i.e. each draft version becomes a decimal place larger.
- The final version of the research document should be labelled 'Version 1.0' and dated and it is this version which should be submitted to the ethics committee.
- The University of Surrey logo must be present on the top of the information sheet and consent form together with any collaborator's logo.

- If you have more than one participant information sheet, please add the name of the target group next to the title of **each** information sheet e.g. *Participant Information Sheet For [insert target group e.g. participant, parent/caregiver, child, service user, service provider etc.].*

2.2. General style and format

- One size does not fit all: the information sheet and consent form to support consent for a questionnaire study will not be the same as that used for recruitment into a drug trial.
- Should not be too lengthy. We suggest a good length is 2-4 pages and no longer than 8 pages.
- For a long or complex research study, you may want to consider designing the information sheet as two parts, with a simple part 1 and more specific details in part 2.
- Information sheets should only contain relevant information (i.e. to allow the participant to decide whether to participate or not).
- First impressions count e.g. use a clear title that the average member of the lay public can understand.
- Make sure that you use language suitable for your target audience, especially when describing research methods and the background. Lay language should be equivalent to a reading age of 12.
- Check for typos and grammatical errors and avoid jargon or terminology that may have alternative meanings. Pictures or diagrams can help participants understand and engage better.
- Use an informal, conversational style. The active voice can be more effective than using the passive voice. For example, use 'We will post a questionnaire to you…', instead of 'questionnaires will be posted …'.

3. Guidance on the research study sections in the 'Information Sheet Template'

Please note that the **example** 'Information Sheet Template' document, which accompanies this guidance, will need tailoring to meet your study requirements in a style suitable for the target audience. All elements of the study that will involve the participant or the data you collect from them should be described in detail within the information sheet. All elements of the information sheet should be reflected within the consent form.

3.1. Invitation paragraph

This should be tailored to suit your study but should include:

- who is undertaking the research (insert the name of the researcher, their Department/School, the University of Surrey and name any other collaborating institutions),
- if the researcher is a student, include details of the course and educational qualification that the study is part of e.g. undergraduate course work as part of a Nursing degree etc,
- the purpose of the information sheet,
- the nature of the study,

- that participation is voluntary,
- that they can discuss the study with others if they wish,

3.2. What is the purpose of this study?

Give a brief, but clear and succinct outline of the purpose of the study e.g. why are you doing the study and give a clear outline of the aim of the study (i.e. the overall purpose of the research) and the objectives, (i.e. the steps that address how the research aim will be achieved).

3.3. Who is responsible for this study?

If relevant, include any information on collaborators external to the University of Surrey and explain what their role is.

3.4. Why have I been invited to take part?

- The participant must understand why you have specifically approached them, how they have been identified as a potential research participant and who else will be approached. Example statement: *We are inviting you and other similar potential participants to take part because you are a (healthy volunteer, professional qualified as an X, student, person with condition X, athlete etc.).*
- Explain the inclusion criteria i.e. any requirements which must be met in order to participate. *Example statement: To be eligible to take part in this study, you must be over 18 and a retail shop assistant.*
- Exclusion criteria should be mentioned here if appropriate. *Example statement: You are not eligible to take part in the study if you do not have internet access.*
- If you have obtained the contact details of potential participants from a publicly accessible source, you must clearly explain this.
- If a third party is contacting potential research participants about the study, you must explain to the participant that the third party did not directly pass their contact details onto the University of Surrey and that it is up to the participant to choose if they want to contact the University to find out more.

3.5. Do I have to take part?

Emphasise that participation in the study is voluntary. Explain that they can ask any questions at any time before deciding whether to take part. State how long the participants will have to read the information sheet and decide whether to participate

3.6. What will happen to me if I decide to take part?

This section needs to inform the participant of exactly what they are being asked to do and the potential burden and time commitment involved outside of their normal day to day activities.

Include the following:

- what will happen during participation, stating clearly the sequence of activities the participants would need to do and whether any parts are optional,

- how long the participant will be involved in the study,
- the venue or site where participation will take place,
- if there are multiple visits or procedures, the frequency and length of these must be clearly outlined,
- if the study is complex, include a simple table or chart,
- what personal information will be held and what data will be collected,
- if using either paper or online surveys, the participants need to know whether the survey will still be used if they haven't answered all the questions,
- if taking quotations/biometrics/photographs/audio or video recordings, you need to:
    - ensure that there is a clear explanation as to how these recorded media will be used and if so, say when and how they will be destroyed. Example statement: *Tapes will be identified only by a code and will not be used or made available for any purposes other than the research project. We will destroy these tapes at the end of the study.*
    - explain if these recordings will remain identifiable and if they will be disseminated beyond the research team. Example statement: *Your [audio recording/video recording/photo] will be shared outside the research team and there will be no attempt made to either hide or obscure your [facial/voice] identity in any subsequent publications/presentations etc.*
    - explain how the recorded media will be stored and who else will have access to it. Example statement: *The recordings will be held securely at the University of Surrey with the recordings being stored on the recording devices in locked cupboards and the transcripts being stored on a secure university server. Only the research team and responsible members of the University may be given access to this.*

3.7. What happens if I do not want to take part or if I change my mind?

- Details of how the participant can withdraw their participation from the study.
- Details of the last date or time point at which their data can be removed from the study. Example statement: *Furthermore, I understand that data already collected can only be withdrawn up to [insert date if stated on Information Sheet] OR [insert text clearly defining time limit e.g. "one month after the interview"].*
- Any limitations to the withdrawal of data, e.g. a) not being able to guarantee that their data will be removed from a focus group discussion, or b) not being possible to remove data once anonymised. Example paragraph: *You will also be able to withdraw your data you have provided up to one month after each interview. Following this time, as the interview will be transcribed and fully anonymised, it will not be possible to remove the information you have provided. We will delete all personal information provided by you.*

3.8. What are the possible benefits in taking part?

- Any benefits to the participants that can reasonably be expected should be stated.
- Where there is no intended benefit to the participant from taking part in the study, this should be stated clearly. Example sentence: *'Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will….'*
- Provide a clear statement of any reimbursements such as reasonable expenses to compensate for the participant's time, inconvenience, costs of travel and subsistence.

3.9. Are there any potential risks involved?

- Explain if there are any foreseeable discomforts, disadvantages or possible consequences of key research procedures. Clearly explain the risks and their relative likelihoods, as well as what you will do to mitigate these risks.
- With questionnaires or interview questions that may cause distress, outline what would happen if a participant becomes upset and any support that might be available. Example statement: *Depending on the nature of your experiences, it is possible that matters that we touch on may be sensitive to you. You may ask for a break from the interview or withdraw from it at any time. Information on sources of support can be found at the end of this information sheet.*
- Explain what will happen to the participant if there are risks found from incidental findings requiring follow up (e.g. high blood pressure or indications of depression etc.). Example statement: '*Your GP will be notified of any of incidental findings during the study' OR 'you will be notified that incidental findings were present and given a letter to take to your GP'.*

3.10. How is the project being funded?

- You should tell potential participants which organisation(s) is/are funding your research (e.g. medical research charity, pharmaceutical company, academic institution).
- Any conflict of interest must be disclosed to the participant, for example, if the researcher is employed at a senior level by the financial supporter of the research.

3.11. Will my participation be kept confidential?

- You should explain that all information collected about the participants will be kept strictly confidential and briefly describe how. *Example statement: All the information that we collect about you during the course of the research will be kept strictly confidential and only accessed by either members of the research team or responsible members of the University for auditing and/or monitoring purposes. You will not be able to be identified in any ensuing reports or publications.*
- There may be a reason why confidentiality cannot be guaranteed:
    - Example paragraph: *We advise you that participants' confidentiality will be respected at all times, unless there are compelling and legitimate reasons for this to be breached. We*

have a duty of care to report to the relevant authorities any possible harm or danger to participants or others.

3.12. Will my data be shared or used in future research studies?

- Explain that you will be keeping study data for use in future studies and state whether this data will remain identifiable or not. Example statement '*We would like your permission to use anonymised data in future research studies, and to share data with other researchers (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public'.*

- Explain if you will be sharing identifiable study data. Example wording: *We expect to use your contributed information in various outputs, including a report and content for a website. Some photographs of you may be used and we will obtain your permission before sharing a photograph of you.*

- Explain to participants if research data will be deposited in a recognised repository, and what that repository is (e.g. UK Data Service). Specify in which form the data will be deposited, e.g. de-identified (anonymised) transcripts, audio recording, etc.

- State that information may be subject to review by responsible individuals from the University of Surrey and/or regulators for monitoring and audit purposes

3.13. What will happen to the results of the study?

- Explain how the findings will be summarised and disseminated e.g. through publication (journals, newsletter, bulletins, website, theses), conferences or depositing data in an archive. Example wording: *We will publish the results from the research study in peer reviewed scientific journals and present them at conferences. Any published findings or quotations will use pseudonyms and will maintain your confidentiality and anonymity. You will not be personally identified in any reports or publications.*

- Explain how the participant can request a copy of the results or how the results can be accessed e.g. a study website. It is preferable to ask participants to contact the research team to obtain findings after a certain time interval rather than retaining personal details.

- Add funder requirements should there be any such as open access etc.

3.14. Who has reviewed this study?

- Add the name of the ethics committee who has reviewed the study.

- Clearly state whether the researcher has completed an ethical self-assessment which indicated an ethical review by a committee was not required.

4. Guidance on the 'Your Personal Data' section of the 'Information Sheet Template'

4.1. What is personal data?

- Personal data is any information that relates to and is capable of identifying a living person either directly or indirectly, in particular by reference to an identifier.

- GDPR provides the following (non-exhaustive) list as personal identifiers:
    - Name
    - ID number
    - Location data; and
    - an online identifier (includes email and IP addresses, online user names and cookie identifiers which may allow a person to be identified).
    - Other factors that can identify an individual such as audio or video recordings and photographs

- This broad GDPR definition therefore covers *any data that may lead to the identification of an individual* to be classed as personal data.

- Special category data is a subset of personal data that requires additional safeguards. GDPR defines special category data as including information relating to:
    - Racial or ethnic origin
    - Political opinions
    - Religious or philosophical beliefs
    - Trade Union membership
    - Genetic (includes inherited or acquired genetic characteristics) or biometric data (e.g. facial recognition, images, fingerprints etc)
    - Physical or mental health
    - Medical information
    - Sexuality or sex life

- Include specific details of any 'special category data' you intend to collect (see list above).

- You should consider whether even the minimal information you collect could lead to a person being identified e.g. you may be collecting first names, but an unusual first name may still lead to the identification of that person. You should also consider whether you hold personal data for reasons other than for the analytic part of your project such as contact details or consent forms.

- Data that allows indirect identification of a person is also personal data. Indirect identification can result from combining data sets or identifiers from specific factors such as physical, physiological, genetic, mental, economic, cultural or social identity of that person. For example, if you are collecting or using data that on their own does not allow direct identification of a person e.g. music preferences or shopping trends, consider whether it may allow an individual to be indirectly identified when combined with other information such as age or place of work. Research studies with a potential to indirectly identify individuals will need to comply with data protection legislation.

- Data that has been pseudonymised through coding and removal of personal identifiers still falls within the scope of the GDPR when the code can be linked back. Anonymised data, is when all personal data is permanently removed and deleted, so it is no longer available and

therefore the research data cannot be traced back to an individual. Anonymised data does not fall under the scope of the GDPR or other UK data protection legislations.

- As a researcher, you must determine whether the information you collect and/or use during your research study can be pieced together to reasonably establish someone's identity. If it can, then your study uses personal data and you must comply with data protection and privacy laws. In your research protocol, you must make clear what personal data you intend to collect and how it will be processed. You must also make this clear on your Participant Information Sheet.

- There is even more importance to ensure data minimisation when using special category data- i.e. you should only collect the minimal amount of data that is required to fulfil the objectives of your study and you must not collect anything more. As this data is more sensitive in nature and could create more significant risk to a person's fundamental rights and freedom (e.g. potential risk of unlawful discrimination), additional controls should be implemented to ensure a higher level of security and protection.

- If the research study involves the collection, storage or use of personal data (i.e. data processing activities), the information sheet will form part of the transparency information that Data Controllers must provide to potential research participants, in order to be compliant with current data protection legislation. This includes any personal data for the purpose of recruitment (see list above).

- If you are collecting contact details of the participant, this will mean you are processing personal data and you must include details of how this is handled in the 'Your Personal Data' section of your information sheet.

- If you are collecting anonymous data, i.e. you have not collected any personal identifiable data at all (including no contact details such as an email address), you can remove the 'Your Personal Data' section from your information sheet.

4.2. Who is handling my personal data?

- Include details of who the Data Controller will be (i.e. the organisation which determines the purposes and means of processing the data), which will probably be the University of Surrey. However, this may not be the case if the study is part of a collaboration where the University of Surrey is not the lead institution (refer to your data sharing legal agreement or contract for more information). If you are unsure, contact RIGO for guidance.

- Include details of whether personal data including special category data will be shared with other collaborating organisations. Example statement: *We will not share any of your personal details with the collaborating universities on this project, and any research data will only be shared once this has been fully anonymised beforehand, so that you are no longer identifiable.*

- If a third party data processor is involved (e.g. a transcription service), include a statement to say if the data processor will delete and/or return all personal data to the controller. You may need to have an agreement in place with the third party. Contact RIGO if you are unsure.

4.3. What will happen to my personal data?

- Participants should be informed how long the personal data they provide will be stored for, in what format, and by whom and how it will be accessed. You should state how long you intend to keep any personal data after completion of the study. This will vary depending on the nature of your study. For example, for student projects it is possible that personal identifiers will be removed once they have completed their studies whereas staff projects may be required to hold personal identifiers for longer. Contact the information compliance unit if you are unsure at dataprotection@surrey.ac.uk .

- In order to lawfully process special category data, you must identify both a **lawful basis** ('processing is necessary for the performance of a task carried out in the **public interest'**) and a separate **condition** for processing special category data ('processing is necessary for archiving purposes in the public interest, scientific or historical **research purposes** or statistical purposes'). This must be stated in the information sheet.

- In very limited circumstances, the lawful basis and condition may be consent. You must consult RIGO if you think you need to capture consent for data protection purposes.

- You must ensure that you only collect and hold the minimum amount of special category data you need for your research purpose and hold no more than that.

- NHS Research Only section, please see guidance in template

5. Guidance on the 'Further Information' section of the 'Information Sheet Template'

5.1. What if something goes wrong?

- You should inform participants how complaints will be handled and what the process is. You should provide contact details of a member of the research team for the participants to contact should they have any concerns.

- You should also include the full contact details of someone independent of the research team for complaints (e.g. the Research Integrity and Governance Office).

5.2. Who should I contact for further information?

- Please give the full contact details of either the researcher or all the research team, using their name, job title, university address, university email and phone number.

- For safety reasons, ensure that the contact details are the researchers' University of Surrey contact details, rather than personal contact details. If using a mobile phone, this should be a research specific mobile phone and not a personal phone.

- If you wish the participants to message a social media account, you must ensure that this is not a personal one, as defined in the university's Social Media Policy.

6. Guidance for human tissue studies

If the study involves human tissue, the researcher must follow the requirements of the Human Tissue Act 2004.

In the section, '**What will happen to me if I decide to take part',** you must add the following information:

6.1. What samples will I have to give?

- provide details of the samples are to be collected, how, when and by whom (it should be by a trained member of the research team).
- details of all samples that will be taken, how much will be taken, and at what frequency (i.e. how often this will happen).
- Please state the limits to the sample size and frequency Example statement: *We will not collect more than x amount of blood in y amount of time and that all participants donating over a certain amount in a [specific period of time] must be tested for anaemia.*
- State what the samples will be used for. Example text: *We will check the levels of ____ in the blood/saliva/urine/stool*.
- if required, give details on what cannulation is. Example statement: *a cannula (a small plastic tube) will be inserted into a vein in your arm. This may sting slightly*….
- If taking material from staff and students, they must be informed to:
    - NOT donate material to own project,
    - NOT overdonate,

6.2. What will happen to any samples I give?

- what the samples will be used for (state all anticipated research uses).
- where the samples will be processed, identified and stored for the duration of the study.
- any collaborators or other researchers in the UK and/or abroad to whom the samples will be sent.
- where and how long the tissue will be stored, for all envisaged uses.
- who will have access to the stored samples.
- when and how the samples will be disposed of.
- whether there will be DNA analysis.
- whether any tissue or cells will be stored for the purpose of genetic testing.
- whether consent will be sought for continued storage of surplus tissue for future ethically approved studies or whether samples will be disposed following completion of the study. If samples are to be stored for future use, provide details e.g. samples and copies of consent forms will be held in secure locations under the University's HTA licence and that participants can request for these to be withdrawn at any time - details must be provided as to whom to contact for this e.g. RIGO.

- whether any samples in this study or future studies will be used in other countries.
- whether any samples in this study or future studies will involve commercial organisations.

In the section, '**Are there any potential risks involved'**, you must add the following information:

6.3. Are there any risks involved in donating samples?

- with blood samples: the possibility of bruising and/or fainting.
- with tissue biopsies: the possibility of bruising, infection.
- if taking blood samples with a cannula, mention if they will be replaced and indicate how often this will occur and the likelihood of problems.
- explain that despite checking veins at the screening visit it is not possible to predict how the participant will react following multiple sample collections.
- if the tests conducted on the sample could potentially reveal unexpected or incidental findings, please state this, outlining the process you would follow if this were to happen.

In the section, '**What happens if I do not want to take part or if I change my mind'**, you must add the following information:

6.4. What will happen to my samples if I decide to withdraw from the study?

- that study participants are free to withdraw their consent at any time and give details of how participants can withdraw consent from the study.
- if consent is withdrawn, need to include whether the surplus samples will be destroyed.
- Provide details of what can happen in the event of withdrawing consent. For example, samples cannot be destroyed if the tissue has already been used but it may still be possible to remove the data collected from the sample.
- if someone withdraws consent for samples to be used in any future projects, this does not mean that research data collected so far should be withdrawn from any existing projects.
- if withdrawal is offered for only a limited period after consent has been obtained (e.g. before the sample is anonymised and used in research), there must be a clear reason on the information sheet for the time limit on withdrawal of consent.

7. Guidance on providing information to children or young people

For research with children or young people, separate information sheets for the child (different age-specific sheets), young person and parent/guardian/care giver are required.

7.1. Guidance on giving information to a child or young person

- Common law presumes that young people aged between 16 and 18 are usually competent to give consent. Case law suggests that if a young person has sufficient understanding and intelligence to understand fully what is proposed, and can use and weigh this information in reaching a decision (i.e. they are 'Gillick competent'), he or she can give consent
- For pre-adolescent participants (aged up to 16), information sheets should explain briefly and in simple terms the background and aim of the study, so the child can consider assent. It also should contain an explanation that their parents/guardians will be asked for consent.
- Information should be given in an age/stage of development appropriate language and format and at an appropriate pace. The Health Research Authority has published some age specific template's at http://www.hra-decisiontools.org.uk/consent/examples.html.
- It may be necessary to produce several versions of an information leaflet, for example when the research involves children and young people with a wide variety of ages or cognitive abilities.
- Use simple section titles in the information sheet e.g. What will happen', 'What will I have to do ', 'Why is this project being done', 'Why me', 'When will this happen? ', Will I have a choice' and 'What if I don't want to do this anymore'.
- break the information into smaller chunks, so it is clear for children and young people to read.
- Consider whether the child or young person has a learning difficulty or lack of capacity due to cognition or another factor.

7.2. Information required on the parent/guardian/caregiver information sheet

- An information sheet for the parents/guardian/caregiver is required, to inform them about the nature of the study and the option to include their child in the study if they so wish.
- Information sheets should indicate how the study will affect the child at home, school or other activities.
- Tailor the section headings (e.g. 'Why has my child been invited to take part', 'Does my child have to take part', 'Will my child's data be shared or used in future research?'.
- Researchers working directly and unsupervised with children or young people may require a DBS disclosure. Please look at the universities Child Protection and Adults at Risk Policy for more information.
- If a DBS check is required, provide a statement declaring that the researcher has undergone an appropriate level of DBS check (obtained either via the University of Surrey or another external organisation). *Example wording: All of our researchers are fully trained, have experience of working with children in school settings, and all have received enhanced disclosure from the Disclosure and Barring Service (DBS).*

8. Guidance on providing information to adults at risk (vulnerable adults)

Special consideration must be taken for research with vulnerable adult populations. Vulnerable groups include people with learning or communication difficulties, or who receive care services

because of a disability, age or illness, or who may be unable to take care of themselves or protect themselves against significant harm or exploitation,

8.1. Guidance on giving information to adults at risk (vulnerable adults)

- Tailor the information sheet to take in consideration whether the participant has a learning difficulty or lack of capacity due to cognition or another factor.
- Additional care is needed to fully inform participants about the nature of tasks which may be distressing.
- The researcher should use the most appropriate media for communication, including e.g. larger fonts, double spacing and clear visual aids, verbal explanations and diagrams or photographs as appropriate.
- In most cases, researchers working directly and unsupervised with vulnerable adults may require a DBS disclosure. If so, provide a statement declaring that the researcher has undergone an appropriate level of DBS check (obtained either via the University of Surrey or another external organisation).

8.2. Research which falls under the Mental Capacity Act 2005

- If you are recruiting participants aged 16 years of age or older and lacking the capacity to make decisions, they can only take part in the study if it has been approved in accordance with the Mental Capacity Act 2005
- Ethical approval must be sought from a recognized NHS Research Ethics Committee (REC) under the Health Research Authority Approval Process. University RECs are not permitted to approve research involving adults who lack capacity. You must contact RIGO if your research involves participants under the Mental Capacity Act rigo@surrey.ac.uk.

9. Guidance for international research studies

For international research consider the following:

9.1. The sharing and transfer of personal data overseas

- If personal data will be shared with others outside the EU, you should make potential participants aware of this as such countries might not offer the same level of protection of privacy as that demanded by law in the UK. You may need a data sharing legal agreement in place too. *Example statement: Your personal data may be transferred to, and stored at, a destination outside the UK. Identifiable data will be removed whenever possible and any data transfer will be done securely and with a similar level of data protection as required under UK law.*
- Inform potential participants of the steps you will take to ensure that any transfer of information abroad will not compromise confidentiality and will be in line with the UK Data Protection laws. You must obtain explicit consent for the transfer of personal data. Contact RIGO if you are unsure.

9.2. Additional considerations for overseas research

- Whether documents/scripts are written in lay language, tailored to the participant groups' literacy level.
- Cultural differences in the role of family and community in the consent process.
- Differences in the role and status of other participant groups in society/ gender issues.
- Provisions for counselling research participants prior, during and/or after the research.
- How will complaints be reported and to whom.
- Possibility of including officials from the area in the monitoring of the research.
- Providing non-English participant information sheets with translated versions, together with assurance that the translation was either done or checked by someone independent of the research team.
- The researcher will have to check whether they require approvals or have to follow local laws for target countries.