

# Guidance Notes: Preparation of Consent Forms for Research for adult participants with capacity to consent

**Introduction**

The purpose of these Guidance Notes is to provide advice on the preparation of Consent Forms that are required to support applications to one of Aston University’s Research Ethics Committees (RECs), NHS RECs or to the Health Research Authority (HRA).

The Guidance Notes are based around an Aston Consent Form Template which should be used for all Aston research projects where written informed consent will be received from research participants.

A Consent Form is a short document (usually no longer than a side of A4) that concisely covers the core statements to which a research participant is being asked to agree in clear and concise language.

The Consent Form for a research study should give research participants the opportunity to agree or disagree with statements by initialling each statement. They are also asked to sign, print their name and date the form. Space is also provided on the Consent Form for the investigator receiving consent to sign, print their name and date the form.

When conducting remote sessions e.g. interviews via MS Teams or by telephone then you can send the participant the information sheet and consent form by email, post or secure online form and ask them to return their completed consent form to you.

Online or Electronic consent: if the consent form is to be presented electronically then the form must be tailored accordingly. For example, you may require participants to click to agree to a statement or to type their initials. The online form should be completed by the participant before any data collection takes place. If the study involves interviews or focus groups, the researcher should check that consent has been completed before collecting data. For online surveys or experiments, the consent form must always precede the presentation of the questionnaires or experimental stimuli. Agreement for every non-optional statement should be provided before participants are allowed to continue.

If fully anonymous responses are to be submitted then a consent statement should still be provided. This should confirm that participants agree to take part and that, once submitted, responses cannot be withdrawn (as they cannot be linked back). Any participants completing online measures must be reminded of how they can withdraw at any point prior to submission of responses (e.g., by closing their browser) and that no data will be collected.

Verbal consent: Verbal consent should only be used if you are not able to get written consent (either in paper format or electronically). If you are taking verbal consent, this should be recorded with the person stating their name and date (or just the date if it is an anonymous study). The consent statements should be read out to the participant and they should verbally agree to each one. The researcher should also state their name and date. This recording should be made separately from the recording of any other data, such as an interview, so that consent can be retained for the required length of time.

# Updates to these Guidance Notes

These guidance notes will be updated as required to comply with legislation, regulations and best practice guidelines so researchers should ensure that they are using the latest version of the guidelines by consulting the University website.

# Guidance on using the Aston Consent Form template

1. Add collaborator/participating organisation logos to Header if required. If not, you can delete the box.

Collaborator/participating organisations could, for example be: a commercial organisation that is funding the study and/or a collaborator university/research organisation and/or a NHS organisation.

If research is to be undertaken at multiple sites there should be site specific sheets with a header which include: the Aston Logo; funder logo (if applicable); research collaborator logo(s) (if applicable); and the logo of the host organisation.

When submitting an application for a multi-site study the easiest approach is to put a “text box” in the header indicating that site logos will be added e.g.:



1. Add Version Number and Date to the footer.

Note: for projects in receipt of approval from an Aston REC the REC ID number should be used as the project identification number – this will be issued upon submission of your application and should be added before the sheets are used. :

e.g. - REC ID: 1234, Version 1, 20220101

For projects seeking HRA approval the Integrated Research Application System (IRAS) number for the project should be used as the project identification number (this will be generated by the system when you create the application and you can add this at any time):

e.g. - IRAS ID: 300000, Version 1, 20220201

1. Add study specific information where indicated by **red** text in the template.
2. Delete any statements in **green** text if not relevant to your study (statements 1, 2 and 15 in the template must be included in all consent forms.)
3. When all statements are finalised ensure that all text is in **black**.

**Notes:**

If using the statements about interviews and focus groups use the pleural if the participant will be involved in multiple interviews and/or focus groups.

Statements relating to audio and video recording may need to be combined to form one statement where participants are being audio and video recorded.

e.g. *“I agree to the focus group being audio and video recorded and to anonymised direct quotes from me being used in publications resulting from the study”.*

Statements relating to interviews and focus groups may need to be combined to form one statement where participants are participating in both.

e.g. *“I agree to the interview and focus group being audio and video recorded and to anonymised direct quotes from me being used in publications resulting from the study”.*

1. Proofread to ensure any drafting guidance has been removed.

 

Site or Collaborator Logo(s)

(to be added- if required)

 **ADD PROJECT TITLE AS STATED ON ETHICS APPLICATION FORM**

**Consent Form**

**Name of Chief Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Please initial boxes**

|  |  |  |
| --- | --- | --- |
|  | I confirm that I have read and understand the Participant Information Sheet [insert version number and date] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
|  | I understand that my participation is voluntary and that I am free to withdraw at any time during the study, without giving a reason and without my legal rights being affected. |  |
|  | I understand that this study is anonymous and that I am not able to withdraw after submitting my answers. |  |
|  | I understand that I am able to withdraw my data up to [X] days after taking part in the study by contacting the research team, after this time my data will be anonymised and I will no longer be able to withdraw. |  |
|  | I agree to my personal data and data relating to me collected during the study being processed as described in the Participant Information Sheet. |  |
|  | I agree to my GP being informed of my participation in the study. |  |
|  | I understand that if during the study I tell the research team something that causes them to have concerns in relation to my health and/or welfare they may need to breach my confidentiality. |  |
|  | I agree to my interview being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study. |  |
|  | I agree to the focus group being audio recorded and to anonymised direct quotes from me being used in publications resulting from the study. |  |
|  | I agree to study visits being video recorded. |  |
|  | I agree to [insert sample type] samples being taken as described in the Participant Information Sheet. |  |
|  | I agree to any [insert sample type] samples remaining at the end of the study being used in anonymised form for future research. |  |
|  | I agree to my anonymised data being used by research teams for future research. |  |
|  | I agree to my personal data being processed for the purposes of inviting me to participate in future research projects. I understand that I may opt out of receiving these invitations at any time.   |  |
|  | I agree to take part in this study. |  |

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Name of participant Date Signature

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Name of Person receiving Date Signature

consent.

[The name, date and signature are not needed for anonymous online studies]

|  |
| --- |
| If you wish to receive a lay summary of the research project upon its completion, please provide an email address to which the summary can be sent. |
| Email address: |