



Manchester
Metropolitan
University

**Research & Knowledge
Exchange**

Guidance Note Withdrawal from Research

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University Research Ethics
and Governance



Planning for withdrawal

The possibility of withdrawal is something that has to be considered from the planning stage of the project and the research protocol should reflect this. The research protocol should describe what measures are allowed in case of withdrawal, depending on the specific characteristics of the project that is undertaken. Therefore, the protocol should answer questions such as: what data would be deleted, what data would be kept, when is deletion no longer possible, should the participant be told, should contact with participant cease or not?

If there is a deadline for withdrawal (a point where withdrawal is no longer possible because the data could no longer be removed), the participants must be told of this in the Participant Information Sheet.

Categories of withdrawal

Withdrawal of a participant can occur in any research project and it falls under one of two categories:

- a) withdrawal by researcher or
- b) withdrawal at the request of the participant.

A. Withdrawal by researcher

Withdrawal by researcher is performed when it is found that the participant no longer meets the inclusion criteria, or the participant is considered too distressed/at risk of harm to continue (despite them seeming willing to force themselves to do so). This type of withdrawal is focussed on stopping the collection process and/or excluding the participant's data from analysis and it is not necessarily concerned with destruction of their personal data.

Upon deciding to withdraw the participant, the researcher should consider whether it is necessary or not to inform the participant of this fact. There are several situations where the participant should be notified of the occurrence:

- the data collection process is not yet complete (the participant will likely wonder why you suddenly ceased contact);
- the research included procedures that may show long term after effects;
- the participant was promised a copy of the results (this is even more relevant in cases where participants choose to remain identifiable in publications);
- the researchers have obligations towards the participant that remain regardless of withdrawal.

As seen in the above, the researcher should always consider if they have obligations remaining to the participant even after withdrawal has been decided. For example, in research where invasive/ingestion/harmful procedures were undertaken, the participant should continue to receive the full course of aftercare as all other participants. The same principle applies where the data that you continue to hold about the participant after withdrawal can cause harm to them in the event of a breach. In all such cases the researcher still has a responsibility to the participant.

Another important step is to consider if the withdrawal should be accompanied by the destruction of personal data held from the participant. In the case of withdrawal by researcher, no personal data of the

participant should be destroyed if:

- the withdrawal only affects the current analysis but the participant's data can still be used in future research (if appropriate consent was secured from the start for this);
- it was not possible to remove all the data points about the participant from data sets that had already been aggregated.
- it is found that the researcher still has responsibilities to the wellbeing and interests of the participant.

Where the researcher deems that deletion of [personal data](#) should form part of the withdrawal by researcher process, this should first be discussed with a [data protection representative](#) and the ethics team. This is not a requirement where the researcher withdraws a participant but will continue to retain their personal data in line with the retention period already communicated to the participant.

After all of the above have been considered, the researcher should take the following steps to operationalise the withdrawal:

- write a record of withdrawal and insert it into the research record;
- write any letters of notification (if relevant);
- separate the affected data and mark it with a note of withdrawal for easy future identification.

B. Withdrawal at the request of the participant

Any participant can withdraw from research until the withdrawal deadline or at any point if no deadline was specified in the Participant Information Sheet.

1. Receiving a withdrawal request

The request for withdrawal is valid regardless of how it was performed: it makes no difference if the request was spoken (face to face, on telephone, online), written (paper letter, text message, email) or even wordless. A participant who refuses all further contact with you is a withdrawal. This aspect is even more important in research with children, where often no verbalisation is necessary for the wish to withdraw to become obvious.

No demands must be put on the participant who withdraws. The participant must not be asked to complete any form to withdraw, to contact a higher authority to withdraw, or any similar thing. These can be interpreted as delay and discourage tactics by both participants and those who monitor your research.

No justifications can be demanded from a withdrawing participant: no asking for the reason for withdrawal, no asking them to fill in a feedback form about the procedure undertaken, or any similar thing. No attempts to cause an emotional response are allowed either: no speeches about the importance of the research and their participation in it, no talk about losing benefits or failing to help others, or any similar thing. All these can be interpreted as pressure tactics by both participants and those who monitor your research.

If the manner of requesting withdrawal allows it (e.g. the participant hasn't cut off all contact with you), confirmation of receipt of request should be given along with an estimation of when the withdrawal will be completed by the researcher. If you plan on contacting them again to report completion of the withdrawal, let them know you plan to do so as soon as possible.

2. Processing a withdrawal request

After receiving a withdrawal request, the researcher must identify what can be destroyed and what needs to be kept. As a rule, all data/documents/artefacts that can still be identified to the participant should be destroyed. This includes but is not limited to:

- Audio, video, photographic recordings;

Known difficulties: There are situations where the data collection was done in a group, which means that audio, photo, or video recordings of the withdrawing participant is held within the group recording. The researcher must always anticipate such a situation in group collection and must plan for one of two possibilities:

a) The researcher has the necessary software and skills to remove the withdrawn participant from the recordings. In photographs, the withdrawn participant can be edited altogether or covered with a black/white silhouette. In audio recordings, the withdrawn participant's words will be cut out (researcher can mark this with an audio timestamp if they feel necessary). In video recordings, the image of the withdrawn participant will be blurred and their audio cut to silence; if another participant's contribution is dependent on the withdrawn participant's contribution, the researcher will provide a very short description of the withdrawn statement, featuring as few details as possible.

b) If the researcher does not have the necessary software or skills to perform the operations described in point a), then the Protocol, PIS and Consent form must clearly state that withdrawal from the group procedure is not possible.

- Consent forms;

Exception: There are projects where all personal information can be destroyed except the consent forms. This happens when it is essential to still know how to contact the participant in case something goes wrong. Biomedical projects often feature this rule. It is also sometimes required by funders. If your project requires for you to keep identifiable data about the participant even after withdrawal, then this should have been specified in your ethics application and you should have informed participants in the PIS.

- All correspondence;
- All processed data that is still identifiable;
- Artefacts created by participants for the project;
- Samples;
- The participant's line in the Identification Log;
- Transcripts.

Examples:

Mary received a withdrawal request in her project. She deleted the audio recording of the interview, the consent form, the emails with the participant. Mary then removed the participant ID from the interview transcript. She described the transcript and all the data she had already included in graphs, tables and paper drafts featuring quotes as having been anonymised and kept it. **Mary was wrong!** She obviously knew which interview belonged to the participant and it will always be very easy for her to check quotes and data points against it. This means that Mary confused "anonymised" with "no longer identifiable to the participant", these are not synonymous. She should have removed all the data because she could always tell who it belonged to.

Jane received a withdrawal request in her project. She deleted the consent form and the correspondence with the participant because of it. As part of her protocol, she had already destroyed the audio recording and the transcripts by the time the request of withdrawal had been made. Her data was fully broken down into aggregated strands and she could no longer tell which participant it had come from. So, Jane kept this data. **Jane was right!** She had no way left to tell what data belonged to that one participant.

3. Recording the withdrawal

After the researcher knows exactly what must be destroyed and what must be kept, it is time to document the event in the research record. A record of withdrawal must be created. This document can be formatted in any way necessary to perfectly match your research record. If your research record is fully on paper, then the record of withdrawal will be too, and it will be stored within it. If your research record is electronic, then the record of withdrawal will be too, and it will be stored in the same place as it.

There are mandatory elements that your record of withdrawal must feature:

- Use the same headers/logos that you used in your PIS and Protocol.
- Make sure the footer lists the project short title, as well as the version number and date of the record of withdrawal.
- Throughout the entire record of withdrawal, never refer to the participant by name. Always refer to them by their Participant Identification Number that is found on their Consent Form.
- Start by declaring to whom the withdrawal pertains. (e.g. This withdrawal concerns participant number ...)
- Continue by describing how the request for withdrawal was made and to whom.
- Continue by declaring if the researcher has any continuing obligations to the participant, which mean that their contact details have to be kept on record. Say where their details are being moved to and who has access to them. (If this happens, you must keep these contact details separate from the regular ID Log where you keep all other participants that are still active).

If there is no reason to keep the consent form (and the identity of the participant), then you still need proof that the consent existed, you will need a witness. When this record of withdrawal is typed up, contact a member of your Faculty RKE ethics support team. Arrange a meeting with them and bring them the consent form. The consent form will be in whatever medium you have it stored (paper, electronic form, audio recording etc.). The Faculty RKE Officer will look/listen and will have lines in your record of withdrawal to mark the following:

- Consent form existed;
- Consent form featured project short title, version number and date;
- Consent form declared which PIS was shown to participant (version number and date);
- Consent form featured both signatures of participant and researcher taking consent, as well as dates of consent. Forms where one signature is missing are not valid. Forms where researcher signed before the participant are not valid.
- Place for signature of the witness to the consent form (the Faculty RKE Officer).
- The record of withdrawals must continue with two tables. A table listing the data/documents/artefacts that were destroyed. Against each item you must list the method of destruction and whom it was performed by. Another table listing the data/documents/artefacts that still remain because they are no longer identifiable to the participant.
- You must declare if a letter of confirmation of withdrawal is sent to the participant or not. The draft letter (with no names/addresses), if it exists, must be appended to this document.
- Any other relevant details to the withdrawal can be added here.
- The record of withdrawal ends with signatures and dates. If the researcher performing the withdrawal is the only researcher in the project, only their signature and date will be featured. If the project comprises a team of researchers, the signature of the Principal Investigator of the project must also feature to confirm the withdrawal.

4. Finalising the withdrawal

The researcher must make sure that all data/documents/artefacts listed as destroyed have been destroyed and whatever remains has been appropriately stored. Letters of notification of completion of the process must go out (if they were deemed necessary).

Who to contact for further advice

If you need any further information, please contact your Faculty Head of Research Ethics and Governance. Details of who to contact within your Faculty can be found on the Research Ethics and Governance webpages via this link: <https://www2.mmu.ac.uk/research/staff/ethics-and-governance/ethics/> in the contacts section.

If you require more advice than can be provided by the Faculty ethics team, please contact the RKE Research Ethics and Governance team via **ethics@mmu.ac.uk**.

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