

Standard Operating Procedure

Complaints

SOP DC007 version 1

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Introduction and aim of procedure

onCore UK has safety, ethics, quality and service as its core values. It aims to be fair and transparent in its operations, in particular in the process of managing complaints, in order to bring about a mutually agreeable solution for all parties.

Complaints may be made by any external person or organisation and can be received by any member of onCore UK staff. The aim of this procedure is to describe the process of receipt, logging, and resolution of all complaints received by onCore UK.

Applications and Restrictions

This procedure applies to the receipt recording and resolution of complaints by onCore UK staff, from whatever source they are derived.

Related documents

Form DC007.1 - Complaint Reporting Form

Form DC007.2 - Complaint Logging and Investigation

Form DC007.3 - Telephone Conversation with an External Party

Form DC007.4 - Complaints Log

Definitions

HQS	- Head of Quality and Standards
CELL System	- The onCore UK software and database used to store data about the donor and sample collection, processing, shipping, storage and relevant documentation
BDN	- Biosample Donation Network
CLI	- Complaints Logging and Investigation form

Procedure

1. All complaints should be directed to the Head of Quality and Standards (HQS). The HQS will delegate responsibility for further investigation as deemed appropriate.
2. Complaints can be received via the completion of the onCore UK Complaint Reporting form, which can be downloaded from the onCore UK website or the CELL system. Complaints may also be received via e-mail, fax or telephone call.
3. Complaints received by other members of staff via form, e-mail or fax, should be passed **immediately** to the HQS.
4. Complaints received via a telephone call should be transferred to the HQS or, in their absence, should be logged by completing sections A) - Complaint Receipt, B)- Complainant Details, C) - BDN Information and D)- Description of Complaint, in the Complaint Logging and Investigation (CLI) form.
5. Where other members of staff have logged the call the form should be passed **immediately** to the HQS.
6. The HQS will allocate a unique number which will consist of the year (yy), month (mm) and consecutive number (01, 02) e.g. 08-02-01.
7. The unique number will be entered onto the CLI form. This number should be added to all documents created during the investigation and referred to in all communications between onCore UK and the complainant or other interested external organisations.
8. The HQS will review the details of the complaint and discuss with other Heads of Department as appropriate to agree a course of actions and responsibilities.
9. A decision regarding further investigation of the complaint will be recorded in section E) - Further Investigation, of the CLI form.
10. If the decision is that further investigation is required, details of initial contacts must be recorded in Section E) and any agreed actions, with responsibilities, should be entered into section F) - Agreed Actions.

11. Any further discussion by telephone should be recorded onto a Telephone Conversation with an External Party log.
12. The log should contain the complaint reference number, the name of the onCore UK staff member and the name of the contact, the organisation, and any changed or new agreed actions and attached to the CLI form.
13. Any further correspondence received should be date stamped, the complaint reference number added and attached to the CLI form.
14. Agreed actions must also be added to section F) of the CLI form.
15. As each agreed action is completed the date of completion should be added to section F).
16. When all actions have been concluded section G) - Complaint Closure should be completed by the person dealing with the complaint.
17. If any of the agreed actions have not been completed but the complaint is considered to be resolved, a justification for closure should be added to section G).
18. Section G) should be signed and dated by the person responsible for completing the investigation.
19. The completed form plus any appended documents should be passed to the HQS for final review.
20. After review of all documentation provided, the HQS may return the complaint form for further investigation if considered necessary.
21. If the complaint is considered to be closed the HQS will sign and date section H) - Quality Review and Closure, and place the form in the appropriate file.
22. Where the HQS notes trends in complaint types the Corrective and Preventative Action (C.A.P.A.) process will be implemented in agreement with the relevant Head of Department.

History

Version	Date issued	Changes to previous version
1		None, new procedure

END

Uncontrolled when printed