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ICREC Safety Reporting

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Version	Date	Reason for Change
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1. PURPOSE

This SOP describes the process for managing and reporting Adverse Events for Imperial College Research Ethics Committee (ICREC).

A Serious Adverse Event is any untoward, unfavourable occurrence to a study participant, whilst involved in a research project or any occurrence that may impact on the integrity of the research outcomes.

2. INTRODUCTION

It is essential that all Serious Adverse Events which occur during the course of study participants' involvement in a research project are appropriately recorded and reported in order to ensure their continuing safety.

It is important that this SOP is followed as failure to report incidents, or deal with incidents adequately, can result in ethics approval being withdrawn from an individual project, or, in extreme cases, from all research carried out by the Principal Investigator (PI). It is accepted that Adverse Events will vary depending on the type of research being conducted. Adverse Events involving Investigators conducting research taking place overseas must be addressed by the Head of Department.

The Joint Research Compliance Office acts on behalf of Imperial College Research Ethics Committee (ICREC) for the purposes of adverse event reporting. The Head of Department (HOD) must be notified for escalation and oversight purposes.

3. PROTOCOL DEVIATION AND VIOLATION

A protocol that has received ethics approval (and regulatory approval as applicable) is a formal document defining what can and cannot be done as part of a research project and must be adhered to so that participant safety and research integrity can be maintained.

In some circumstances it may be necessary to deviate from protocol to protect the safety of a research participant, which is classed as an urgent safety measure.

Deviations from protocol can occur for a number of reasons and depending on the occurrence can be classes as protocol deviation or protocol violation. A protocol deviation occurs when a process or criteria has not been actioned in line with the approved protocol. For example, a study visit outside defined visit schedule, or a variation in the management of a participant due to minor safety concerns. Deviations are occurrences which can be classed as minor and do not affect participant safety or the integrity of the research.

A protocol violation occurs when there is a consistent variation in practice from the defined protocol. For example, changes to the protocol that have not been approved by an ethics committee or regulator that are classed as substantial amendments (see JRCO/SOP/006 Amendments to Healthcare Research). A violation is a significant occurrence or event which may affect participant safety or the integrity of the research.

An urgent safety measure occurs when a research participant has been identified as being at risk of harm in relation to their involvement in a research project and urgent action, which deviates from the protocol, is required to manage the event and protect the participant.

A protocol deviation may become a violation if it occurs on multiple occasions and/or affects multiple participants.

Non-compliance with the inclusion and exclusion criteria is always classed as a significant protocol violation regardless of how minor the deviation appears to be, as these criteria define the participant group in relation to the scientific requirements of the protocol.

4. PROCEDURE

The procedure for notification of Serious Adverse Events can be divided in to 6 key areas:

4.1 Identifying and notifying the Sponsor of an Adverse Event
4.2 Initial reporting to the Joint Research Compliance Office
4.3 Assessment of an Adverse Event
4.4 Notification to the Head of Division/ Department
4.5 Escalation of a Serious Adverse Event to ICREC
4.6 Planning and implementing corrective action

4.1 Identifying and Notifying Sponsor of an Adverse Event

It is the responsibility of the Principal Investigator(s) to continually monitor the progress throughout the study; this may be delegated to a suitably qualified or experienced member of the research team. If delegated, this should be formally documented and the JRCO and Sponsor notified.

In addition Imperial College London may audit the project as part of their Quality Assurance procedures.

Any serious adverse events identified either through monitoring, audit or by other means must be reported to the JRCO Co-ordinator within 24 hours of the Adverse Event being identified and confirmed.

4.2 Initial reporting to the Joint Research Compliance Office

The PI will collate all available information and complete the Report of Serious Adverse Events Form (SAE).

The PI sends the form via e-mail to the JRCO Co-ordinator within 24 hours of the adverse event being identified and confirmed.

The form should be sent to: researchethicscommittee@imperial.ac.uk

If the JRCO Co-ordinator is unavailable, the initial report should be emailed to the Joint Research Compliance Office generic email account: jrco@imperial.ac.uk.

4.3 Assessment of an Adverse Event

Upon receipt of a Report of Serious Adverse Events Form (SAE) the Head of Regulatory Compliance and the JRCO Co-ordinator will discuss the issue with the Principal Investigator to identify how the Adverse Event impacts the subject/participant safety and/or the scientific integrity of the study.

The Head of Regulatory Compliance may meet with the /Principal Investigator and the study team to discuss the adverse event and instruct on compilation of evidence to support notification to Imperial College Research Ethics Committee (ICREC).

The JRCO Co-ordinator will work with the Principal Investigator to identify the extent of the adverse event and to initiate any corrective actions that may be required.

4.4 Notification to the Head of Division/Department

If the adverse event is confirmed as serious by the JRCO, the PI will notify the Head of Division/Department. The PI will send a copy of the Report of Serious Adverse Events Form (SAE) by email to the Head of Division/Department within 24 hours of the adverse event being identified and confirmed.

The PI must notify the JRCO Co-ordinator that the HOD has been notified.

4.5 Escalation of a Serious Adverse Event to ICREC

If the Adverse Event is deemed serious and requiring further review the JRCO Co-ordinator will escalate the concern to Imperial College Research Ethics Committee.

The JRCO Co-ordinator will send the Report of Serious Adverse Events (and any other relevant documents) to all committee members by email. The JRCO Co-ordinator will be the contact person for all correspondence with Imperial College Research Ethics Committee.

4.6 Planning and Implementing Corrective Action

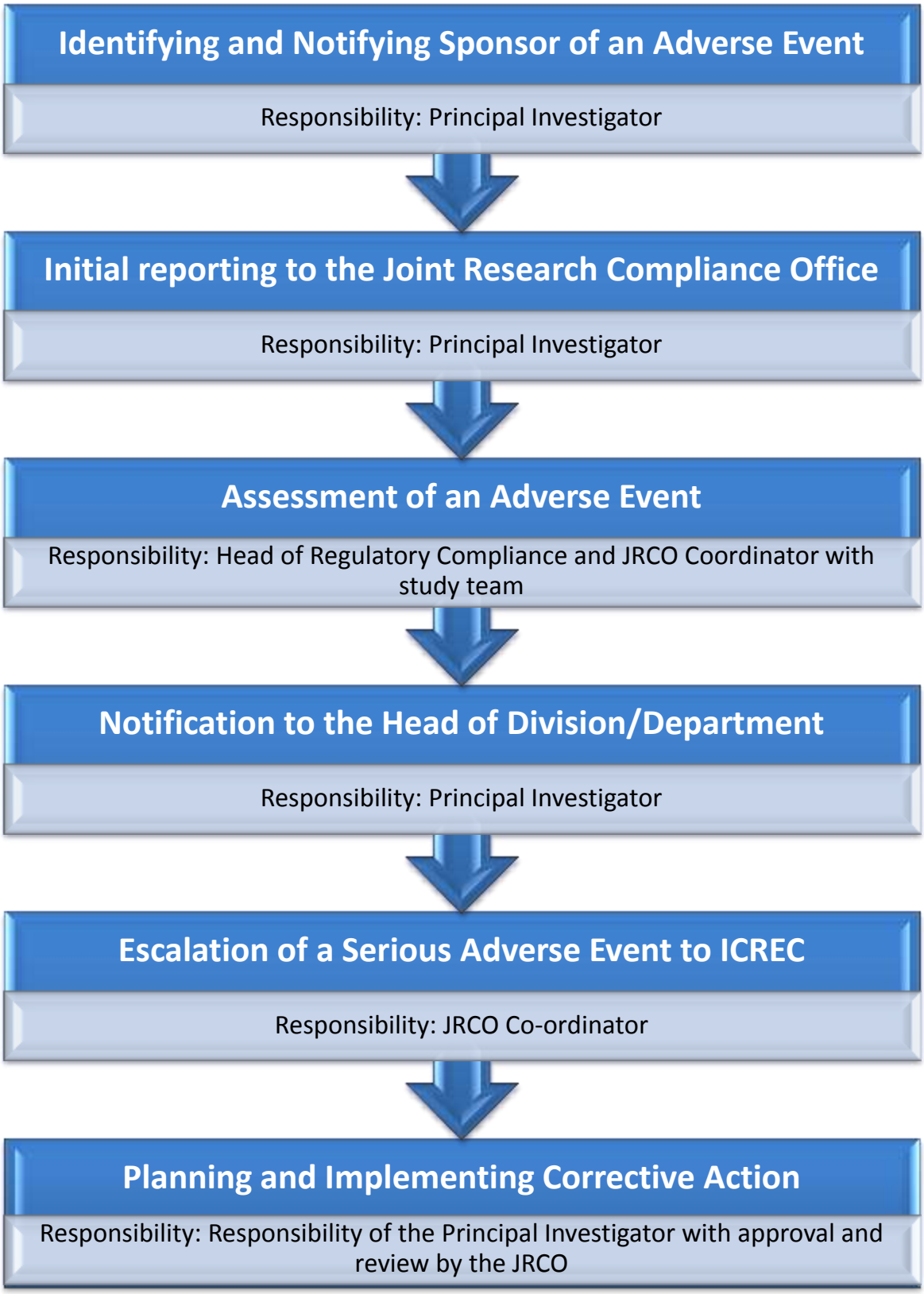
The JRCO will work with the study team to devise a formal plan of corrective action to address the Serious Adverse Event. The corrective action plan will be submitted to the HoD and Imperial College Research Ethics Committee on their request and a copy held on file.

Depending on the initial assessment of seriousness and impact, the JRCO may carry out a full audit of the study and general study management systems and procedures.

Any corrective action plan will be approved by the JRCO and a timeline for completion identified. The Principal Investigator or delegate will be required to provide regular progress updates to the JRCO until the plan is completed.

The JRCO will publish general information on the Serious Adverse Event, in an anonymised form, in their newsletter to educate and inform researchers about errors that can occur in the study process and to facilitate an open environment for reporting such occurrences.

Map of Safety Reporting Escalation Process



5. APPENDICES

5.1 Appendix 1 – Report of Serious Adverse Event (SAE)

REPORT OF SERIOUS ADVERSE EVENT (SAE)

The Principal Investigator should report any SAE that is both related to the research procedure and is unexpected. Please send the report to the JRCO Co-ordinator within 24 hours of the PI becoming aware of the event.

1. Details of the Principal Investigator

Name	
Address	
Telephone	
Email	
Fax	

2. Details of the Study

Full title of study	
ICREC reference number	
Research Sponsor	
Sponsors reference for this report (if applicable)	

3. Type of event

Please categorise this event, ticking all appropriate actions:

Death	☐	**Persistent or significant disability or incapacity**	☐
Breach of Confidentiality	☐	**Protocol Violation**	☐
Life threatening	☐	**Injury**	☐
Hospitalisation or Medical Treatment	☐	**Other**	☐

4. Circumstances of event

Date of SAE	
Location	
Describe the circumstances of the event *(Attach copy of detailed report if necessary)*	
What is your assessment of implications, if any, for the safety of study participants and how will these be addressed?	
Date SAE resolved	

5. Declaration

Signature of Principal Investigator	
Print name	
Date of submission	

6. Acknowledgement of receipt by ICREC

Signed	
Name	
Position on ICREC	
Date	

Signed copy to be sent back to the Principal Investigator (or other person submitting report), original to be kept for information by ICREC.

5.2 Appendix 2 – Notification Examples

Issue:	**Would ICREC have expected this case to be notified?**
Participant Information Sheet and Informed Consent updated without amendment approval.	Yes, if there was a significant impact on the safety of participants or integrity of the research.
Visit date deviation.	No. Minor protocol deviation, which does not meet the criteria for notification.
Investigator failed to report a single SAE as defined in the protocol.	Yes, if there was a significant impact on the safety of participants or integrity of the research.
Investigator does not comply with the conditions of ethics approval (if any).	Yes. This would trigger immediate suspension of the research and escalation to ICREC and the HoD.
Additional data not included in the protocol is routinely captured as part of the research activity	Yes. This would be classed as a violation of the approved research protocol.
A participant is injured or experiences significant emotional distress during the research procedure	Yes.
Breach of confidentiality and data security.	Yes