



Event Adjudication
306-00

1. Purpose

The objective of this standard operating procedure (SOP) is to outline the process for the adjudication of events by the site investigators and the Methods Centre (MC) as outlined in the study protocol.

2. Responsibilities

Qualified Investigator: Conduct of event adjudication activities at the research site, following study procedures.

Methods Centre: Facilitating the adjudication process for the qualified investigator.

Adjudication Committee: Adjudication of study specific events.

3. Procedures

3.1 Event adjudication is a process of review to assess the validity of outcomes for a particular study.

Event Adjudication at the Research Site

3.2 Unless otherwise stated, the qualified investigator at the research site is responsible for performing any event adjudications.

3.3 The qualified investigator will follow all study specific procedures concerning event adjudication. Examples of types of event adjudications include, but are not limited to:

- 3.3.1 Patient eligibility
- 3.3.2 Protocol violations
- 3.3.3 Infections

3.4 The Methods Centre will provide the qualified investigator with procedures, algorithms and definitions to enable the qualified investigator at the site to make an adjudication determination.

3.5 The qualified investigator will perform event adjudication on a particular patient once all data has been entered into the case report form (CRF), outstanding data has been resolved (i.e. data cleaned) and the CRF is considered finalized (i.e. no further changes anticipated).

3.6 Following finalization of the CRF, the MC will extract the elements of data relevant for an adjudication determination, either electronically or manually, and provide to the qualified investigator.

3.7 The qualified investigator will document the adjudication determination as per study procedures.

Event Adjudication at the Methods Centre

3.8 When applicable, events will be adjudicated centrally at the MC by a committee (or by an individual).

3.9 Central adjudication may occur at any time following adjudication determinations made by the qualified investigator at the research sites.

3.10 The adjudication committee will review the case information and make an adjudication determination. The determination will be tracked and documented as per study specific procedures.



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- 3.11 If there is a disagreement between the central adjudication and the site adjudication, the issues will be queried until an agreement can be reached. Any updates or corrections to existing study data or adjudication determinations will be documented as per study procedures.