

Section 9: Quality assurance, feasibility and reporting	Yes	No	N/A	Page Number(s)
described?				
9.8 Is there a system in place for independent review of study results?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27

Comments:

Tentative study timelines given in the agreement between EPID Research and the study funder.
Exact timelines impossible to predict.

Section 10: Ethical issues	Yes	No	N/A	Page Number(s)
10.1 Have requirements of Ethics Committee/Institutional Review Board approval been described?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26
10.2 Has any outcome of an ethical review procedure been addressed?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.3 Have data protection requirements been described?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26

Comments:

Name of the coordinating study entity¹: EPID Research

Name of (primary) lead investigator²: Pasi Korhonen

Date: 28/05/2012

Signature: _____

Pasi Korhonen, PhD, Adj. prof. Biostatistics

¹ A legal person, institution or organisation which takes responsibility for the design and/or the management of a study. The (primary) lead investigator is the person authorised to represent the coordinating study entity.

² A person with the scientific background and experience required for the conduct of a particular pharmacoepidemiological or pharmacovigilance study. The lead investigator is responsible for the conduct of a study at a study site. If a study is conducted at several study sites by a team of investigators, the (primary) lead investigator is the investigator who has overall responsibility for the study across all sites.