



Site Initiation Meeting Package

Clinical Research Stage:

Development

Pre-Initiation

Active Study

Close-out

ACRC Partner Organizations

Alberta Health Services

Alberta Innovates

Alberta SPOR Support Unit

College of Physicians & Surgeons

Covenant Health

University of Alberta

University of Calgary

The ACRC is committed to quality and continuous enhancement. We welcome your input! Forward comments, suggestions and any feedback from Health Canada inspections to: acrc@albertainnovates.ca

Site initiation is the checkpoint to make sure all approvals, documentation and procedures are in place before a study starts and participants can be enrolled. A site initiation visit is held near the desired study start up time in order to train the study staff on the protocol and procedures. The site initiation Meeting Package includes:

Site Initiation Agenda

A sample site initiation agenda outlining key topic areas that are covered in a site initiation meeting.

Inclusion/Exclusion Worksheet

This worksheet is included to work through the screening process with each potential participant.

Confidential Master Identification Log

This log contains all the subject contact information and study numbers. It is strictly confidential and is an essential document which should be kept separately from all other study documents.¹

Site Screening and Enrollment log

This is a log which is used to list subjects screened; it includes those who fail screening and those who are enrolled. This is an essential document, and should be kept in the regulatory binder.²

Informed Consent Worksheet

This is a worksheet to guide you through the informed consent process. This may be used as a training checklist to make sure all elements of the process are included.

Adverse Event Log and Reporting

Throughout the study, adverse event tracking and reporting is necessary³. An Adverse Event (AE) is defined by N2 as: any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended

¹ ICH GCP E6 8.3.21

² ICH GCP E6 8.3.22

³ C.05.012 (e) records with respect to adverse event reporting must be kept (including drug and dosing information)

sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.⁴

Serious Adverse Event Tracking and Reporting

A serious adverse event (SAE)/serious adverse drug reaction is defined as an adverse drug reaction that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity that is life threatening, or that results in death. This is considered to be a serious unexpected adverse drug reaction if it is not identified in nature, severity or frequency in the risk information set out in the investigator's brochure or on the label of the drug.⁵ According to the Food and Drug Regulations, serious unexpected adverse reactions that result in fatal or life-threatening events are required to be reported within seven days after becoming aware of the event. Non-fatal or non-life threatening reactions are to be reported within 15 days of becoming aware of the event⁶.

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Reasonable efforts have been made to ensure accuracy of information and compliance with the regulations however, the ACRC and partner organizations are not responsible for any omissions or errors.

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⁴ N2

⁵ N2

⁶ C.05.014