Participant-Level Monitoring Form Template for Investigator-initiated Trials

Notes to users

Why use this template?	This template is appropriate for clinical trials of investigational products but may be adapted for all clinical research. The information requested by this template will help to ensure that the Sponsor-Investigator meets their Sponsor responsibilities for monitoring their trial in accordance with the Integrated Addendum to ICH E6 (R1) Guideline for Good Clinical Practice E6 (R2) Section 5.18 Monitoring.
How to use this template?	1. Instructions in brackets, i.e. [x] are used to indicate specific information to be provided, e.g. dates, version numbers. 2. *Purple italics* under each section heading and within each section is used to indicate what information should be contained in that section. 3. *Green italics* is used for suggested or example wording in standard sections. 4. You will need to input your study specific information under each heading and remove explanatory information. 5. As this is a template, users are reminded that not all sections or examples may be applicable to their study. Please delete any sections that are not relevant to your study. 6. Remove this page (Notes to users). 7. Please refer to CRDO SOP, "Monitoring Visit Activities for Clinical Trials of Investigational Products" for a full explanation of what needs to be monitored at the participant level.
Version	Participant-Level Monitoring Form Template for Investigator-Initiated Trials Version 1.0, Dated 08 November 2018 This template has been developed by the Clinical Research Development Office (CRDO) for the Melbourne

	Children's Trials Centre (MCTC).

[Insert Name of Department/Group Responsible for Monitoring Trial] MCRI, The Royal Children's Hospital Flemington Road, Parkville, VIC 3052 Phone: (+61) 3 9936 6328	**PARTICIPANT-LEVEL MONITORING FORM** **Informed Consent, CRF Review, Safety Reporting, Serious Breaches Reporting, Investigational Product Accountability**
Sponsor-Investigator/Site Principal Investigator: [Insert full name] *Delete non-applicable role depending on whether the recruiting site is the lead site or a participating site*	
Study Site: [Insert full name of organisation] [Insert Site Address]	
Protocol:[Insert official title of the protocol]	

Monitor Name/Date of Involvement:	1. [Insert Name] 2.	1. [Insert Start Date] to [Insert End Date or Ongoing] 2.

Participant Initials:	☐☐☐	**DOB:**	☐☐-☐☐-☐☐ D D M M M Y Y
Screening Number: *Modify number format as appropriate to your study*	SC☐☐-☐☐☐		
Randomisation Number: *Modify number format as appropriate to your study*	☐☐-☐☐		

1. Retain electronic copy of this form for each participant screened on study using the following file naming convention: CRF Review Form [Insert Participant ID (re-identifiable)].

PARTICIPANT INFORMED CONSENT REVIEW			
Checklist **Date of consent:** ☐☐-☐☐-☐☐ **D D M M M Y Y**	**Yes**	**No**	**Comments** **Date of monitoring visit:** ☐☐-☐☐-☐☐ **D D M M M Y Y**
PICF signed by participant/parent/guardian and person taking informed consent on same day and before any study-related procedures conducted?			
Version of PICF: current approved version used?			*Provide version number and date*
For studies with optional consent components, all optional consent questions completed?			*Enter Not Applicable if no optional consent components to study*
Signed PICF (both information statement and form) is filed in a secure location separate from the TMF/ISF?			*Provide location*
All versions of PICF associated with protocol amendments during participant enrolment on study have been signed and filed? *Answer this question at each monitoring visit.*			
CRF REVIEW			
Template Instruction: • *The following sections of the template should be designed to match the design of the study CRF, indicate when and what has been*			

reviewed and the type of review (data entered, SDV undertaken), in accordance with the approved study Source Document Plan and Clinical Monitoring Plan. Amend the sample text below as appropriate to your study.

- *Sometimes source data will be entered directly into the CRF – this must be made clear in the Source Document Plan.*
- *Add additional visits according to number of protocol visits and add monitoring tasks in accordance with study Clinical Monitoring Plan*
- *Include/delete participating site/lead site tasks as appropriate to your study, e.g. checks that reporting to stakeholders is undertaken following safety events, serious breaches, patient payments due etc*

Instructions for CRF Review & SDV

1. *Review CRF to ensure all fields completed and that entries are legible*
2. *Review data entered against source data in accordance with current approved Source Data Plan to verify data entered is accurate.*
3. *Use the comments column to provide details about any discrepancies or other issues that require action*

Screening **Date of Visit:** ☐☐-☐☐-☐☐ **D D M M M Y Y**	**CRF Data Entered ? (✓/✖)**	**Data matches Source Data? (✓/✖)**	**Comments** **Date monitored:** ☐☐-☐☐-☐☐ **D D M M M Y Y**
Informed Consent Date *Provide date in DD/MMM/YYYY format*			
Version of PGIF			
Date signed:			
Signed by Parent/Guardian, Researcher and Witness (if applic)			
Demographics: *Add data items as per protocol*			
DOB:			
Sex:			
Weight:			

Inclusion Criteria: *Insert all inclusion criteria as per protocol*			
Aged between 1 – 10 years of age			
Weight ≥ 7 kg			
Confirmed allergy to peanuts (SPT or peanut sIgE)			
Exclusion Criteria *Insert all exclusion criteria as per protocol*			
History of severe anaphylaxis			
Current asthma with any of following: 1. *Ventolin >3 times/week for exercise or when resting* 2. *>6 asthma flares in last year* 3. *Waking ≥ 1/week due to asthma*			
Underlying medical conditions that increase the risks associated with anaphylaxis			
Past or current major illness that in opinion of Investigator may affect the subject's ability to participate			
Subjects who in the opinion of the Investigator are unable to follow the protocol			
Reason for Declining Consent (if applic)			*Check against the Screening Log*
Medical History/Physical Exam: *Modify as appropriate to protocol*			
Physical Exam			
Skin			
Head, eyes, ears, nose and throat			

Respiratory			
Cardiovascular			
Gastrointestinal			
Neurological			
Musculoskeletal			
Other (Specify in comments)			
Performed by (Name, Signature, Date)			Name: Date: Delegation Log:
Laboratory Tests *Modify as per protocol*			
PBMC			
Liver Function			
Insert all other data items collected at visit in accordance with data collected in the CRF and as per study-specific Clinical Monitoring Plan			
Concomitant medications *Complete concomitant medication section of this form if conmeds taken during this study period*			
Adverse Events *Complete AE section of this form If adverse events occurred during this study period*			
Person Completing Screening CRF – signed, dated and on Delegation Log?			
Additional Comments:			

RANDOMISATION NUMBER ALLOCATION *Remove this section if not applicable to study*			
Date of Randomisation: ☐☐-☐☐-☐☐ **D D M M Y Y**	**Yes**	**No**	**Comments** **Date monitored:** ☐☐-☐☐-☐☐ **D D M M Y Y**
Randomisation Allocation Form completed?			
Verify stratification into correct cohort *Remove if not applicable*			
Randomised treatment assignment	Provide details here		
Verify Pharmacist signature on delegation & training logs			
Participant added to participant screening and enrolment logs?			
Add additional checks as appropriate to study			

CRF REVIEW			
Visit ID [Insert visit name as per protocol]	**CRF**	**Data**	**Comments**

Date of Participant Visit: D D M M M Y Y	Data Entered ? (✓/✗)	matches Source Data? (✓/✗)	Date monitored: D D M M M Y Y
Visit Assessments *Insert data elements in accordance with data to be collected in the CRF for this visit. Use a separate row for each element.*			
Spirometry			
Vital signs			
ECG			
Laboratory test results			
Concomitant medical conditions and concomitant medications			
Concomitant medical conditions			
Concomitant medications			
Cross-checked concom medical conditions CRF with AE and concom med CRF for consistency?			
Adverse Events *Add all data elements here in accordance with data that is to be captured in the CRF. At a minimum, the list below should be retained.*			
Description of adverse event			
Date and time of event			
Date and time of resolution of event			
Date and time of last admin of intervention			
Assessment of seriousness			
Assessment of severity			
Assessment of causality			
Assessment of expectedness (Remove if this assessment is undertaken by the			

Sponsor-Investigator rather than the Site PI)			
Expedited reporting to stakeholders as per protocol, ethics approval, governance authorization, and applicable regulatory requirements [local and international (if applic)]			
AE Review conducted by person on delegation log with appropriate delegation for this task?			
Protocol Deviations including Serious Breaches			
Description of protocol deviation, including date and details of event			
All protocol deviations recorded in the CRF? *For any protocol deviations not recorded in the CRF, instruct study staff to update the CRF and arrange for PI review ASAP.*			
For Site PIs ONLY *Suspected serious breaches reported by the Site PI to the Sponsor Investigator within 72 hours of becoming aware of the breach?*			
For Site PIs ONLY *Confirmed serious breaches (from Sponsor-Investigator) reported by the Site PI to RCH Research Governance within 72 hours of being notified of the serious breach?*			
For Site PIs ONLY *For any suspected breach where the Sponsor disagrees with the Investigator's assessment and is unwilling to notify the HREC, the Investigator has reported the breach to the HREC?*			

Note in this case the Site PI will need to retain all documentation of correspondence and their assessment of why the protocol deviation is a serious breach.			
For Sponsor-Investigators ONLY *Confirmed Serious Breaches reported to:*			
The approving HREC within 7 calendar days of confirming serious breach			
Participating site Principal Investigator with 7 calendar days of confirming serious breach			

Investigational Product Accountability

For blinded randomised trials, where performing IP accountability tasks may unblind the monitor to treatment assignment, a separate "unblinded monitor" must perform the IP accountability tasks. This process must be detailed in the study-specific Clinical Monitoring Plan. In this circumstance, the unblinded monitor must develop a separate participant-level monitoring form for undertaking product accountability checks.

Add all investigational product accountability checks in accordance with the study-specific Clinical Monitoring Plan.

Product dispensing	**Comments**
Prescription filed?	
Date of dispensing?	
Verified dispensed product against overall accountability log?	
Verify Pharmacist signature(s) against delegation log?	
Product returns	

Return is labelled correctly (eg. treatment arm allocation concealed)?	
Verify Pharmacist signature(s) for product return against delegation log.	
Product quantity confirmed by monitor	*Provide details of quantity and how this compares with pharmacy dispensing and returns log*
Check if returned product quantity corresponds to participant diary entries	
Add additional checks as required to have an assurance of safety and data integrity for the study	

Comments:

Action Items:

Have all action items from the previous visit been completed?	☐ *Yes*	☐ *No*	☐ *NA*

List any items that require action by the site staff, monitor or Sponsor-Investigator below:

Item	**Task Owner(s)** *Provide Full Name*	**Target Completion Date:**
1.		
2.		
3.		

4.		
5.		

Monitor Name / Signature	Date
Name / Signature on behalf of the Sponsor-Investigator:	Date