THE UNIVERSITY OF SYDNEY

FDA's CDASH (Clinical Data Acquisition Standards Harmonization) standards
Case Report Form (CRF)

The following pages are included in each clinical trial CRF:

- Front page
- CRF Completion Instructions
- Demographics (including informed consent details, but the ethnicity is not compulsory)
- Inclusion and Exclusion Criteria
- Eligibility Review and sign off
- Trial Medication Administration (choose the appropriate method of administration, or add your own)
- Trial Assessments
- Study completion
- Adverse events page
- Concomitant Medications table
- Principal Investigator's sign off

Instructions

Complete the CRF using a black / blue ballpoint pen and ensure that all entries are complete and legible.

Avoid the use of abbreviations and acronyms.

The CRF should be completed as soon as possible after the scheduled visit.

Do not use participant identifiers anywhere on the CRF, such as name, hospital number etc., in order to maintain the confidentiality of the participant. Ensure that the header information (i.e. participant's initials and ID number) is completed consistently throughout the CRF. Missing initials should be recorded with a dash (i.e. D-L).

Each CRF page should be signed and dated by the person completing the form.
The 'completed by' Name in the footer of each page must be legible and CRFs should only be completed by individuals delegated to complete CRFs on the Site Delegation log (and signed by the PI).

Ensure that all fields are completed on each page:

- If a test was Not Done record ND in the relevant box(es)
- Where information is Not Known write NK in relevant box(es)
- Where information is not applicable write NA in the relevant box(es)

Corrections to entries
If an error is made, draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change.
Do NOT

- Obscure the original entry by scribbling it out
- Try to correct/ modify the original entry
- Use Tippex or correction fluid

Medications taken by the participant during the trial should be recorded on the "Concomitant Medications Log" using the generic name whenever possible, except combination products which will be recorded using the established trade name. All non-IMPs mentioned in the protocol should also be recorded on the "Concomitant medication Log" for the duration of the trial.

Verbatim Adverse Event terms (initial medical term) should be recorded as the final diagnosis whenever possible.

Complete all dates as day, month, year i.e. 13/NOV/2008. Partial dates should be recorded as NK/NOV/2008.

All times are to be recorded in 24 hour format without punctuation and always use 4-digits; i.e. 0200 or 2130. Midnight is recorded as 0000.

Weights should be recorded to the nearest 0.1 kg.

Source documents such as lab reports, ECG reports etc. should be filed separately from the CRF (if not in the medical notes) for each participant and be signed and dated by a delegated Investigator as proof of review of the assessment during the trial. Questionnaire should be considered as the CRF appendices (except standard approved questionnaire e.g. EQ-5D)

If a participant prematurely withdraws from the trial a single line must be drawn across each uncompleted page to correspond with the last visit of the participant as mentioned on the "Trial Completion" page.

The protocol deviation/violation/serious breach log should be used to record comments relating to each CRF visit that cannot be captured on the page itself. This includes reason for delayed or missed protocol visits or trial assessments, unscheduled visits etc.

The Chief Investigator (for lead site)/Principal Investigator is responsible for the accuracy of the data reported on the CRF. The CI/PI must sign and date the Principal Investigator's Sign Off page to certify accuracy, completeness and legibility of the data reported in the CRF.

Serious Adverse Events (SAEs)
SAEs should be faxed within 24 hours of the site being aware of the event using the trial specific SAE report form to the local site HREC and relevant governance office as required by the NHMRC registered HREC.

Storage
CRF documents should be stored in a locked, secure area when not in use where confidentiality can be maintained. Ensure that they are stored separately to any other documents that might reveal the identity of the participant.

Monitoring Plan
Ensure all visits are referenced/aligned to the clinical trial monitoring plan for the study.

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

Study Title: Effects of animal and plant origin diet on sleep health in healthy adults.
Study No: 2018/715
Site name: University of Sydney, Lidcombe campus
PI Name: Chin-Moi Chow
CRF Version: CRF-V1-18-01-2019.

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 2 0 3 1 9

VISIT 1 SCREENING Demographic Data

Date of Birth	D D M M Y Y

Ethnicity				
White	White British ☐	White Irish ☐	White Other ☐	
Mixed Race	White & Black Caribbean ☐	White & Black African ☐	White & Asian ☐	Other mixed background ☐
Asian or Asian British	Indian ☐	Bangladeshi ☐	Pakistani ☐	Other Asian background ☐
Black or Black British	Caribbean ☐	African ☐	Black Other ☐	
Chinese or other ethnicity	Chinese √	Other ☐ (please specify)		

Gender	√ Male	Female

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 01 CL	C L	12/03/19

VISIT 1 SCREENING Informed Consent Process

Informed Consent Process		
Date & Time Participant/relative/witness given Participant Information Sheet	Date: 12/03/19	Time: 08:30
Date & Time Participant/relative/witness signed Written Consent Form	Date: 12/03/19	Time: 08:30
Date & Version Number of Participant Information Sheet consented to	Date: 10/01/18	Version: v 3
Name of person taking Informed Consent	Name: Mitchel Bones	
Has a copy of the signed consent form/participant information sheet been given to the Participant?	Yes √ No ☐	At time of consent Yes ❑ No ☐ Posted to Participant Yes ☐ No ☐ Date posted If not please explain …… …**Emailed**…… 12/03/19
Has a copy of the signed consent form/participant information sheet been filed in the study notes?	Yes √ No ☐	If not please explain …… ……
Has a written entry detailing the consent process been made in the main body of the study notes?	Yes √ No ☐	If not please explain …… ……

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 01 CL	C L	1 2 0 3 1 9

VISIT 1 SCREENING Inclusion Criteria

Date of Assessment	1 1 0 3 1 9

Inclusion Criteria				
		YES	NO	N/A
1.	Participants from healthy adults of 18 -70 years	√	☐	☐
2.		☐	☐	☐
3.		☐	☐	☐
4.		☐	☐	☐
5.		☐	☐	☐
6.		☐	☐	☐
7.		☐	☐	☐
8.		☐	☐	☐
9.		☐	☐	☐
10.		☐	☐	☐
If any of the above criteria is answered NO, the Participant is not eligible for the trial and must not be included in the study.				

Exclusion Criteria			
		YES	NO
1.	People with cognitive impairment, an intellectual disability or mental illness: depression, bi-polar, schizophrenia, or sleep disorders: insomnia, periodic leg movements, sleep apnoea, narcolepsy, REM sleep behaviour disorder	☐	√
2.	Other major medical conditions (cardiovascular and respiratory diseases, anorexia nervosa, bulimia, metabolic syndrome), diabetes, who are on any medication, including herbal and vitamin that affect sleep	☐	√
3.	Participants who are pregnant and the human fetus or planning to become pregnant within next eight weeks	☐	√
4.	Shift workers	☐	√
5.	Vegans	☐	√
6.	People who consume ≥2 standard alcohol drinks on any day will be excluded from the study	☐	√
7.		☐	☐
8.		☐	☐
9.		☐	☐
10.		☐	☐
If any of the above criteria is answered YES, the Participant is not eligible for the trial and must not be included in the study.			

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 | 2 | 0 | 3 | 1 | 9
VISIT 1 SCREENING Medical History		

Medical History	
Has the Participant had any relevant medical history?	No √ Yes ☐ complete below If not please explain …………………………… ……………………………………………………………
Date of Assessment	1 | 2 | 0 | 3 | 1 | 9

Condition/Illness / surgical Procedure	Start Date (DD/MM/YYYY)	Stop Date (DD/MM/YYYY)	OR tick if on going at screening visit
N/A	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐
	______/ ______/________	______/ ______/________	☐

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 | 2 | 0 | 3 | 1 | 9

VISIT 1 SCREENING Medical History

SIGNIFICANT MEDICAL HISTORY (within the past 5 years)
- Make multiple copies of this page if required

Does the participant have a history of any background/concomitant conditions/symptoms according to the following schedule?
☐1 Yes √2 No

If **Yes**, detail in the table below and reference the ICD10 system code
http://apps.who.int/classifications/apps/icd/icd10online/

Code	Title	Code	Title
1	Certain infectious and parasitic diseases	12	Diseases of the skin and subcutaneous tissue
2	Neoplasms	13	Diseases of the musculoskeletal system and connective tissue
3	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	14	Diseases of the genitourinary system
4	Endocrine, nutritional and metabolic diseases	15	Pregnancy, childbirth and the puerperium
5	Mental and behavioural disorders	16	Certain conditions originating in the perinatal period
6	Diseases of the nervous system	17	Congenital malformations, deformations and chromosomal abnormalities
7	Diseases of the eye and adnexa	18	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified
8	Diseases of the ear and mastoid process	19	Injury, poisoning and certain other consequences of external causes
9	Diseases of the circulatory system	20	External causes of morbidity and mortality
10	Diseases of the respiratory system	21	Factors influencing health status and contact with health services
11	Diseases of the digestive system	22	Codes for special purposes

SIGNIFICANT MEDICAL HISTORY (within the past 5 years)

Code	Condition/Symptom	Onset Date	Stop Date
		D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
		D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
		D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
		D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
		D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 2 0 3 1 9

VISIT 1 SCREENING Measurements

Measurements	
Were vital signs performed?	No ☐ Yes √1 complete below If not please explain …… ……
Date of Vital Signs	1 2 0 3 1 9
Time of Vital Signs	0 9 1 0
Blood Pressure supine/standing/seated	120 ____ / 82 mmHg
Blood Glucose (fasting)_____5.5__ _____mmol/L	
Working memory 31415161718191_____ _____	
Mood and alertness ____9_____ _____	
Pulse ~~62~~ ____ ____ beats/min	
Weight 97.5____ ____ kg ____ Height 1. 74 ____ m ____	

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 2 0 3 1 9

VISIT 1 SCREENING Concomitant Medication

Concomitant Medications							
Date of Assessment							
		1	2	0	3	1	9
Is the Participant taking any concomitant medications?					No √ Yes ☐ complete below		

Medication	Reason for use	Dose & Units	Frequency	Route	Start Date (DD/MM/YYYY)	Stop Date (DD/MM/YYYY)	OR tick if on going at time of screening visit
1.					___/___/ ___	___/___/ ___	☐
2.					___/___/ ___	___/___/ ___	☐
3.					___/___/ ___	___/___/ ___	☐
4.					___/___/ ___	___/___/ ___	☐
5.					___/___/ ___	___/___/ ___	☐
6.					___/___/ ___	___/___/ ___	☐
7.					___/___/ ___	___/___/ ___	☐
8.					___/___/ ___	___/___/ ___	☐
9.					___/___/ ___	___/___/ ___	☐
10.					___/___/ ___	___/___/ ___	☐
11.					___/___/ ___	___/___/ ___	☐
12.					___/___/ ___	___/___/ ___	☐

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 2 0 3 1 9

VISIT 1 SCREENING Smoking / Alcohol

Date of Assessment	1 2 0 3 1 9

Smoking / Alcohol	
Has the Participant ever smoked?	No √ Yes ☐ complete below
☐ Current Smoker	Participant's average daily use: Number smoked per day ____ ____
☐ Former Smoker	Smoked for ____ ____ months / years Date when smoking ceased D D M M Y Y
Participants alcohol consumption Wine ____ ____units per week / month Beer ____ ____ units per week / month Spirits ____ ____ units per week / month	

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 2 0 3 1 9

VISIT 1 SCREENING Participant Eligibility Review

Date of Assessment	1 2 0 3 1 9

Participant Eligibility Review			
		YES	NO
1.	Does the Participant satisfy the inclusion/exclusion criteria?	√	☐
2.	Have the medical history and concomitant medication pages been completed?	√	☐
3.	Is the Participant still willing to proceed in the trial?	√	☐

Participant's eligibility Investigator sign-off	
Is the Participant eligible to take part in the Clinical Trial? Principal Investigator's (or delegated individual*) Signature: Chin Moi Chow Chin Moi Chow Digitally signed by Chin Moi Chow Date: 2019.05.18 08:54:18 +10'00' Date: _12__ ___ / __03_ ___/ _2019__ ___ ___ (DD/MM/YYYY) Investigator's Name: Mitchel Bones *Must be reflected in the Delegation of Authority Log	√YES ☐ NO Please give reason below
Reason(s) for screen failure	
1.	
2.	
3.	

Participant Enrolment	
Participant Study Number Allocated	Participant ID __0001CL
Date of Enrolment	1 2 0 3 1 9

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 2 0 3 1 9

VISIT 1 SCREENING Investigational product or service

Date of Assessment	1 2 0 3 1 9

Investigational Diets			
		YES	NO
1.	Has the Participant been advised of the interventional diet as per protocol?	√	☐ If NOT explain ……
2.	Has the Participant received instruction / guidance on how to take the trial diet?	√	☐ If NOT explain ……
3.	Will the participant complete the diet as instructed?	√	☐ If NOT explain ……
4.	Will the participant complete the food diary and sleep diary as instructed?	√	☐ If NOT explain ……
5.	Will the participant follow the instructions on how to wear and when to wear the actiwatch.	√	☐ If NOT explain ……

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	2 6 0 3 1 9

VISIT 2

Visit Checklist			
		YES	NO
1.	Did the Participant experience any new or changes to existing adverse events since the screening visit/previous visit? If YES, please complete adverse event page *(If an AE is marked as serious this must be reported to the Sponsor within 24 hours of the research team being made aware of the event, utilising the Sponsor SAE form.*	☐	√
2.	Have there been any changes to existing diet, or the Participant has taken any new diet since the screening visit/previous visit? If YES, please complete concomitant medication page	☐	√
3.		☐	☐
4.		☐	☐

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 01 CL	C L	26/03/19

VISIT 2

Measurements	
Were vital signs performed?	No ☐ Yes √ complete below If not please explain …… ……
Date of Vital Signs	26/03/19
Time of Vital Signs	0845

Blood Pressure supine/standing/seated ____ ____ ~~130~~ / ~~88~~ ____ ____ mmHg

Blood Glucose (fasting) _____ _5.1_____mmol/L

Working memory: Digit span test - 31415161718191

Mood and alertness: 9

Pulse ~~60~~ ~~beats/min~~

Weight ~~98.34~~ ~~kg~~ Height 1 . ~~74~~ ~~m~~

Investigational Diets			
		YES	NO
1.	Has the Participant been advised of the interventional diet as per protocol?	√	☐ If NOT explain
2.	Has the Participant received instruction / guidance on how to take the trial diet?	√	☐ If NOT explain ……
3.	Has the participant completed the diet as instructed?	√	☐ If NOT explain ……
4.	Has the participant completed the food diary and sleep diary as instructed?	√	☐ If NOT explain ……
5.	Has the participant followed the instructions on how to wear and when to wear the actiwatch.	√	☐ if NOT explain ……

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	0 2 0 4 1 9 (D D M M Y Y)

VISIT 3

Measurements	
Were vital signs performed?	No ☐ Yes √ complete below If not please explain …… ……
Date of Vital Signs	0 2 0 4 1 9 (D D M M Y Y)
Time of Vital Signs	0 9 0 5 (H H M M)
Blood Pressure supine/standing/seated	124 ____ ____ / 87 ____ ____ ____ mmHg
Blood Glucose (fasting) _____5.4___ _____mmol/L	
Working memory: Digit span test 31415161718191	
Mood and alertness: 5	
Pulse 6 ~~9~~ ~~beats~~/min	
Weight ____ 96.49 ___kg Height 1. 73____ ___m	

Investigational Diets			
		YES	NO
1.	Has the Participant been advised of the interventional diet as per protocol?	√	☐ If NOT explain ……
2.	Has the Participant received instruction / guidance on how to take the trial diet?	√	☐ If NOT explain ……
3.	Has the participant completed the diet as instructed?	√	☐ If NOT explain ……
4.	Has the participant completed the food diary and sleep diary as instructed?	√	☐ If NOT explain ……
5.	Has the participant followed the instructions on how to wear and when to wear the actiwatch.	√	☐ If NOT explain……

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 8 0 4 1 9 (D D M M Y Y)

VISIT 4

Measurements	
Were vital signs performed?	No ☐ Yes √ complete below If not please explain …… ……
Date of Vital Signs	1 8 0 4 1 9
Time of Vital Signs	0 8 4 5
Blood Pressure supine/standing/seated	126/ 84 mmHg
Blood Glucose (fasting) _____4.2_mmol/L	
Working memory: 31415161718191	
Mood and alertness:8	
Pulse ~~61~~ beats/min	
Weight ~~95.4~~ kg Height 1.74 m	

Investigational Diets			
		YES	NO
1.	Has the Participant been advised of the interventional diet as per protocol?	√	☐ If NOT explain ……
2.	Has the Participant received instruction / guidance on how to take the trial diet?	√	☐ If NOT explain ……
3.	Has the participant completed the diet as instructed?	√	☐ If NOT explain ……
4.	Has the participant completed the food diary and sleep diary as instructed?	√	☐ If NOT explain ……

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:											
00	01	CL	C	L		2	6	0	4	1	9
						D	D	M	M	Y	Y

VISIT 5

Measurements	
Were vital signs performed?	No ☐ Yes √ complete below If not please explain …… ……
Date of Vital Signs	2 6 0 4 1 9 D D M M Y Y
Time of Vital Signs	0 8 1 0 H H M M
Blood Pressure supine/standing/seated ~~138/88~~ mmHg	
Blood Glucose (fasting) _____5.2 _____mmol/L	
Working memory: 31415161718191	
Mood and alertness: 6	
Pulse ~~62~~ beats/min	
Weight ~~96.1~~ kg Height 1.74m	

Investigational Diets			
		YES	NO
1.	Has the Participant been advised of the interventional diet as per protocol?	√	☐ If NOT explain ……
2.	Has the Participant received instruction / guidance on how to take the trial diet?	√	☐ If NOT explain ……
3.	Has the participant completed the diet as instructed?	√	☐ If NOT explain ……
4.	Has the participant completed the food diary and sleep diary as instructed?	√	☐ If NOT explain ……
5.	Has the participant followed the instructions on how to wear and when to wear the actiwatch.	√	☐ If NOT explain ……

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 0 0 5 1 9 D D M M Y Y

VISIT 6

Measurements	
Were vital signs performed?	No ☐ Yes √ complete below If not please explain ……. ……
Date of Vital Signs	1 0 0 5 1 9 D D M M Y Y
Time of Vital Signs	0 8 4 5 H H M M
Blood Pressure supine/standing/seated	146 / 98 mmHg
Blood Glucose (fasting) _____4.6_ _____mmol/L	
Working memory ___31415161718191_	
Mood and alertness ____6_____ _____	
Pulse ~~59~~ ~~beats~~/min	
Weight 96.0 kg Height 1.74 cm	

Investigational Diet			
		YES	NO
1.	Has the Participant been completed the trial diet study as per protocol?	√	☐ If NOT explain ……
2.	Has the Participant received instruction / guidance on how to end the study?	√	☐ If NOT explain

Trial diet not followed			
	Trial Diet Name	Quantity Returned	Date of Return DD/MM/YYYY
1.			/ /
2.			/ /
3.			/ /
4.			/ /

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 0 | 0 5 | 1 9 (D D | M M | Y Y)

Telephone Contact

√ *Telephone contact not performed*

If Telephone contact not performed, complete the Subject Deviation form

	Date of Contact Attempt			Time	Contact Occurred	Outcome
	Month (MO)	Day (DD)	Year (YYYY)			
Contact Attempt #1				☐[1] AM ☐[2] PM	☐[1] Yes ☐[0] No	☐[1] No answer ☐[2] Left Voice message ☐[3] Left Message w/_____ ☐[4] Line Busy ☐[5] Other: _____
Contact Attempt #2				☐[1] AM ☐[2] PM	☐[1] Yes ☐[0] No	☐[1] No answer ☐[2] Left Voice message ☐[3] Left Message w/_____ ☐[4] Line Busy ☐[5] Other: _____
Contact Attempt #3				☐[1] AM ☐[2] PM	☐[1] Yes ☐[0] No	☐[1] No answer ☐[2] Left Voice message ☐[3] Left Message w/_____ ☐[4] Line Busy ☐[5] Other: _____

QUESTION(S) TO BE ASKED	
Since your last study contact, have you had any changes in health status, medical conditions, or adverse events?	☐ Yes √☐ No
Concomitant Medications Log completed *(if applicable)*? Not applicable	☐ Yes ☐ No
Adverse Event Symptoms reviewed with Subject? Not applicable	☐ Yes ☐ No
Adverse Event Tracking Log Completed (same log form for all visits)? Not applicable	☐ Yes ☐ No
• If any AE has 'Yes' in Serious column, complete SAE form	☐ Yes ☐ No
Does the medical history form need to be updated?	☐ Yes √☐ No
Were there any activities that deviated from the defined protocol?	☐ Yes √☐ No
• If yes, completed the Deviation/Violation form	☐ Yes ☐ No
Subject payment confirmed *(if applicable)*	√☐ Yes ☐ No
OTHER QUESTION TO ASK*(if applicable) Not applicable*	☐ Yes ☐ No

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

THE UNIVERSITY OF SYDNEY

Participant ID:	Participant Initials:	Visit Date:
00 | 01 | CL	C | L |	1 0 0 5 1 9 D D M M Y Y

END OF TRIAL

Date of trial completion/withdrawal	1 0 0 5 1 9 D D M M Y Y
Date last trial food is taken and actiwatch warn	0 9 0 5 1 9 D D M M Y Y

Trial Participation Outcome	YES	NO
Completed trial	√	☐
Withdrawn from trial (complete withdrawal form below)	☐	☐

Trial Withdrawal Form

Reason for Withdrawal	YES	NO
Lost to follow up	☐	☐
Non-compliance	☐	☐
Concomitant medication	☐	☐
Medical contraindication	☐	☐
Consent withdrawn	☐	☐
AE/SAE/SUSAR (complete SAE form)	☐	☐
Death (complete SAE form)	☐	☐
Other (explain) ……. ……..	☐	☐

Chief/ Principal Investigator Sign Off

I …Chin Moi Chow ……(name)confirm that I have reviewed the case report form and confirm that to the best of my knowledge, the information contained within is accurate and complete.

Signature Chin Moi Chow Digitally signed by Chin Moi Chow Date: 2019.05.18 08:55:27 +10'00' …….. Date 11 / 05 / 2019 DD/MM/YYYY

Completed by: Mitchel Bones Signature: M. Bones Date: 22-04-2019

Concomitant Medications Form	Participant ID:	Participant Initials:

Have there been any changes to existing medication, or the Participant has taken any new medication since the screening visit? NO ☐ YES ☐ (record below)

	Medication name (Generic term preferred)	**Reason for use**	**Start Date** (DD/MM/YYYY)	**End Date** (DD/MM/YYYY)	**Dose**	**Unit**	**Route**	**Frequency**	**Continuing at the end of the study?**
1.			/ /	/ /					☐
2.			/ /	/ /					☐
3.			/ /	/ /					☐
4.			/ /	/ /					☐
5.			/ /	/ /					☐
6.			/ /	/ /					☐
7.			/ /	/ /					☐
8.			/ /	/ /					☐
9.			/ /	/ /					☐
10.			/ /	/ /					☐
11.			/ /	/ /					☐
12.			/ /	/ /					☐

Completed by: Signature: Date:

Adverse Events Form	Participant ID	Participant Initials:

	Adverse Event Description	**Start Date** (DD/MMM/YYYY)	**End Date** (DD/MMM/YYYY)	**In case of SAE- Please specify the criteria** 1= Death 2 = Life threatening 3 = Hospitalisation 4 = Medically significant 5 = Congenital abnormality/birth defect	**Severity** 1= Mild 2 = Moderate 3= Severe	**Causality assessment** 1= Certain 2 = Probable/ Likely 3 = Possible Unlikely 4 = Conditional/ Unclassified 5 = Assessable/ Unclassifiable	**Action taken with trial treatment** 1=Dose modification 2=Discontinuation of the IMP 3= Not applicable 4 = Treatment continued without change	**Outcome** 1=Resolved 2=Resolved with sequelae 3= Ongoing 4= Fatal 5= Unknown
1.		/ /	/ /					
2.		/ /	/ /					
3.		/ /	/ /					
4.		/ /	/ /					
5.		/ /	/ /					
6.		/ /	/ /					
7.		/ /	/ /					
8.		/ /	/ /					
9.		/ /	/ /					
10.		/ /	/ /					

Completed by: Signature: Date: