



## **Appendix 3: Example Annotated CRFs**



**5.1a** Average no. of cigarettes/cigars/pipes per day

**5.1b** Age when started smoking

(CigNo)

(SmAge)

**5.2** If Former smoker, year stopped

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(SmYrSt)





46342

**Visit 1 Life Style Profile**

Participant

ID

Participant  
AcrosticDate  
of Visit / 

MMM (eg. JAN)

YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Staff  
ID   **6. Alcohol use** (please select one only): (Al) 1 Current 2 Former 3 Never

SECTION A2

**6.1** If Current or Former drinker (Alcdays)**6.1a** How often do you usually drink alcohol? (please select one only) 1 < once per week 2 1-2 days per week 3 3-4 days per week 4 5-6 days per week 5 every day

(Alno)

**6.1b** On a day that you drink alcohol, how many standard drinks\* would you usually have? (please select one only) 1 1-2 drinks 2 3-4 drinks 3 5-8 drinks 4 9-12 drinks 5 13-20 drinks 6 > 20 drinks**6.1c** Do you drink more on the weekends? 1 Yes 0 No

(AlkWknd)

**7. Previous aspirin use**

SECTION B1

**7.1** Immediately prior to your involvement in ASPREE, were you taking aspirin regularly? Yes No

(Asp)

If YES **7.1a** What dosage? (please select one only) (AspDose) ≤ 100mg 325mg 500mg Unknown**7.1b** How often? (please select one only)

(AspOften)

 ≤ once per week 2-5 days per week >6 days per week**7.1c** For how long? (please select one only)

(AspYear)

 <1 year 1-4 years 5-9 years 10+ years**8. Level of Education** (please select one only) (Edu)

SECTION A1

 1 < 9yrs education 2 9-11yrs education 3 12yrs education 4 13-15yrs education 5 16yrs education 6 17-21yrs education**Please hand back to Research Staff****AUS** \* One standard drink is defined as one pot/half a pint (285ml) of full strength (4.8%) beer OR one 30ml shot of 40% strength spirit. Alternatively, a standard bar/pub wine-glass serve (150ml) of 12.5% strength wine is 1.5 standard drinks**US**\* One standard drink is defined as one 12oz can or bottle of beer, one 6oz glass of wine, one shot of liquor.



# Visit 1 Life Style Profile

Participant

ID

Acoustic Participant

of Visit Date

DD

MMM (eg. JAN)

YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Staff ID



## QUESTIONS 9 & 10: TO BE COMPLETED BY THE RESEARCH STAFF

## SECTION B2

### 9. Blood Pressure & Heart Rate

9.1 a 1st BP: SBP    /    DBP mmHg

9.1 b 2nd BP: SBP    /    DBP mmHg

9.1 c 3rd BP: SBP    /    DBP mmHg

BP2No

Participant declined

BP3No

Participant declined

### 9.1d Mean Blood Pressure:

SBP    /    DBP mmHg  
SBP\_Mean DBP\_Mean

9.2 a 1st HR:    (HR1)  Manual  Participant declined

9.2 b 2nd HR:    (HR2)  Manual  Participant declined

9.2 c 3rd HR:    (HR3)  Manual  Participant declined

(HRDNC)

Participant declined

(HR2No)

Participant declined

(HR3No)

Participant declined

### 9.2d Mean Heart Rate:

HR\_Mean

9.3 Was there an irregular heartrate on any BP measurement?  Yes  No IrregularHB

If YES: Notify the participant's GP/PCP, and follow up regarding diagnosis of AF.

### AUS only

### 10. Clinical Audit - complete only if participant's GP is taking part

Check medical records for:

10.1 Date of last lipid profile   /    /

DD

MMM (eg. JAN)

YYYY

Unknown

10.2 No. of visits to GP in last 12 months

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS



63921



# Visit 2 Assessments

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant ID

Participant Acrostic

Staff ID

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

BLOCK LETTERS Cross box like this

## 1. Controlled Oral Word Association Test (COWAT) (COWAT- words collected on 'Comments' form)

Complete the COWAT

SLFTNo  Participant declined

## 2. Hopkins Verbal Learning Test - Revised (HVLTR)

a) Complete the HVLTR Recall (Trials 1-3)

Participant declined

b) Complete the HVLTR Delayed Recall (Trial 4) & Delayed Recognition

Participant declined

Staff ID

(Complete Staff ID if different from the above)

HVLTRNo

## 3. Symbol Digit Modalities Test (SDMT) (SDMT - see SDMT source document)

Complete the SDMT

Participant declined

SDMTNo

## 4. Physical Performance

Unit

### 4.1 Grip Strength Test Handedness

Dynamometer Unit Number:

Handedness: 1 Left 2 Right

#### RIGHT Hand

RightGrip1

RightGrip2

RightGrip3

RightGripDNC

4.1 a Grip Strength Test 1 (RH) Kg

4.1 b Grip Strength Test 2 (RH) Kg

4.1 c Grip Strength Test 3 (RH) Kg

Participant declined (RH)

#### LEFT Hand

LeftGrip1

LeftGrip2

LeftGrip3

LeftGripDNC

4.1 d Grip Strength Test 1 (LH) Kg

4.1 e Grip Strength Test 2 (LH) Kg

4.1 f Grip Strength Test 3 (LH) Kg

Participant declined (LH)

## 4.2 Gait Speed Test

4.2 a Gait Speed Test 1 . secs

Gait1

RightGripDNC

Participant declined (Test 1)

4.2 b Gait Speed Test 2 . secs

Gait2

LeftGripDNC

Participant declined (Test 2)

4.2 c Identify if any item was used as an aid during the execution of the Gait Speed Test:

1 None 2 Cane 3 Walking frame

GaitWalkAid 4 Other

WalkAidOth

Specify:

## 5. Physical Measurements

5.1 Height  .   m

Participant declined

HtNo

5.2 Weight    .  kg

Participant declined

WtNo

5.3 Abdominal circumference    cm

Participant declined

ACNo

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**6. Additional Information to collect**

CC =1

6.1 SF-12 Health Survey SF12  Participant declined

6.2 Participant Contact Details ContactDt  Participant declined

6.3 Participant Medical History - Baseline (PMHB) PtMedHistory  Participant declined

6.4 Concomitant Medications ConMeds  Yes  No (No qualifying meds)  Participant declined

6.5 Medicare number  Not applicable

6.5.1 AUS Medicare No.   No. that precedes name  
*AusMedicareNo*

6.5.2 US Medicare No.  
*USMedicareNo*

6.6 DVA card number  Not applicable

6.6.1 DVA Card No. -

**7. (AUS Only) Inclusion in sub-studies** *(Operational Data, not released)*

Has the participant consented to the following sub-studies as appropriate for your site:

7.1 **BIOBANK** (all AUS)  Yes  No- refused  No- not offered  No- pt interested

7.2 **SNORE** (AUS excluding Tasmania)  Yes  No- refused

**(VICTORIA ONLY)**

7.3 Is the participant interested in participating in an imaging sub study at Monash Biomedical Imaging (MBI) within the next 4 weeks?

**NOTE:** MBI is on Blackburn Road in Clayton and parking is easily available.

Yes  No- refused  Not discussed - inappropriate  Not discussed - no time

7.4 Is the participant interested in participating in a HEARING sub-study?

Yes  No- refused  Not discussed - inappropriate  Not discussed - no time

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS



63921



# Visit 2 Assessments

Participant ID

Participant Acrostic

Staff ID

Date of Visit   /   /     
DD MMM (eg. JAN) YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

30/04/2014

Page 2 of 2

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**Part 1b: Other Medical History**

Please indicate below if you have been diagnosed or treated for any of the following medical conditions. There will be an opportunity to discuss your responses with an ASPREE staff member at your next visit.

**Have you ever been diagnosed or treated by a doctor for any of the following:**

- 1) Asthma **ASM** ..... Yes  1 No  0 Unsure  -1
- 2) Benign Prostatic Hyperplasia (BPH; enlarged prostate)..... **BPH** ..... Yes  1 No  0 Unsure  -1
- 3) Bowel polyp ..... **BWP** ..... Yes  1 No  0 Unsure  -1  
**(If Yes):** How many polyps have you had?..... **PolypCat** ..... 1  1 2-5  2 5+  3 Unsure  -1
- 4) Deep Vein Thrombosis (DVT)..... **DVT** ..... Yes  1 No  0 Unsure  -1
- 5) Depression..... **DPR** ..... Yes  1 No  0 Unsure  -1
- 6) Diabetes..... **DAB** ..... Yes  1 No  0 Unsure  -1
- 7) Gastro–Oesophageal Reflux disease (GORD), gastritis or dyspepsia  
(stomach upset requiring treatment)..... **GOR** ..... Yes  1 No  0 Unsure  -1
- 8) Gout..... **GOU** ..... Yes  1 No  0 Unsure  -1
- 9) High blood pressure (Hypertension)..... **HBP** ..... Yes  1 No  0 Unsure  -1
- 10) High cholesterol..... **HCH** ..... Yes  1 No  0 Unsure  -1
- 11) Kidney disease (excluding kidney stones, bladder infection or  
incontinence)..... **KDN**... Yes  1 No  0 Unsure  -1  
**(If Yes):** Have you required dialysis treatment ..... **Dialysis** ..... Yes  1 No  0 Unsure  -1
- 12) Have you ever had a kidney transplant..... **KidTrans** ..... Yes  1 No  0 Unsure  -1  
**(If Yes):** At what age did you have the transplant?..... **KidTransAge**
- 13) Macular degeneration..... **MDG**..... Yes  1 No  0 Unsure  -1
- 14) Minor bleeding (e.g., nose bleeds; bruising; blood in the urine,  
bowel, or vagina; tarry/black stools)..... **MNB**..... Yes  1 No  0 Unsure  -1
- 15) Osteoarthritis..... **OST**..... Yes  1 No  0 Unsure  -1
- 16) Parkinsons Disease..... **PKS**..... Yes  1 No  0 Unsure  -1
- 17) Pneumonia ..... **PNM**..... Yes  1 No  0 Unsure  -1
- 18) Ringing in the ears ..... **RIE**..... Yes  1 No  0 Unsure  -1
- 19) **Have you had any other medical conditions**..... **O.T.H.**..... Yes  1 No  0 Unsure  -1

**(If Yes):** Please specify: \_\_\_\_\_

**Thank you for completing Part 1b. Please turn over for questions about screening tests.**

**Part 2: In the past, have you ever had any of the following cancer screening tests:****For colorectal cancer:** (please tick all that apply)

Sigmoidoscopy.....  **Col\_Sig**  Barium enema.....  **Col\_Bar**   
 Colonoscopy.....  **Col\_Sco**  Biopsy.....  **Col\_Bio**   
 Virtual colonoscopy (CT colonoscopy).....  **Col\_Ctc**  Other test/Unsure.....  **Col\_Oth**   
 Stool based test.....  **Col\_Stb**  None of the above.....  **Col\_None**

↓  
 If you have had a stool based test, please specify what type of test:

Fecal occult blood test (FBT).....  **Col\_Fbt**  DNA test.....  **Col\_Dna**   
 Fecal immunochemical test (FIT).....  **Col\_Fit**  Other test /Unsure.....  **Col\_None**

**For breast cancer:** (please tick all that apply)

Mammogram.....  **Bre\_Mam**  Biopsy.....  **Bre\_Bio**   
 Breast ultrasound.....  **Bre\_Ult**  Other test/ Unsure.....  **Bre\_Oth**   
 MRI.....  **Bre\_Mri**  None of the above.....  **Bre\_None**   
 Physical exam by Healthcare provider.....  **Bre\_Phy**   
 (clinical breast exam)

**For cervical cancer:** (please tick all that apply)

Not applicable.....  Biopsy.....  **Cer\_Bio**   
 Pap smear.....  **Cer\_Pap**  Other test/Unsure.....  **Cer\_Oth**   
 HPV test.....  **Cer\_Hpv**  None of the above.....  **Cer\_None**

**For prostate cancer:** (please tick all that apply)

Not applicable.....  Biopsy.....  **Pro\_Bio**   
 **Pro\_Ant**   **Pro\_Oth**   
 PSA (Prostate Specific Antigen- blood test).....  Other test/ Unsure.....   
 Physical exam by Healthcare Provider.....  **Pro\_Phy**  None of the above.....  **Pro\_None**   
 (digital rectal exam)

**For lung cancer:** (please tick all that apply)

Chest x-ray.....  **Lun\_Xra**  Other test/Unsure.....  **Lun\_Oth**   
 Chest CT scan.....  **Lun\_Cts**  None of the above.....  **Lun\_None**   
 Biopsy.....  **Lun\_Bio**

**For skin cancer:** (please tick all that apply)

Photographic Mole Check.....  **Skn\_Ph**  Other test/Unsure.....  **Skn\_Oth**   
 Physical exam by Healthcare Provider.....  **Skn\_Phy**   
 Biopsy.....  **Skn\_Bio**

**End of questionnaire. Thank you for your time!**

None of the above.....[Skn\\_None](#).....

***Please return this form to the ASPREE staff member at your next visit.***





# Visit 1 Family History Profile

Participant ID:

Acrostic Participant

Staff ID:

of Visit Date:   /   /

DD MMM (eg. JAN) YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

**Family History:** If the following blood relatives have been diagnosed with any of the listed conditions, please specify the NUMBER and age (<50 or 50+) when relative was diagnosed. If diagnosis occurred at age 50, please put a '1' in the '50+' box.

## Mother - General Medical History

Mo_HA	<50	50+
Heart Attack	1	2
Stroke Mo_Stroke		
Dementia Mo_De entia		

	<50	50+
Kidney Disease Mo_Kidney <small>(do not include kidney stones, bladder infections or incontinence)</small>		
Dialysis Treatment Mo_Kidney Dialysis		
Kidney Transplant Mo_Kidney Transplant		

No/Unsure/Adopted

1 - Reported <50  
2- Reported 50+  
3 - Reported at unknown age  
4- Reported <50 and 50+

## Mother - Cancer History

Yes  No/Unsure/Adopted

Has your mother ever been diagnosed with cancer? Yes  No/Unsure/Adopted

If yes, complete the following for primary cancer site:

MO_Cr_Bla	<50	50+
Bladder	1	2
Blood* MO_Cr_Bla		
Brain Mo_Cr_Bra		
Breast Mo_Cr_Bre		
Cervical Mo_Cr_Cr		
Colon / Rectum Mo_C_Col		

	<50	50+
Gallbladder / Bile Ducts Mo_C_Gal		
Kidney Mo_Cr_K		
Liver Mo_Cr_Liv		
Lung Mo_Cr_Lun		
Melanoma Mo_C_Mel		

	<50	50+
Ovarian / Endometrium Mo_r_Ova		
Pancreas Mo_Cr_Pan		
Stomach/Oesophageal Mo_C_Sto		
Thyroid Mo_Cr_Thy		
Unknown Mo_Cr_Unk		
Other Mo_Cr_Oth		
Specify: _____		

Is your mother still living?  Yes  No

## Father - General Medical History

FA_HA	<50	50+
Heart Attack	1	2
Stroke FA_Stroke		
Dementia FA_De ntia		

	<50	50+
Kidney Disease FA_Kidney <small>(do not include kidney stones, bladder infections or incontinence)</small>		
Dialysis Treatment FA_Kidney Dialysis		
Kidney Transplant FA_Kidney Transplant		

No/Unsure/Adopted

1 - Reported <50  
2- Reported 50+  
3 - Reported at unknown age  
4- Reported <50 and 50+

## Father - Cancer History

Yes  No/Unsure/Adopted

Has your father ever been diagnosed with cancer? Yes  No/Unsure/Adopted

If yes, complete the following for primary cancer site:

FA_Cr_Bla	<50	50+
Bladder	1	2
Blood* FA_Cr_Blo		
Brain FA_Cr_Bra		

	<50	50+
Gallbladder / Bile Ducts FA_C_Gal		
Kidney FA_Cr_K		
Liver FA_Cr_Liv		
Lung FA_Cr_Lun		
Melanoma FA_C_Mel		

		<50	50+
Pancreas	FA_Cr_Pam		
Prostate	FA_Cr_Pro		
Stomach/Oesophagea <sup>5</sup>	FA_C_ _Sto		
Thyroid	FA_Cr_Thy		
Unknown	FA_Cr_Unk		
Other	FA_Cr_Oth		
Specify: _____			

Breast	FA_Cr_Bre		
Colon / Rectum <sup>5</sup>	FA_C_ _Col		

Is your father still living?      1 Yes      0 No

\* (Blood Cancer: e.g. leukemia, myeloma, lymphoma)



27255

# Visit 1 Family History Profile

Participant

ID

Acoustic Participant

of Visit Date

DD

MMM (eg. JAN)

YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Staff ID

## Sibling - General Medical History

How many siblings do you have?

Numerical

	<50	50+
Heart Attack <b>SB_HA</b>	1	2
Stroke <b>SB_Stroke</b>		
Dementia <b>SB_Dementia</b>		

	<50	50+
Kidney Disease <b>SB_Kidney</b> <small>(do not include kidney stones, bladder infections or incontinence)</small>		
Dialysis Treatment <b>SB_Kidney_Dialysis</b>		
Kidney Transplant <b>SB_Kidney_Transplant</b>		

No/Unsure/Adopted

- 1 - Reported <50
- 2 - Reported 50+
- 3 - Reported at unknown age
- 4 - Reported <50 and 50+

## Sibling - Cancer History

Have any of your siblings ever been diagnosed with cancer?

Yes

0 No/Unsure/Adopted

If yes, complete the following for primary cancer site:

	<50	50+
Bladder <b>SB_Cr_Bla</b>	1	2
Blood* <b>SB_Cr_Blo</b>		
Brain <b>SB_Cr_Bra</b>		
Breast <b>SB_Cr_Bre</b>		

	<50	50+
Gallbladder / Bile Ducts <b>SB_Cr_Gal</b>		
Kidney <b>SB_Cr_Kid</b>		
Liver <b>SB_Cr_Li</b>		
Lung <b>SB_Cr_Lun</b>		
Melanoma <b>SB_Cr_Mel</b>		

	<50	50+
Ovarian / Endometrium <b>SB_Cr_Ova</b>		
Pancreas <b>SB_Cr_Pan</b>		
Prostate <b>SB_Cr_Pro</b>		
Stomach/Oesophageal <b>SB_Cr_Sto</b>		
Thyroid <b>SB_Cr_Thy</b>		
Unknown <b>SB_Cr_Unk</b>		
Other <b>SB_Cr_Oth</b> Specify: _____		

Cervical **SB\_Cr\_Cer**

Colon / Rectum <sup>5,0</sup> **SB\_Cr\_Col**

Do you have any living siblings?

1 Yes

0 No

## Children - Cancer History

Numerical

How many children do you have?

- 1 - Reported <50
- 2 - Reported 50+
- 3 - Reported at unknown age
- 4 - Reported <50 and 5

Have any of your children ever been diagnosed with cancer?

Yes

0 No/Unsure/Adopted

If yes, complete the following for primary cancer site:

CH_CR_Bla	<50	50+
Bladder	1	2
Blood* CH_CR_Bo		
Brain CH_CR_Ba		
Breast CH_CR_Bre		
Cervical CH_CR_Cer		
Colon / Rectum CH_CR_Co		

	<50	50+
Gallbladder / Bile Ducts CH_CR_Gal		
Kidney CH_CR_Kid		
Liver CH_CR_Liv		
Lung CH_CR_Lun		
Melanoma CH_CR_Mel		

	<50	50+
Ovarian / Endometrium CH_CR_Ova		
Pancreas CH_CR_Pan		
Prostate CH_CR_Pro		
Stomach/Oesophageal CH_CR_Sto		
Thyroid CH_CR_Thy		
Unknown CH_CR_Unk		
Other CH_CR_Oth Specify: _____		

Do you have any living children?  Yes  No

\*(Blood Cancer: e.g. leukemia, myeloma, lymphoma)

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS



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# 3MS Examination

Participant ID

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant Acrostic

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Staff ID

Please indicate year of Examination:  Screening Visit  Year 1  Year 3  Year 5  Year 6

Handedness: Left / Right

## The Modified Mini-Mental State (3MS) Examination

*(NB. Australian terms appear in brackets and italics)*

Maximum Possible Score Score

### 1 Simple personal information

"Can you tell me your date and place of birth?" (score 1 point for each correct answer)

Date of birth: Year: \_\_\_\_\_ Month: \_\_\_\_\_ Day: \_\_\_\_\_ 3MS\_DobSc (3)

Place of birth: Town/City: \_\_\_\_\_ State/Country: \_\_\_\_\_ 3MS\_PobSc (2)

### 2 Remembering information *(Circle the words as the participant says them)*

"I am going to say three words for you to remember. Repeat them after I have said all three words".

3MS\_Now (3)

**"AIRPLANE (AEROPLANE)... BROWN... HONESTY"**

Number of words recalled - score 1 point for each that is correct after 1st attempt.

Number of presentations needed for three word recall (max. 6)

### 3 Numbers & word reversal test

A) "Please count from one to five".

Check that the participant can count correctly.

3MS\_CntAcc (2)

"Now count backwards from five to one". Record Response: \_\_\_\_\_

If completely accurate, score 2 points. Up to two errors, score 1 point. If more than two errors, score 0 points.

B) "Spell the word WORLD".

Check that the participant can spell the word correctly.

3MS\_Spl (5)

"Now spell it backwards, please". Record Response: \_\_\_\_\_

**DLROW** (Count the number of moves needed to make the spelling correct and subtract from 5)

### 4 First recall of previous information "What are the three words that I asked you to remember?"

A) **AIRPLANE (AEROPLANE)**

Tick one only

(3)

If spontaneous recall of AIRPLANE (AEROPLANE).....  Score 3 points 3MS\_Rcl1Shrt

*(If no spontaneous recall, proceed to 1st prompt. If recall is wrong mode of transport, proceed to 2nd prompt)*

1st prompt: "A mode of transport" .....  Score 2 points

2nd prompt: "TRAIN, AIRPLANE (AEROPLANE), AUTOMOBILE". (Alternative: SHIP) .....  Score 1 point

If not recalled .....  Score 0 points

B) **BROWN**

Tick one only

(3)

If spontaneous recall of BROWN.....  Score 3 points 3MS\_Rcl1Brwn

*(If no spontaneous recall, proceed to 1st prompt. If recall is wrong colour, proceed to 2nd prompt)*

1st prompt: "A color" .....  Score 2 points

2nd prompt: "BLUE, BLACK, BROWN". (Alternative: RED) .....  Score 1 point

If not recalled .....  Score 0 points

C) **HONESTY**

Tick one only

(3)

If spontaneous recall of HONESTY.....  Score 3 points 3MS\_Rcl1Hnst

*(If no spontaneous recall, proceed to 1st prompt. If recall is wrong personal quality, proceed to 2nd prompt)*

1st prompt: "A good personal quality" .....  Score 2 points

2nd prompt "HONESTY, CHARITY, MODESTY". (Alternative: COURAGE) .....  Score 1 point

If not recalled .....  Score 0 points

# 3MS Examination

Date

of Visit

DD

/				/			
	MMM (eg. JAN)				YYYY		

Participant ID 

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Participant Acrostic 

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Acrostic 

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Staff ID 

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Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

## The Modified Mini-Mental State (3MS) Examination

Maximum (continued) re

um Sco  
Possible Score

### 5 Understanding of temporal orientation

- A) "What year is it?" \_\_\_\_\_ 3MS\_YrMs 8  
If accurate, score **8** points. If missed by one year, score **4** points.  
If missed by two to five years, score **2** points.
- B) "What season is it?" \_\_\_\_\_ 3MS\_Seasn 1  
If accurate or within one month, then score **1** point.
- C) "What month is it?" \_\_\_\_\_ 3MS\_MthMs 2  
If accurate or within five days, score **2** points.  
If missed by one month, score **1** point.
- D) "What date in the month is it?" \_\_\_\_\_ 3MS\_DyMthMs 3  
If accurate, then score **3** points. If missed by one to two days, score **2** points.  
If missed by three to five days, score **1** point.
- E) "What day of the week is it?" \_\_\_\_\_ 3MS\_DyWk 1  
If accurate, then score **1** point.

If the participant is unable to provide each piece of information to the required accuracy, then score **0** points.

### 6 Understanding of spatial orientation

- A) "What State are we in?" \_\_\_\_\_ 3MS\_State 2
- B) "What County (City/Shire) are we in?" \_\_\_\_\_ 3MS\_Cntry 1
- C) "What Town/City (Suburb/Town) are we in?" \_\_\_\_\_ 3MS\_City 1
- D) "Are we in a medical clinic or office building\* or home?" \_\_\_\_\_ 3MS\_Place 1  
(\* alternative location)

### 7 Naming body parts (Tick each correct answer)

"Now I am going to point to different parts of my body. As I point to each part, please name that body part." 3MS\_FnChnSh  
Do not wait for the participant to mentally search for the name.  
Score **0** points if the participant cannot name it readily or gives an incorrect name.

Forehead	Chin	Shoulder	(score 1 point for each correct answer)	3
Elbow	Knuckle		(score 1 point for each correct answer)	2

### 8 Recounting as many Four Legged Animals in 30secs as possible

"Name as many animals with four legs as you can."  
Allow **30 seconds** for a response. If the participant gives no response in **10 seconds**, repeat the question once. Score **1** point for each correct response, up to a maximum of ten animals. 3MS\_ElbKnuk 10

Use this space to record responses

3MS\_Animals



3MS\_SimArmkg

9 Understanding similarities between objects

A) "In what way are an arm and a leg alike?" \_\_\_\_\_  
Score 2 points if the participant mentions "body part", or "limb". Score 1 point for a less correct answer.

2

If not a response that scores 2 points, participant should be reminded of the correct answer only for part A.

B) "In what way are laughing and crying alike?" \_\_\_\_\_

3MS\_SimLghCy

Score 2 points if the participant mentions "emotion", or "feeling". Score 1 point for a less correct answer.

2

C) "In what way are eating and sleeping alike?" \_\_\_\_\_

3MS\_SimEatSp

Score 2 points if the participant mentions "essential for life". Score 1 point for a less correct answer.

2



# 3MS Examination

Participant ID

Date of Visit / /   
DD MMM (eg. JAN) YYYY

Participant Acrostic

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Staff ID

## The Modified Mini-Mental State (3MS) Examination

(continued)

Maximum Possible Score Score

### 10 Repetition of spoken sentence *(Use the normal tempo of a spoken sentence. Cross out the missed letter(s)/word(s))*

A) "Repeat what I say, 'I WOULD LIKE TO GO HOME' ". **OR** "Repeat what I say, 'I WOULD LIKE TO GO OUT' ".  
 Use "home" if the participant is not at home, otherwise use "out". 3MS\_RepCrct1 (2)   
 Score 2 points if the participant is accurate. Score 1 point if one or two words are missed or wrong.

B) "Now repeat what I say, 'NO IFS, ANDS OR BUTS.' "*(Cross out the missed letter(s)/word(s))* 3MS\_RepCrct2 (3)   
 For each of the phrases "no ifs", "ands", "or buts": Score 1 point if accurate, score 0 points if the participant misses the "s".

**PLEASE PREPARE PARTICIPANT WITH 3MS WORKSHEET AND A PENCIL BEFORE CONTINUING**

### 11 Reading and Obeying instructions

Tick one only

Hold up the piece of paper (3MS worksheet) on which the command "close your eyes" is printed and say "Please do this". If the participant obeys without prompting, score 3 points.  (3)

If the participant does not close his or her eyes within five seconds, prompt him or her by pointing to the sentence and saying "Read and do what this says". If the participant obeys after prompting, score 2 points.  3MS\_CIEyes1

If the participant has already read the sentence aloud spontaneously, simply say "Do what this says". Allow five seconds for this response. If the participant reads sentence aloud but does not close their eyes, score 1 point.

Participant did not obey at all, score 0 points.

### 12 Write a spoken sentence, 1 minute allowed

3MS\_Write

Ask the participant to write (on worksheet provided) "I would like to go home/out". *(As per section 10)*  
 Repeat the sentence, word by word if necessary, but **allow a maximum of 1 minute** after the first reading of the sentence for the response. Score 1 point for each correct word, up to a max of five. (5)

### 13 Copying Two Pentagons, 1 minute timeframe

On the worksheet provided, **allow 1 minute** for copying.

#### First Pentagon

Pentagon 1

If Pentagon 1 has 5 approximately equal sides, score 4 points. 3MS\_Pentgn1 (4)   
 If Pentagon 1 has 5 unequal (>2:1) sides, score 3 points.  
 If Pentagon 1 resembles an enclosed figure, score 2 points.  
 If Pentagon 1 has 2 or more lines, score 1 point.

#### Second Pentagon

Pentagon 2

If Pentagon 2 has 5 approximately equal sides, score 4 points. 3MS\_Pentgn2 (4)   
 If Pentagon 2 has 5 unequal (>2:1) sides, score 3 points.  
 If Pentagon 2 resembles an enclosed figure, score 2 points.  
 If Pentagon 2 has 2 or more lines, score 1 point.

#### The Intersection of the Pentagons

Intersection

If the intersection is a 4 corner enclosure, score 2 points. 3MS\_Intersectn (2)   
 If the intersection is not a 4-corner enclosure, score 1 point.

### 14 Ability to understand a three stage command

Confirm whether the participant is left or right handed before proceeding.

Hold up a piece of paper in plain view of the participant but out of his or her reach and say, "Take this piece of paper with your (non-dominant) hand, fold it in half and hand it back to me".

After saying the command, hold the paper within reach of the participant. Do not repeat any part of the command. Do not give visual cues.

Tick and score 1 point for each of A-C:

A) Participant takes paper with non-dominant hand...  (3)   
 B) Participant folds paper in half.....   
 C) Participant hands paper back to you .....  3MS\_Paper

OR

D) Did not obey at all..... ... Score 0 points



64694



# 3MS Examination

Date of Visit   /     /

DD                      MMM (eg. JAN)                      YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Participant ID

Participant Acrostic

Staff ID

## The Modified Mini-Mental State (3MS) Examination

(continued)

Maximum Possible Score	Score
------------------------	-------

### 15 Second recall of previous information

"What are the three words that I asked you to remember?"

#### A) AIRPLANE (AEROPLANE)

If spontaneous recall of AIRPLANE (AEROPLANE).....  Tick one only Score 3 points

(If no spontaneous recall, proceed to 1st prompt. If recall is wrong mode of transport, proceed to 2nd prompt)

1st prompt: "A mode of transport" .....  Score 2 points

2nd prompt: "TRAIN, AIRPLANE (AEROPLANE), AUTOMOBILE". (Alternative: SHIP) .....  Score 1 point

If not recalled .....  Score 0 points

③

3MS\_Rcl2Shrt

#### B) BROWN

If spontaneous recall of BROWN .....  Tick one only Score 3 points

(If no spontaneous recall, proceed to 1st prompt. If recall is wrong colour, proceed to 2nd prompt)

1st prompt: "A color" .....  Score 2 points

2nd prompt: "BLUE, BLACK, BROWN". (Alternative: RED) .....  Score 1 point

If not recalled .....  Score 0 points

③

3MS\_Rcl2Brwn

#### C) HONESTY

If spontaneous recall of HONESTY .....  Tick one only Score 3 points

(If no spontaneous recall, proceed to 1st prompt. If recall is wrong personal quality, proceed to 2nd prompt)

1st prompt: "A good personal quality" .....  Score 2 points

2nd prompt "HONESTY, CHARITY, MODESTY". (Alternative: COURAGE) .....  Score 1 point

If not recalled .....  Score 0 points

③

3MS\_Rcl2Hnst

### Confirmation Details

#### Reference to section 1: (Staff to confirm with participant)

Confirmation of Date of birth: Year: \_\_\_\_\_ Month: \_\_\_\_\_ Day: \_\_\_\_\_

Confirmation of Place of birth: Town/City: \_\_\_\_\_ State/Country: \_\_\_\_\_

#### Reference to section 6: (Staff to complete)

State: \_\_\_\_\_ County: \_\_\_\_\_ Town/City: \_\_\_\_\_

Location: Medical Clinic  Office building  Home  Other  \_\_\_\_\_  
(specify)

3MS IS COMPLETE. PLEASE CHECK YOU HAVE FILLED IN THE SCORES WHERE REQUIRED.

3MS\_OverallScore

TOTAL SCORE:

Did any **significant** sensory or motor impairment affect 3MS performance?  Yes  No

If YES: Select all that apply  Visual  Auditory  Motor

Provide details, eg. sections that participant was unable to complete

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS

*This page has been left blank intentionally*



# 3MS Examination

Date of Visit   /    /      
DD MMM (eg. JAN) YYYY

Participant ID

Participant Acrostic

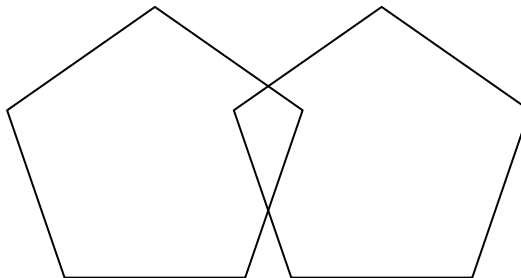
Staff ID

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

# CLOSE YOUR EYES

Write the spoken sentence below

Copy this drawing in the space provided below





## Delayed Recognition Instructions

The Delayed Recognition (Forced Choice) trial is administered immediately after the Delayed Recall trial. Say the following:

**Now I am going to read a longer list of words to you. Some of them are words from the original list, and some are not. After I read each word, I'd like you to say "Yes" if it was on the original list, or "No" if it was not.**

Read the words of the Delayed Recognition trial list in numerical order. Allow the individual as much time as needed to respond. You may use the prompt, "**Was hail on the list? Yes or no?**" The individual must give you a response for every word. If the individual is not sure, ask for a guess.

Delayed Recognition (Forced Choice)							
1. HAIL	Y N	7. window	Y N	13. HERRING	Y N	19. SHARK	Y N
2. bass	Y N	8. CEILING	Y N	14. SALMON	Y N	20. hurricane	Y N
3. SNOW	Y N	9. canyon	Y N	15. tornado	Y N	21. elbow	Y N
4. bank	Y N	10. RAIN	Y N	16. trout	Y N	22. CATFISH	Y N
5. FLOOR	Y N	11. ladder	Y N	17. melon	Y N	23. WALL	Y N
6. mustard	Y N	12. STORM	Y N	18. ROOF	Y N	24. door	Y N

HVLTRec1

Total number of true-positive responses ("hits"): \_\_\_\_\_ /12 (no shading)

Semantically-related false-positive errors: \_\_\_\_\_ /6 (light shading)

Semantically-unrelated false-positive errors: \_\_\_\_\_ /6 (darker shading)

Total number of false-positive errors: HVLTRec2 /12

	Raw score	T score
<b>Total Recall</b> (sum of total correct responses for Trials 1, 2, & 3)		
<b>Delayed Recall</b> (Trial 4)		
<b>Retention (%)</b> [(Trial 4 ÷ Higher score of Trials 2 and 3) x 100]		
<b>Recognition Discrimination Index</b> (Total no. of true-positives) – (Total no. of false-positives)		

Normative table (Appendix A): \_\_\_\_\_

# SDMT



Date of Visit:   /    /

DD                      MMM (eg. JAN)                      YYYY

Participant ID

Participant Acrostic

Staff ID

Please indicate year of Visit:  Visit 2 Assessments     Year 1     Year 3     Year 5     Year 6

## KEY

Γ	V	∖	-	/	∩	×	∩	∧
1	2	3	4	5	6	7	8	9

Overall score is the sum of all correct digits excluding sample items.  
Correct digits score 1 point.

### Sample Items

Γ	/	V	Γ	∖	∩	V	-	Γ	∩	V	Γ	∩	Γ	V
Sample items note counted - Sample items not counted														

-	∩	Γ	V	/	∩	∖	-	Γ	V	∩	∧	-	∖	∩

-	/	×	∩	Γ	∖	×	-	∩	/	V	∧	∖	-	×

V	-	/	Γ	∩	-	Γ	/	∩	×	∧	∩	∖	∩	-

∧	/	∩	∖	∩	×	-	/	V	∖	×	∧	V	∩	Γ

∩	∧	×	V	∖	∩	-	∧	Γ	×	V	/	∩	∩	-

V	∩	×	∧	∖	×	∩	/	Γ	∧	V	Γ	-	∖	∩

/	V	Γ	∩	-	V	Γ	∩	∧	×	∖	/	-	∩	∧

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_



# CES-D 10

Participant ID

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant Acrostic

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Staff ID



Please indicate year of Questionnaire:

- Year 1  
  Year 2  
  Year 3  
  Year 4  
  Year 5  
  Year 6  
  Year 7

TO BE COMPLETED BY THE PARTICIPANT

BLOCK LETTERS

Cross box like this:

## Center for Epidemiologic Studies Short Depression Scale (CES-D 10)

Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the **past week**.

During the past week...	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	All of the time (5-7 days)
1 I was bothered by things that usually don't bother me	Cesd1 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
2 I had trouble keeping my mind on what I was doing	Cesd2 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
3 I felt depressed	Cesd3 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
4 I felt that everything I did was an effort	Cesd4 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
5 I felt hopeful about the future	Cesd5 <input type="text" value=""/>	<input type="text" value="2"/>	<input type="text" value="1"/>	<input type="text" value="0"/>
6 I felt fearful	Cesd6 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
7 My sleep was restless	Cesd7 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
8 I was happy	Cesd8 <input type="text" value="3"/>	<input type="text" value="2"/>	<input type="text" value="1"/>	<input type="text" value="0"/>
9 I felt lonely	Cesd9 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>
10 I could not "get going"	Cesd10 <input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>

**Thank you for completing the questionnaire. Please hand back to staff.**

CES-D 10 score:

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS

# CES-D 10

Participant ID

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant Acrostic

Staff ID

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.



Please indicate year of Questionnaire:

- Year 1  
  Year 2  
  Year 3  
  Year 4  
  Year 5  
  Year 6  
  Year 7

**TO BE COMPLETED BY STAFF**      **BLOCK LETTERS**      Cross box like this:

The below items are not included in the ASPREE Baseline release

1. Prior to your enrolment in ASPREE, have you ever been **diagnosed** with depression?       YES       NO       Participant declined

*(You may prompt the participant with the year of enrolment from the AVSR)*

Please note, a response is not collected for question 2 if the answer to question 1 is **NO**

2. If the answer to question 1 is **YES**, please ask the participant: Did you receive any of these treatments?
- a) Medication       YES       NO       Participant declined
- b) Psychotherapy or counselling       YES       NO       Participant declined
- c) Other e.g. Electroconvulsive Therapy (ECT)       YES       NO       Participant declined

If the answer to question 2c is **YES**, please specify other treatment \_\_\_\_\_

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS



# Life Disability Form

Participant ID Date of Visit  /  /   
DD MMM (eg. JAN) YYYYParticipant Acrostic Staff ID 

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

Please indicate year of Questionnaire:

- 
- Screening visit
- 
- Year 1
- 
- Year 2
- 
- Year 3
- 
- Year 4
- 
- Year 5
- 
- Year 6

**ASPREE STAFF USE ONLY**

If this is a 6-month follow up to confirm a Katz ADL Loss then tick this box AND the Annual Visit year for which the reassessment is being undertaken (i.e. if it was year 3 then tick Year 3 box above):

 Katz ADL Loss ReassessmentBLOCK LETTERS   Cross box like this: 1 How was the interview completed?    1 By the participant    2 By telephone (InterviewCmp)2 In the past two weeks, have you done any walking outside the home?    1 Yes    0 No    -1 Don't Know / Refused (WalkOutside)

If YES, complete question 3 and question 4.

If NO, go straight to question 5.

3 When you walked in the past two weeks, what is the longest amount of time that you walked without sitting down to rest?

	Less than 10 minutes	10 to 15 minutes	16 to 30 minutes	More than 30 minutes	Don't know / Refused
(WalkTime)	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> -1

4 When you walked in the past two weeks, what is the farthest distance you walked at one time without sitting down to rest?

	Less than ¼ mile (about 2-3 blocks)	¼ to ½ mile (about 3-6 blocks)	More than ½ to 1 mile (about 7-12 blocks)	More than 1 mile (over 12 blocks)	Don't know / Refused
Australian participants: 1 mile = (1.6km)	(<400m)	(400-800m)	(800m-1.6km)	(>1.6km)	
(WalkDistance)	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> -1

5 Because of a health or physical problem, do you have any difficulty walking a distance of one mile, which is about 8 to 12 blocks (or 1.6km)?    1 Yes    0 No    -1 Don't know / Refused (WalkDifficult)6 Could you walk up and down every aisle in a grocery store without sitting down to rest or leaning on a cart?    1 Yes    0 No    -1 Don't know / Refused (WalkGrocery)7 Could you walk ¼ mile, that is about 3-4 blocks (or 400 metres), without sitting down to rest?    1 Yes    0 No    -1 Don't know / Refused (WalkQmile)**During the past month, how much difficulty have you had...**

No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	Don't know refused
---------------	---------------------	-----------------	---------------------	---------------------------	------------------------------	--------------------

8 Walking for a quarter of a mile, which is about 3 or 4 blocks (or 400 metres), because of your health?    1    2    3    4    5    6    -1 (WalkQmileHealth)





# Life Disability Form

Participant ID Date of Visit  /  /   
DD MMM (eg. JAN) YYYYParticipant Acrostic Staff ID 

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

BLOCK LETTERS Cross box like this: 

## During the past month, how much difficulty have you had...

No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	Don't know / refused
---------------	---------------------	-----------------	---------------------	---------------------------	------------------------------	----------------------

9 Walking across a small room because of your health? 1 2 3 4 5 6 -1

Katz1\_Walking

a. Do you usually receive help from **another person** when you walk across a small room?Katz1\_Help 1 Yes 0 No -1 Don't know / Refused

10 Bathing or showering because of your health? 1 2 3 4 5 6 -1

Katz2\_Bathing

a. Do you usually receive help from **another person** when you bathe or shower?Katz2\_Help 1 Yes 0 No -1 Don't know / Refused

11 Moving in and out of a chair or bed because of your health? 1 2 3 4 5 6 -1

Katz3\_Chair

a. Do you usually receive help from **another person** when you move in or out of a chair or bed?Katz3\_Help 1 Yes 0 No -1 Don't know / Refused

12 Using the toilet because of your health? 1 2 3 4 5 6 -1

Katz4\_Toilet

a. Do you usually receive help from **another person** when you use the toilet?Katz4\_Help 1 Yes 0 No -1 Don't know / Refused

13 Dressing yourself because of your health? 1 2 3 4 5 6 -1

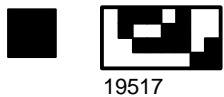
Katz5\_Dressing

a. Do you usually receive help from **another person** when you get dressed?Katz5\_Help  Yes  No  Don't know / Refused

14 Feeding yourself because of your health? 1 2 3 4 5 6 -1

Katz6\_Feeding

a. Do you usually receive help from **another person** when you feed yourself?Katz6\_Help 1 Yes 0 No -1 Don't know / Refused



# Life Disability Form

Participant ID Date of Visit  /  /   
DD / MMM (eg. JAN) / YYYYParticipant Acrostic Staff ID 

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

BLOCK LETTERS Cross box like this: 15 Do you have to use a cane, walker, crutches or special equipment to help you get around?  Yes  No  Don't know / Refused  
*LifeDisabilityWalkAid*

## During the past month, how much difficulty have you had...

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	Don't know refused
16 Doing light housework because of your health? <i>Housework</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17 Walking several blocks because of your health? <i>WalkBlocks</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18 Lifting heavy objects because of your health? <i>Lifting</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19 Preparing your own meals because of your health? <i>PrepMeals</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20 Participating in community activities because of your health? <i>CommunityAct</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 Walking 1 block because of your health? <i>Walk1Block</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22 Lifting or carrying something as heavy as 10 pounds (i.e., a bag of groceries) because of your health? <i>Lift10Pounds</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23 Managing your money because of your health? <i>MngMoney</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24 Visiting with relatives or friends because of your health? <i>Visiting</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25 Gripping with your hands because of your health? <i>Gripping</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26 Using the telephone because of your health? <i>Telephone</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27 Getting in and out of a car because of your health? <i>GetInCar</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28 Taking care of a family member because of your health? <i>FamilyCare</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29 Raising your arms above your head because of your health? <i>RaiseArms</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30 Doing errands because of your health? <i>Errands</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31 Climbing 1 flight of stairs because of your health? <i>ClimbStairs</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS

**Date of Visit:**

□	□	/	□	□	□	/	□	□	□	□
DD			MMM (eg.JAN)				YYYY			

Participant ID: □ □ □ □ □ □

Participant Acrostic: □ □ □ □ □

Staff ID: □ □ □ □

Complete ALL questions. Retain original for the participant file. Record Visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

# Your Health and Well-Being

TO BE COMPLETED BY THE PARTICIPANT

**This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!***

**For each of the following questions, please mark an  in the one box that best describes your answer.**

**Qo1 1. In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
1	2	3	4	5

**2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**

Yes, limited a lot	Yes, limited a little	No, not limited at all
▼	▼	▼

**Qo2** a Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....

1	2	3
1	□	□

Qo13

b Climbing several flights of stairs .....

	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1.....	2	2.....
		3

**Date of Visit:**

		/				/				
DD			MMM (eg.JAN)				YYYY			

**Participant ID:**

**Participant Acrostic:**

**Staff ID:**

Complete ALL questions. Retain original for the participant file. Record Visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

**3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

**Qo14** a Accomplished less than you would like ..... <sub>1</sub> ..... <sub>2</sub> ..... <sub>3</sub> ..... <sub>4</sub> ..... <sub>5</sub>

**Qo15** b Were limited in the kind of work or other activities ..... <sub>1</sub> ..... <sub>2</sub> ..... <sub>3</sub> ..... <sub>4</sub> ..... <sub>5</sub>

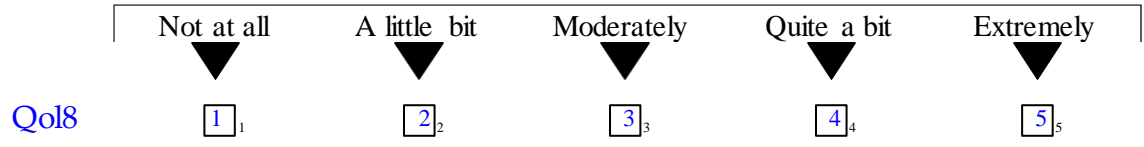
**4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

**Qo16** a Accomplished less than you would like..... <sub>1</sub> ..... <sub>2</sub> ..... <sub>3</sub> ..... <sub>4</sub> ..... <sub>5</sub>

**Qo17** b Did work or other activities less carefully than usual ..... <sub>1</sub> ..... <sub>2</sub> ..... <sub>3</sub> ..... <sub>4</sub> ..... <sub>5</sub>

**5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**



**Date of Visit:**

DD	/				MMM (eg.JAN)	/				YYYY

**Participant ID:**

**Participant Acrostic:**

**Staff ID:**

Complete ALL questions. Retain original for the participant file. Record Visit in participant case notes at GP practice (if applicable) and enter data onto electronic CRF.

**6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

**Qol9** a Have you felt calm and peaceful? ..... <sub>1</sub> ..... <sub>2</sub> ..... <sub>3</sub> ..... <sub>4</sub> ..... <sub>5</sub>

**Qol10** b Did you have a lot of energy? ..... <sub>1</sub> ..... <sub>2</sub> ..... <sub>3</sub> ..... <sub>4</sub> ..... <sub>5</sub>

**Qol11** c Have you felt downhearted and depressed? ..... <sub>1</sub> ..... <sub>2</sub> ..... <sub>3</sub> ..... <sub>4</sub> ..... <sub>5</sub>

**7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

**Qol12** <sub>1</sub> <sub>2</sub> <sub>3</sub> <sub>4</sub> <sub>5</sub>

***Thank you for completing these questions!***

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Print in BLOCK LETTERS



# Annual Visit (Years 1, 3 & 5)

Participant ID

Participant Acrostic

Staff ID

Date of Visit   /    /

DD                      MMM (eg. JAN)                      YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

Please indicate year of Annual Visit:  Year 1     Year 3     Year 5

## 1. Annual Visit Conduct

**BLOCK LETTERS** Cross box like this:

**(AUS Only) 1.1** Has the participant been re-consented?  Yes     No     Refused

If Yes, what version of the consent form has the participant signed?    Version #

**1.2** How was the Annual Visit conducted? **Conduct**

**SECTION H1**

(Refer to checklist on page 4 to see what information should be collected)

- In person
- Information obtained by telephone/mail from participant (& Medical Records)
- Information obtained through medical records ONLY

**(AUS Only)** Has the participant been to the practice since the last ASPREE Study visit?  Yes     No

If YES, date of last GP visit:   /    /

## 2. Living Situation

Do you currently live: (please select one only) **Live**

**SECTION A1**

- At home alone                       In a nursing home
- At home with family, friends or a spouse     In a Residential home (supervised care or assisted living)

Not Collected

## 3. Smoking Status

Do you currently smoke?  Yes     No **SmkStatus**

**SECTION A2**

If **YES**, average number of cigarettes/cigars/pipes a day:   **SmkNo**

Not Collected

If **NO**, have you stopped since your previous visit?  Yes     No **SmkStatusNo**

## 4. Alcohol use **AlcDrinker**

**4.1** Do you currently drink alcohol?  Yes     No

Not Collected

**4.2** If current drinker then:

**AlcDays**

**4.2a** How often do you usually drink alcohol (please select one only)

- < once per week     1-2 days per week     3-4 days per week     5-6 days per week     every day

**AlcNo**

**4.2b** On a day that you drink alcohol, how many standard drinks\* would you usually have? (please select one only)

- 1-2 drinks     3-4 drinks     5-8 drinks     9-12 drinks     13-20 drinks     > 20 drinks

**AlcWknd**

**4.2c** Do you drink more on the weekends?  Yes     No

**AUS** \* One standard drink is defined as one pot/half a pint (285ml) of full strength (4.8%) beer OR one 30ml shot of 40% strength spirit. Alternatively, a standard bar/pub wine-glass serve (150ml) of 12.5% strength wine is 1.5 standard drinks

**US**\* One standard drink is defined as one 12oz can or bottle of beer, one 6oz glass of wine, one shot of liquor.



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# Annual Visit (Years 1, 3 & 5)

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant ID

Participant Acrostic

Staff ID

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

## 5. Blood Pressure & Heart Rate

SECTION B2

5.1 a 1st BP: SBP  /  DBP   
mmHg mmHg  Participant declined

5.1 d Mean Blood Pressure:

5.1 b 2nd BP: SBP  /  DBP   
mmHg mmHg  Participant declined  
SBP3 DB3

SBP  /  DBP   
mmHg mmHg  
SBP\_Mean DBP\_Mean

5.1 c 3rd BP: SBP  /  DBP   
mmHg mmHg  Participant declined

5.2 a 1st HR:  HR1  HR1Manual Manual  Participant declined

5.2 b 2nd HR:  HR2  HR2Manual Manual  Participant declined

5.2 d Mean Heart Rate:

5.2 c 3rd HR:  HR3 Manual  Participant declined

5.3 Was there an irregular heartrate on any BP measurement?  1 Yes  0 No IrregularHB

## 6. Physical Measurements

6.1 Weight  Kg  Participant declined **Wt**  
6.2 Abdominal circumference  cm  Participant declined **AC**  
6.3 Height  m  Participant declined **Ht**

Participant declined

Participant declined

(Year 5 ONLY)

Participant declined

## 7. CES-D 10

Complete the CES-D 10  Participant declined

## 8. 3MS

Complete the 3MS  Participant declined

## 9. Controlled Oral Word Association Test (COWAT)

Complete the COWAT  Participant declined

Staff ID

(For sections 9, 10 & 13: Complete Staff ID if different from the above)

## 10. Hopkins Verbal Learning Test - Revised (HVLT-R)

a) Complete the HVLT-R Recall (Trials 1-3)  Participant declined

b) Complete the HVLT-R Delayed Recall (Trial 4) & Delayed Recognition  Participant declined

## 11. LIFE Questionnaire

Complete the LIFE Questionnaire  Complete the SF-12 Health Survey

## 12. SF-12

13. Symbol Digit

Modalities Test

**(SDMT)**

Complete the SDMT

Participant declined

**14. Release of Medical Records**

Ask the participant to re-sign the **Release of Medical Records** consent form

Participant declined

Participant declined

Participant declined

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**REFER TO THE ANNUAL VISIT SUMMARY REPORT (AVSR)**

15. (AUS Only) Update the **Participant Contact Details** on the AVSR  Yes  No (No change)  Participant declined  
(US Only) Update Participant Contact Details in local file

16. Complete section **3.1a and b Review of Notified AEs/Endpoints** on the AVSR (Page 1-3 of the PMHU)  Yes  No (No events)  Participant declined

17. Complete section **3.1c Participant Recent Medical Screening Tests** on the AVSR (Page 4 of the PMHU)  Yes  Participant declined

18. Complete section **3.2 Family Cancer History Update** on the AVSR  Yes  No (No events)  Participant declined

19. Update the **Concomitant Medications** section on the AVSR  Yes  No (No change)  Participant declined

**20. Study Medication**

20.1 Update the **Study Drug Log** section on the AVSR

20.2 Has study medication been dispensed?  Yes  No

**21. Pathology Results**

Refer to Pathology Window on the AVSR (page 1)

Has the participant's pathology been requested?  Yes  No (All Hx pathology <6 months obtained from Practice)

(AUS Only) If YES, complete 21.1 and 21.2:

21.1 Biomarkers requested:  All routine pathology

OR

Chol, Trig, HDL, LDL:  Use historical data  Requested  GP refused to request

Creatinine:  Use historical data  Requested  GP refused to request

Glucose:  Use historical data  Requested  GP refused to request

Hb:  Use historical data  Requested

uACR:  Use historical data  Requested  GP refused to request

21.2 Pathology Provider:

<input type="checkbox"/> Melbourne Pathology	<input type="checkbox"/> Dorevitch	<input type="checkbox"/> St Vincent's	<input type="checkbox"/> Healthscope
<input type="checkbox"/> St John's of God	<input type="checkbox"/> Gippsland Pathology	<input type="checkbox"/> Launceston Pathology	<input type="checkbox"/> NW Pathology
<input type="checkbox"/> Hobart Pathology	<input type="checkbox"/> Yarra Ranges Pathology	<input type="checkbox"/> Cabrini	<input type="checkbox"/> Capital Pathology
<input type="checkbox"/> ACT Pathology	<input type="checkbox"/> Austin Health	<input type="checkbox"/> Bendigo Health	<input type="checkbox"/> Pathcare
<input type="checkbox"/> IMVS	<input type="checkbox"/> Adelaide Pathology	<input type="checkbox"/> Border Pathology	<input type="checkbox"/> Pathology One
<input type="checkbox"/> Goulburn Valley Health	<input type="checkbox"/> Southern IML	<input type="checkbox"/> Other	<input type="text"/>

Specify

**NOTE: At end of Annual Visit:**  
**Remember to check participant's medical records for**  
**- Supporting documents regarding self-reported ENDPOINTS**  
**- Any other ENDPOINTS NOT previously reported (and supporting documents)**

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_



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# Annual Visit (Years 1, 3 & 5)

Participant ID

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant Acrostic

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

Staff ID



## Checklist (Years 1, 3 & 5)

**Table 1: Sections to complete on Annual Visit source document according to how the Annual Visit was conducted:**

- 1 – In person: See below
- 2 – Phone Calls/Mail (+ Medical Records): See below
- 3 – Medical Records Access only: See below

<u>Key</u>	
✓	<b>Complete (mandatory field)</b>
(✓)	Complete <i>if possible</i>
N/A	Not Applicable

Section No. (Annual Visit CRF)	1 – In person	2 – Phone Calls/Mail (plus Medical Records)	3 – Medical Records Access only
1. Annual Visit Conduct	✓	✓	✓
2. Living Situation	✓	✓	N/A
3. Smoking Status	✓	✓	N/A
4. Alcohol Use	✓	✓	N/A
5. BP & Heart Rate	✓	N/A	N/A
6. Physical Measurements 6.1 Weight 6.2 Abd. Circumference 6.3 Height	✓ ✓ (Year 5 ONLY)	} N/A	} N/A
7. CES-D	✓	(✓) <b>by mail</b>	N/A
8. 3MS	✓	N/A	N/A
9. COWAT	✓	N/A	N/A
10. HVLT-R	✓	N/A	N/A
11. LIFE Disability	✓	✓ <b>by phone</b> [US: (✓) <b>by phone/mail</b> ]	N/A
12. SF-12	✓	(✓) <b>by mail</b>	N/A
13. SDMT	✓	N/A	N/A
14. Release of Medical Records consent form	✓	(✓) <b>by mail</b>	N/A
15. Participant Contact Details (AVSR)	✓	✓	✓
16. Review of Notified AEs/Endpoints (AVSR)	✓	✓	✓
17. Participants Recent Medical Screening Tests (AVSR)	✓	✓	N/A
18. Family Cancer History Update (AVSR)	✓	✓	N/A
19. Con Meds (AVSR)	✓	✓	✓
20. Study Medication	✓	✓ Complete re: study drug retrieved ( <i>at first Annual Visit following cessation</i> ) → N/A thereafter	✓ Complete re: study drug retrieved ( <i>at first Annual Visit following cessation</i> ) → N/A thereafter
21. Pathology	✓	(✓) ( <i>via med. records – within Pathology Window (AVSR)</i> )	(✓) ( <i>within Pathology Window (AVSR)</i> )

**Table 2: Minimum supporting documentation required for each ASPREE Endpoint**

Primary Endpoint	Supporting Documents
<b>Death</b>	ACAS Assessment Report ( <i>AUS only</i> )
	Death Certificate
	Discharge Summary
	ECG
	Imaging Report
	Operation Report
	Pathology
	Specialist Letter
<b>Dementia</b>	Transfusion Record
	ACAS Assessment Report ( <i>AUS only</i> )
	Dementia Assessment Report
	DSM-IV
	Imaging Report (CT/MRI of brain)
	Pathology (e.g. FBE, LFTs, TSH, B12, Folate, Syphilis)
	Specialist Letter
<b>IF the participant CANNOT name a specialist but reports speaking to their GP:</b> GP progress notes	
<b>Physical Disability</b>	ACAS Assessment Report ( <i>AUS only</i> )

Secondary Endpoint	Supporting Documents
<b>Cancer</b>	Pathology (histopathology of tumour)
	Specialist Letter
<b>Clinical Significant Bleeding</b>	Discharge Summary
	Operation Report
	Transfusion Record
	<b>IF the participant DENIES going to hospital:</b> GP progress notes
<b>Hospitalisation for Depression</b>	Discharge Summary
<b>Hospitalisation for Heart Failure</b>	Discharge Summary
	Imaging Report (Echo of heart)
<b>Hospitalisation for Other Reason</b>	Discharge Summary
<b>Fracture</b>	Discharge Summary
	GP progress note for the fracture assessment
	Imaging (X-Ray, CT, MRI of fracture)
<b>Myocardial Infarction</b>	Discharge Summary
	ECG
	Imaging Report (X-Ray of chest)
	Operation Report
	Pathology (Troponin)
	<b>IF the participant DENIES going to hospital:</b> GP progress notes
<b>Stroke</b>	Discharge Summary
	ECG
	Imaging Report (CT/MRI of brain)
	<b>IF the participant DENIES going to hospital:</b> GP progress notes



# Annual Visit (Years 2, 4 & 6)

SubjectID

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant ID

Participant Acrostic

Staff ID

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

Please indicate year of Annual Visit:  Year 2  Year 4  Year 6

## 1. Annual Visit Conduct

**BLOCK LETTERS** Cross box like this:

**(AUS Only) 1.1** Has the participant been re-consented?  Yes  No  Refused

If Yes, what version of the consent form has the participant signed? Version #

**1.2** How was the Annual Visit conducted? **Conduct**

**SECTION H1**

(Refer to checklist on page 4 to see what information should be collected)

- In person
- Information obtained by telephone/mail from participant (& Medical Records)
- Information obtained through medical records ONLY

**(AUS Only)** Has the participant been to the practice since the last ASPREE Study visit?  Yes  No

If YES, date of last GP visit:  /  /

**2. Living Situation** Do you currently live: (please select one only) **Live**

**SECTION A1**

- At home alone  In a nursing home  Not Collected
- At home with family, friends or a spouse  In a Residential home (supervised care or assisted living)

**3. Smoking Status** Do you currently smoke?  Yes  No **SmkStatus**

**SECTION A2**

If **YES**, average number of cigarettes/cigars/pipes a day:  **SmkNo**

If **NO**, have you stopped since your previous visit?  Yes  No **SmkStatusNo**  Not Collected

**4. Alcohol use** **AlcDrinker**

**4.1** Do you currently drink alcohol?  Yes  No  Not Collected

**4.2** If current drinker then:

**AlcDays**

- 4.2a** How often do you usually drink alcohol (please select one only)
- < once per week  1-2 days per week  3-4 days per week  5-6 days per week  every day

**AlcNo**

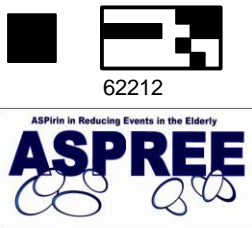
- 4.2b** On a day that you drink alcohol, how many standard drinks\* would you usually have? (please select one only)
- 1-2 drinks  3-4 drinks  5-8 drinks  9-12 drinks  13-20 drinks  > 20 drinks

**Alcwknd**

**4.2c** Do you drink more on the weekends?  Yes  No

**AUS** \* One standard drink is defined as one pot/half a pint (285ml) of full strength (4.8%) beer OR one 30ml shot of 40% strength spirit. Alternatively, a standard bar/pub wine-glass serve (150ml) of 12.5% strength wine is 1.5 standard drinks

**US**\* One standard drink is defined as one 12oz can or bottle of beer, one 6oz glass of wine, one shot of liquor.



# Annual Visit (Years 2, 4 & 6)

Participant ID

Participant Acrostic

Staff ID

Date of Visit  /  /

DD MMM (eg. JAN) YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

## 5. Blood Pressure & Heart Rate

SECTION B2

5.1 a 1st BP: SBP  /  DBP   Participant declined

5.1 b 2nd BP: SBP  /  DBP   Participant declined

SBP1 DBP1  
SBP2 DBP2

~~5.1 c 3rd BP: SBP  /  DBP   Participant declined~~

~~SBP3 DBP3~~

5.2 a 1st HR:   Manual  Participant declined

HR1 HR1Manual

5.2 b 2nd HR:   Manual  Participant declined

HR2 HR2Manual

~~5.2 c 3rd HR:   Manual  Participant declined~~

~~HR3 HR3Manual~~

5.1 d Mean Blood Pressure:

SBP  /  DBP

mmHg SBP Mean DBP Mean

5.2 d Mean Heart Rate:

HR\_Mean

5.3 Was there an irregular heartrate on any BP measurement?  1 Yes  0 No IrregularHB

## 6. Physical Measurements

6.1  Wt  Kg  AC  cm

Participant declined

Participant declined

## 7. Physical Performance

SECTION D1

7.1 Grip Strength Test  Dynamometer Unit Number

RIGHT Hand RightGrip1 RightGrip2 RightGrip3

7.1 a Grip Strength  Kg Test 1 (RH) 7.1 b Grip Strength  Kg Test 2 (RH) 7.1c Grip Strength  Kg Test 3 (RH)  Participant declined (RH)

LEFT Hand LeftGrip1 LeftGrip2 LeftGrip3

7.1 d Grip Strength  Kg Test 1 (LH) 7.1e Grip Strength  Kg Test 2 (LH) 7.1f Grip Strength  Kg Test 3 (LH)  Participant declined (LH)

7.2 Gait Speed Test

7.2 a Gait Speed Test 1  Gait1  secs  Participant declined (Test 1)

7.2 b Gait Speed Test 2  Gait2  secs  Participant declined (Test 2)

7.2 c Identify if any item was used as an aid during the execution of the Gait Speed Test:  1 None  2 Cane  3 Walking frame  4 Other

GaitWalkAid

Specify:

8. LIFE Questionnaire Complete the LIFE Questionnaire  Participant declined

9. SF-12 Complete the SF-12 Health Survey  Participant declined

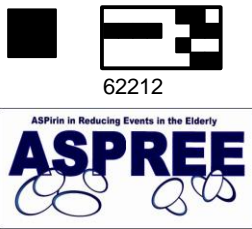
## 10. Release of Medical Records

Ask the participant to re-sign the **Release of Medical Records** consent form

Participant declined

## 11. CESD-10 Complete the CESD-10

Participant declined



# Annual Visit (Years 2, 4 & 6)

Participant ID

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant Acrostic

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

Staff ID

## REFER TO THE ANNUAL VISIT SUMMARY REPORT (AVSR)

**12. (AUS Only)** Update the **Participant Contact Details** on the AVSR  Yes  No (No change)  Participant declined  
**(US Only)** Update Participant Contact Details in local file

**13.** Complete section **3.1a and b Review of Notified AEs/Endpoints** on the AVSR (Page 1-3 of the PMHU)  Yes  No (No events)  Participant declined

**14.** Complete section **3.1c Participant Recent Medical Screening Tests** on the AVSR (Page 4 of the PMHU)  Yes  Participant declined

**15.** Complete section **3.2 Family Cancer History Update** on the AVSR  Yes  No (No events)  Participant declined

**16.** Complete the **Concomitant Medications** section on the AVSR  Yes  No (No change)  Participant declined

### 17. Study Medication

17.1 Update the **Study Drug Log** section on the AVSR

17.2 Has study medication been dispensed?  Yes  No

### 18. Pathology Results

Refer to Pathology Window on the AVSR (page 1)

Has the participant's pathology been requested?  Yes  No (All Hx pathology <6 months obtained from Practice)

**(AUS Only)** If **YES**, complete **18.1** and **18.2**:

18.1 Biomarkers requested:  All routine pathology  
 OR

Chol, Trig, HDL, LDL:	<input type="checkbox"/> Use historical data	<input type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request
Creatinine:	<input type="checkbox"/> Use historical data	<input type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request
Glucose:	<input type="checkbox"/> Use historical data	<input type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request
Hb:	<input type="checkbox"/> Use historical data	<input type="checkbox"/> Requested	
uACR:	<input type="checkbox"/> Use historical data	<input type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request

18.2 Pathology Provider:

<input type="checkbox"/> Melbourne Pathology	<input type="checkbox"/> Dorevitch	<input type="checkbox"/> St Vincent's	<input type="checkbox"/> Healthscope
<input type="checkbox"/> St John's of God	<input type="checkbox"/> Gippsland Pathology	<input type="checkbox"/> Launceston Pathology	<input type="checkbox"/> NWP Pathology
<input type="checkbox"/> Hobart Pathology	<input type="checkbox"/> Yarra Ranges Pathology	<input type="checkbox"/> Cabrini	<input type="checkbox"/> Capital Pathology
<input type="checkbox"/> ACT Pathology	<input type="checkbox"/> Austin Health	<input type="checkbox"/> Bendigo Health	<input type="checkbox"/> Pathcare
<input type="checkbox"/> IMVS	<input type="checkbox"/> Adelaide Pathology	<input type="checkbox"/> Border Pathology	<input type="checkbox"/> Pathology One
<input type="checkbox"/> Goulburn Valley Health	<input type="checkbox"/> Southern IML	<input type="checkbox"/> Other	<input type="text"/>

Specify

**NOTE: At end of Annual Visit:**  
**Remember to check participant's medical records for**  
 - **Supporting documents regarding self-reported ENDPOINTS**  
 - **Any other ENDPOINTS NOT previously reported (and supporting documents)**

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Checklist (Years 2, 4 & 6)

**Table 1: Sections to complete on Annual Visit source document according to how the Annual Visit was conducted:**

- 1 – In person: See below
- 2 – Phone Calls/Mail (+ Medical Records): See below
- 3 – Medical Records Access only: See below

<u>Key</u>	
✓	<b>Complete (mandatory field)</b>
(✓)	Complete <i>if possible</i>
N/A	Not Applicable

Section No. (Annual Visit CRF)	1 – In person	2 – Phone Calls/Mail (plus Medical Records)	3 – Medical Records Access only
1. Annual Visit Conduct	✓	✓	✓
2. Living Situation	✓	✓	N/A
3. Smoking Status	✓	✓	N/A
4. Alcohol Use	✓	✓	N/A
5. BP & Heart Rate	✓	N/A	N/A
6. Physical Measurements 6.1 Weight 6.2 Abd. Circumference	✓ ✓	} N/A	} N/A
7. Physical Performance 7.1 Grip Strength 7.2 Gait Speed	✓ ✓	} N/A	} N/A
8. LIFE Disability	✓	✓ <b>by phone</b> [US: (✓) <b>by phone/mail</b> ]	N/A
9. SF-12	✓	(✓) <b>by mail</b>	N/A
10. Release of Medical Records consent form	✓	(✓) <b>by mail</b>	N/A
11. Participant Contact Details (AVSR)	✓	✓	✓
12. Review of Notified AEs/Endpoints (AVSR)	✓	✓	✓
13. Participants Recent Medical Screening Tests (AVSR)	✓	✓	N/A
14. Family Cancer History Update (AVSR)	✓	✓	N/A
15. Con Meds (AVSR)	✓	✓	✓
16. Drug Log (AVSR)	✓	✓ Complete re: study drug retrieved ( <i>at first Annual Visit following cessation</i> ) → N/A thereafter	✓ Complete re: study drug retrieved ( <i>at first Annual Visit following cessation</i> ) → N/A thereafter
17. Pathology	✓	(✓) ( <i>via med. records – within Pathology Window (AVSR)</i> )	(✓) ( <i>within Pathology Window (AVSR)</i> )

**Table 2: Minimum supporting documentation required for each ASPREE Endpoint**

Primary Endpoint	Supporting Documents
<b>Death</b>	ACAS Assessment Report ( <i>AUS only</i> )
	Death Certificate
	Discharge Summary
	ECG
	Imaging Report
	Operation Report
	Pathology
	Specialist Letter
	Transfusion Record
<b>Dementia</b>	ACAS Assessment Report ( <i>AUS only</i> )
	Dementia Assessment Report
	DSM-IV
	Imaging Report (CT/MRI of brain)
	Pathology (e.g. FBE, LFTs, TSH, B12, Folate, Syphilis)
	Specialist Letter
	<b>IF the participant CANNOT name a specialist but reports speaking to their GP:</b> GP progress notes
<b>Physical Disability</b>	ACAS Assessment Report ( <i>AUS only</i> )

Secondary Endpoint	Supporting Documents
<b>Cancer</b>	Pathology (histopathology of tumour)
	Specialist Letter
<b>Clinical Significant Bleeding</b>	Discharge Summary
	Operation Report
	Transfusion Record
	<b>IF the participant DENIES going to hospital:</b> GP progress notes
<b>Hospitalisation for Depression</b>	Discharge Summary
<b>Hospitalisation for Heart Failure</b>	Discharge Summary
	Imaging Report (Echo of heart)
<b>Hospitalisation for Other Reason</b>	Discharge Summary
<b>Fracture</b>	Discharge Summary
	GP progress note for the fracture assessment
	Imaging (X-Ray, CT, MRI of fracture)
<b>Myocardial Infarction</b>	Discharge Summary
	ECG
	Imaging Report (X-Ray of chest)
	Operation Report
	Pathology (Troponin)
	<b>IF the participant DENIES going to hospital:</b> GP progress notes
<b>Stroke</b>	Discharge Summary
	ECG
	Imaging Report (CT/MRI of brain)
	<b>IF the participant DENIES going to hospital:</b> GP progress notes



# ASPREE Milestone Visit

Participant ID

Participant Acrostic

Staff ID

Date of Visit   /    /

DD MMM (eg. JAN) YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

Please indicate year of Annual Visit:  Milestone Year VisitTime

<b>1. Annual Visit Conduct</b>	<b>BLOCK LETTERS</b> Cross box like this: <input checked="" type="checkbox"/>
<p><b>(AUS Only) 1.1</b> Has the participant been re-consented? <span style="margin-left: 100px;">Consent</span> <input type="text" value="1"/> Yes <input type="text" value="0"/> No <input type="text" value="-1"/> Refused</p> <p>If Yes, what version of the consent form has the participant signed? <span style="margin-left: 150px;">Version #</span> <input type="text"/> <input type="text"/> <span style="margin-left: 20px;">ConsentVersion</span></p>	
<p><b>1.2</b> How was the Annual Visit conducted? (Refer to checklist on page 4 to see what information should be collected)</p> <p><input type="text" value="0"/> In person <span style="margin-left: 20px;">LevelofCompletion</span></p> <p><input type="text" value="1"/> Information obtained by telephone/mail from participant (&amp; Medical Records)</p> <p><input type="text" value="2"/> Information obtained through medical records ONLY</p> <p style="text-align: right;"><span style="margin-left: 100px;">PracticeVisit</span></p> <p><b>(AUS Only)</b> Has the participant been to the practice since the last ASPREE Study visit? <span style="margin-left: 100px;">PracticeVisitDt</span> <input type="text" value="1"/> Yes <input type="text" value="0"/> No</p> <p>If YES, date of last GP visit: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p>	
<p><b>2. Living Situation</b> Do you currently live: (please select one only) <span style="float: right;"><input type="text" value="-1"/> Not Collected</span></p> <p><input type="text" value="1"/> At home alone <span style="margin-left: 50px;">Live</span> <input type="text" value="4"/> In a nursing home</p> <p><input type="text" value="2"/> At home with family, friends or a spouse <input type="text" value="3"/> In a Residential home (supervised care or assisted living)</p>	
<p><b>3. Smoking Status</b> Do you currently smoke? <span style="margin-left: 20px;">SmkStatus</span> <input type="text" value="1"/> Yes <input type="text" value="0"/> No</p> <p>If YES, average number of cigarettes/cigars/pipes a day: <input type="text"/> <input type="text"/> <span style="margin-left: 20px;">SmokeNo</span> <span style="float: right;"><input type="text" value="-1"/> Not Collected</span></p> <p>If NO, have you stopped since your previous visit? <input type="text" value="1"/> Yes <input type="text" value="0"/> No <span style="margin-left: 20px;">SmkStatusNo</span></p>	
<p><b>4. Alcohol use</b> <span style="margin-left: 100px;">AlcDrinker</span></p> <p><b>4.1</b> Do you currently drink alcohol? <input type="text" value="1"/> Yes <input type="text" value="0"/> No <span style="float: right;"><input type="text" value="-1"/> Not Collected</span></p> <hr/> <p><b>4.2</b> If current drinker then: <span style="margin-left: 20px;">AlcDays</span></p> <p><b>4.2a</b> How often do you usually drink alcohol (please select one only)</p> <p><input type="text" value="1"/> &lt; once per week <input type="text" value="2"/> 1-2 days per week <input type="text" value="3"/> 3-4 days per week <input type="text" value="4"/> 5-6 days per week <input type="text" value="5"/> every day</p> <hr/> <p><b>4.2b</b> On a day that you drink alcohol, how many standard drinks* would you usually have? (please select one only) <span style="margin-left: 20px;">AlcNo</span></p> <p><input type="text" value="1"/> 1-2 drinks <input type="text" value="2"/> 3-4 drinks <input type="text" value="3"/> 5-8 drinks <input type="text" value="4"/> 9-12 drinks <input type="text" value="5"/> 13-20 drinks <input type="text" value="6"/> &gt; 20 drinks</p> <hr/> <p><b>4.2c</b> Do you drink more on the weekends? <input type="text" value="1"/> Yes <input type="text" value="0"/> No <span style="margin-left: 20px;">AlkWknds</span></p>	
<p><b>AUS</b> * One standard drink is defined as one pot/half a pint (285ml) of full strength (4.8%) beer OR one 30ml shot of 40% strength spirit. Alternatively, a standard bar/pub wine-glass serve (150ml) of 12.5% strength wine is 1.5 standard drinks</p> <p><b>US</b>* One standard drink is defined as one 12oz can or bottle of beer, one 6oz glass of wine, one shot of liquor.</p>	



9410



# ASPRE Milestone Visit

Participant ID

Date of Visit  /  /

Participant Acrostic

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

Staff ID

## 5. Blood Pressure & Heart Rate

5.1 a 1st BP: SBP    /    DBP

BPDNC  Participant declined

5.1 d Mean Blood Pressure:

5.1 b 2nd BP: SBP    /    DBP

BP2No  Participant declined  
BP3No

SBP    /    DBP     
SBP\_Mean DBP\_Mean

5.1 c 3rd BP: SBP    /    DBP

Participant declined

5.2 a 1st HR:    Manual

HR1Manual  HRDNC  Participant declined  
HR2Manual  HR2No

5.2 b 2nd HR:    Manual

Participant declined  HR3No

5.2 d Mean Heart Rate:

5.2 c 3rd HR:    Manual

Participant declined

HR\_Mean

5.3 Was there an irregular heart rate on any BP measurement?  1 Yes  0 No IrregularHR

## 6. Physical Measurements

6.1 Weight    Kg  6.2 Abdominal circumference    cm  6.3 Height    cm

WtNo  Participant declined ACNo  Participant declined HtNo  Participant declined

## 7. CES-D 10

Complete the CES-D 10  CESD Participant declined

## 8. 3MS

Complete the 3MS  MMMS Participant declined

## 9. Controlled Oral Word Association Test (COWAT)

Complete the COWAT  SLFT Participant declined

Staff ID

(For sections 9, 10 & 13: Complete Staff ID if different from the above)

## 10. Hopkins Verbal Learning Test - Revised (HVLT-R)

a) Complete the HVLT-R Recall (Trials 1-3)  b) Complete the HVLT-R Delayed Recall (Trial 4) &

Delayed Recognition

HVLTN<sub>0</sub>

Participant declined

Participant declined



9410



# ASPRE Milestone Visit

Participant ID

Date of Visit  /  /   
DD MMM (eg. JAN) YYYY

Participant Acrostic

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

Staff ID

## 11 Physical Performance

### 11.1 Grip Strength Test

unit

Dynamometer Unit Number:

RIGHT Hand

RightGrip1

RightGrip2

RightGrip3

RightGripDNC

11.1 a Grip Strength Test 1 (RH)  Kg

11.1b Grip Strength Test 2 (RH)  Kg

11.1c Grip Strength Test 3 (RH)  Kg

Participant declined (RH)

LEFT Hand

LeftGrip1

LeftGrip2

LeftGrip3

LeftGripDNC

11.1 d Grip Strength Test 1 (LH)  Kg

11.1e Grip Strength Test 2 (LH)  Kg

11.1f Grip Strength Test 3 (LH)  Kg

Participant declined (LH)

### 11.2 Gait Speed

11.2a Gait Speed Test 1  .  secs Gait1

Gait1No  Participant declined (Test 1)

11.2b Gait Speed Test 2  .  secs Gait2

Gait2No  Participant declined (Test 2)

11.2c Identify if any item was used as an aid during the execution of the Gait Speed Test:

1 None  2 Cane  3 Walking frame

4 Other

WalkAid

Specify:

## 12. LIFE Questionnaire

Complete the LIFE Questionnaire

Life

Participant declined

## 13. SF-12

Complete the SF-12 Health Survey

SF12

Participant declined

## 14. Symbol Digit Modalities Test (SDMT)

Complete the SDMT

SDMT

Participant declined

## 15. Release of Medical Records

Ask the participant to re-sign the Release of Medical Records consent form

MedRecConsent

Participant declined

## 16. Milestone Questionnaire

Complete the Milestone Questionnaire

MilestoneQnr

Participant declined

## REFER TO THE ANNUAL VISIT SUMMARY REPORT (AVSR)

17. (AUS Only) Update the Participant Contact Details on the AVSR

(US Only) Update Participant Contact Details in local file

1 Yes  0 No (No change)  -1 Participant declined

18. Complete section 3.1a and b Review of Notified AEs/Endpoints on the AVSR (Page 1-3 of the PMHU)

1 Yes  0 No (No events)  -1 Participant declined



# ASPRE Milestone Visit

Participant ID

Participant Acrostic

Staff ID

Date of Visit   /    /

DD MMM (eg. JAN) YYYY

Complete ALL questions. Retain original for the participant file. Record visit in participant case notes at GP practice (if applicable) and enter onto electronic CRF.

## REFER TO THE ANNUAL VISIT SUMMARY REPORT (AVSR)

**19. Complete section 3.1c Participant Recent Medical Screening Tests** on the AVSR (Page 4 of the PMHU)

PtMedTest

Yes  Participant declined

**20. Complete section 3.2 Family Cancer History Update** on the AVSR

Yes  No (No events)  Participant declined

FamilyHistory

**21. Update the Concomitant Medications** section on the AVSR

ConMed

Yes  No (No change)  Participant declined

### 22. Study Medication

22.1 Update the **Study Drug Log** section on the AVSR  
 22.2 Has study medication been dispensed?

MedDis

Yes  No

### 23. Pathology Results

Refer to Pathology Window on the AVSR (page 1)  
 Has the participant's pathology been requested?

PathSlip

Yes  No (All Hx pathology <6 months obtained from Practice)

**(AUS Only)** If YES, complete 23.1 and 23.2: AllPath

23.1 Biomarkers requested:  All routine pathology  
 OR

Chol	Chol, Trig, HDL, LDL:	<input type="checkbox"/> Use historical data	<input checked="" type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request
Cre	Creatinine:	<input type="checkbox"/> Use historical data	<input checked="" type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request
GLU	Glucose:	<input type="checkbox"/> Use historical data	<input checked="" type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request
Hb	Hb:	<input type="checkbox"/> Use historical data	<input checked="" type="checkbox"/> Requested	
ACR	uACR:	<input type="checkbox"/> Use historical data	<input checked="" type="checkbox"/> Requested	<input type="checkbox"/> GP refused to request

23.2 Pathology Provider:

- |   |   |   |  |
|---|---|---|--|
| <input checked="" type="checkbox"/> Melbourne Pathology | <input type="checkbox"/> Dorevitch              | <input type="checkbox"/> St Vincent's         | <input type="checkbox"/> Healthscope       |
| <input type="checkbox"/> St John's of God               | <input type="checkbox"/> Gippsland Pathology    | <input type="checkbox"/> Launceston Pathology | <input type="checkbox"/> NWP Pathology     |
| <input type="checkbox"/> Hobart Pathology               | <input type="checkbox"/> Yarra Ranges Pathology | <input type="checkbox"/> Cabrini              | <input type="checkbox"/> Capital Pathology |
| <input type="checkbox"/> ACT Pathology                  | <input type="checkbox"/> Austin Health          | <input type="checkbox"/> Bendigo Health       | <input type="checkbox"/> Pathcare          |
| <input type="checkbox"/> IMVS                           | <input type="checkbox"/> Adelaide Pathology     | <input type="checkbox"/> Border Pathology     | <input type="checkbox"/> Pathology One     |
| <input type="checkbox"/> Goulburn Valley Health         | <input type="checkbox"/> Southern IML           | <input type="checkbox"/> Other                | <input type="text"/> pathProviderOth       |

Specify

**NOTE: At end of Annual Visit:**  
 Remember to check participant's medical records for  
 - Supporting documents regarding self-reported ENDPOINTS  
 - Any other ENDPOINTS NOT previously reported (and supporting documents)

Please close out any historical pathology and endpoint reports at the time of the record review

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Checklist (Milestone Year)

**Table 1: Sections to complete on Annual Visit source document according to how the Annual Visit was conducted:**

- 1 – In person: See below
- 2 – Phone Calls/Mail (+ Medical Records): See below
- 3 – Medical Records Access only: See below

<u>Key</u>	
✓	<b>Complete (mandatory field)</b>
(✓)	Complete <i>if possible</i>
N/A	Not Applicable

Section No. (Annual Visit CRF)	1 – In person	2 – Phone Calls/Mail (+ Medical Records)	3 – Medical Records Access only
1. Annual Visit Conduct	✓	✓	✓
2. Living Situation	✓	✓	N/A
3. Smoking Status	✓	✓	N/A
4. Alcohol Use	✓	✓	N/A
5. BP & Heart Rate	✓	N/A	N/A
6. Physical Measurements 6.1 Weight 6.2 Abd. Circumference 6.3 Height	✓ ✓ ✓	} N/A	} N/A
7. CES-D10	✓	(✓) <u>by mail</u>	N/A
8. 3MS	✓	N/A	N/A
9. COWAT	✓	N/A	N/A
10. HVLTR	✓	N/A	N/A
11. Physical Performance 11.1 Grip Strength 11.2 Gait Speed	✓ ✓	} N/A	} N/A
12. LIFE Disability	✓	(✓) <u>by phone</u> [ US: (✓) <u>by phone/mail</u> ]	N/A
13. SF-12	✓	(✓) <u>by mail</u>	N/A
14. SDMT	✓	N/A	N/A
15. Milestone Questionnaire	✓	(✓) <u>by phone</u>	N/A
16. Release of Medical Records Consent Form	✓	(✓) <u>by mail</u>	N/A
17. Participant Contact Details	✓	✓	✓
18. Review of Notified AEs/Endpoints (AVSR)	✓	✓	✓
19. Participants Recent Medical Screening Tests (AVSR)	✓	✓	N/A
20. Family Cancer History Update (AVSR)	✓	✓	N/A
21. Con Meds (AVSR)	✓	✓	✓
22. Study Medication	✓	✓ Complete re: Study drug retrieved (at first AV following cessation) → N/A thereafter	✓ Complete re: Study drug retrieved (at first AV following cessation) → N/A thereafter
23. Pathology	✓	(✓) (via Med. Records – within Pathology window (AVSR))	(✓) (via Med. Records – within Pathology window (AVSR))

# Milestone Questionnaire

Date of Assessment   /     /

DD                      MMM (eg. JAN)                      YYYY

Participant ID

Participant Acrostic

Staff ID

1. Over the last 12 months how often have you usually taken your ASPREE medication?  
 0 <1 day/week       1 1-2 days/week       2 3-4 days/week       3 5-6 days/week       4 7 days/week  
[AspreeMedFrequency](#)      **Not applicable: NOT taking ASPREE medication**  -2

2. What time of day do you usually take your ASPREE medication? (please select one only)  
 0 On waking       1 Morning       2 Afternoon       3 Evening (not bedtime)       4 Bedtime  
[AspreeMedIntakeTime](#)      **Not applicable: NOT taking ASPREE medication**  -2

3. What do you think your ASPREE study medication was?  
[AspreeMedType](#)      **Aspirin**  1      **Placebo**  2      **Don't know**  -2

4. If you are no longer taking ASPREE study medication, are you now taking aspirin?  
[AspreePostTaken](#)      Yes  1      No  0  
**Not applicable: STILL taking ASPREE medication**  -2

**If YES, you are now taking aspirin:**

4.1 What dosage? (please select one only) [AspreePostTaken\\_Dose](#)  
 1 100mg or less       2 300-325mg       3 500mg or more       -1 Unknown

4.2 How often? (please select one only) [AspreePostTaken\\_Often](#)  
 1 <once per week       2 2-5 days per week       3 ≥6 days per week

4.3 What time of day do you usually take aspirin? (please select one only) [AspreePostTaken\\_IntakeTime](#)  
 1 On waking       2 Morning       3 Afternoon       4 Evening (not bedtime)       5 Bedtime

4.4 How long have you been taking aspirin? (please select one only) [AspreePostTaken\\_IntakeLength](#)  
 1 <1 year       2 1-2 years       3 3-4 years       4 5-6 years       5 7 years

5. How often do you take prescribed or non-prescribed anti-inflammatory medications? (e.g. Ibuprofen, Naproxen) [MedOften](#)  

	Never	Rarely	Sometimes	Often	Always
		Less than once a month	1-3 times a month	Once a week, or more	Most days
<input type="text"/> 1		<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	<input type="text"/> 5

6. How often do you miss taking any of your prescription medications? [PreMedMissedOften](#)  
 1       2       3       4       5

7. Regarding prescription medications, do you ever take medications that have been prescribed for someone else? [PreMedElseOften](#)  
 1       2       3       4       5

8. Do you get your prescription medicines from more than one pharmacy? [PreMedManyPharm](#)

Yes

1

No

0

# Milestone Questionnaire

Date of Assessment   /    /      
DD MMM (eg. JAN) YYYY

Participant ID          
 Participant Acrostic        
 Staff ID

9. How many **prescription pills** will you take today?

(e.g., For two of the same prescription pill twice per day, please count four)

[PreMedNumPillsToday](#)

- 0    1-3    4-6    7-9    10-12    13-15    16-19    20 or more

10. How many **different types of prescription pills** will you take today?

(e.g., For four of the same prescription pill please count only one)

[NonPreMedNumToday](#)

- 0    1-3    4-6    7-9    10 or more

11. How many **non-prescription or over-the-counter pills** will you take today?

(e.g., For two of the same non-prescription or over-the-counter pills twice per day, please count four)

[NonPreMedNumPillsToday](#)

- 0    1-3    4-6    7-9    10-12    13-15    16-19    20 or more

12. How many **different types of non-prescription or over-the-counter pills** will you take today?

[NonPreMedTypesToday](#)

(e.g., For four of the same non-prescription or over-the-counter pill please count only one)

- 0    1-3    4-6    7-9    10 or more

13. Will you take, or have you taken, any of the following in the past month?

	Yes	No	Please mark one for each	Yes	No
Fish oil <a href="#">FishOil</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0	Vitamin B (including Thiamine) <a href="#">VitB</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Glucosamine <a href="#">Glucosamine</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0	Vitamin C <a href="#">VitC</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Coenzyme Q10 <a href="#">CoenzvmeQ10</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0	Vitamin D <a href="#">VitD</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Zinc supplements	<input type="checkbox"/> 1	<input type="checkbox"/> 0	Vitamin E <a href="#">VitE</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Multivitamin <a href="#">Multivit</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0	Ginkgo Biloba <a href="#">GinBil</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Calcium <a href="#">Calc</a> supplements	<input type="checkbox"/> 1	<input type="checkbox"/> 0	Other supplements, herbal or complementary medicines <a href="#">Other</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Chinese or <a href="#">Chinese_herbal</a> herbal medicines	<input type="checkbox"/> 1	<input type="checkbox"/> 0	Ginseng <a href="#">Ginseng</a>	<input type="checkbox"/> 1	<input type="checkbox"/> 0

14. Would you be willing to consider taking ASPREE study medication [InterestAspreeMed](#) during 2018 until your tablets are revealed as either placebo or aspirin?

Yes  1   No  0

15. Would you be interested in participating in an extension of ASPREE, allowing the study staff to contact you, and collect information about your health?

Yes  1   No  0

[InterestAspreeExt](#)

Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# XT02 VISIT Annual Visit Summary and Checklist (AVSC)

Participant ID: **007159**

Staff ID:

Acrostic: **TSTEZ**

Visit date:   /

**XT02 Visit (due January 2019)**

DD   ( e.g. JAN)

YYYY

Pathology Window: July 2018 - July 2019

Medicare Number: **888 89 99991 - 1**

## VISIT CONDUCT DETAILS

How was the visit conducted

- In person
- Information obtained by telephone/mail from participant (& Medical Records)
- Information obtained through medical records ONLY

**If information obtained through medical records ONLY:**

\$86 2QO\ +DV WKH SDUWFLSDQW EHHQ WR WKH SUDFWLFH VLQFH WKH ODVW \$635(( YLVLW" <HV 1R

If YES, date the last GP/Practice visit: \_\_\_\_/\_\_\_\_/\_\_\_\_

**If conducted in person, (AUS Only) where was this visit conducted? (Not applicable for phone call or MRO visits)**

- At a GP clinic
- At a community venue
- At a clinical trial centre (e.g. ASPREE National Coordinating Centre)
- At the participant's home
- Other location

## PARTICIPANT CONTACT DETAILS (Entered on Pt Contact eCRF)

Please check the details below for each entry and either tick the **Update not required** box OR enter new details in the spaces provided.

**SECTION A1**

### Participant details

Update NOT required

Title: **FATHER**

Surname: **TST**

Firstname: **EZY**

Middle name

Preferred Firstname: **HENRY**

Home Phone: **(03) 9903 0058**

Mobile Phone:

Email:

Residential Address: **GROUND FLOOR, BURNET BUILDING UNKNOWN UNK 9999**

Postal Address: **Same as residential address**

Different postal address?

<HV 1R 3UHIHU QRW WR VDI

If yes:



Mobile Phone:

Email:

Address:

Relationship:

Does the participant want this NOK to receive study information in the event of their death?

<HV 1R 1RW UHTXLUHG YLVLW ZDV 052

**Additional NOK Contact details for someone who DOES NOT LIVE WITH the participant**

Please check the details below for each entry and either tick the **Update not required** box OR enter new details in the spaces provided.

**NOTE: Only complete this section if participant lives alone**

Update NOT required

Title: **MR**

Surname: **EZO**

Firstname: **TST**

Preferred Firstname:

Home Phone:

Mobile Phone: **0416 666 999**

Email:

Address: **8888/8888 TEST STREET ARMADALE  
VIC 3143**

Relationship: **Child**

Does the participant want this NOK to receive study information in the event of their death?

**Yes**

<HV 1R 1RW UHTXLUHG YLVLW ZDV 052

**GP Contact details**

Update NOT required

GP Surname: **UNKNOWN**

GP Firstname: **GP**

Provider No:

Practice Name: **BASS HOUSE SURGERY**

Practice Address: **83 WILMOT ST BURNIE TAS 7320**

If **Participant, NOK and GP contact details** were not completed, please indicate the reason below:

- No - Insufficient time in visit
- No - Participant declined to complete assessment

**CONSENT (Entered via Consent visits)**



Has the 3MS examination been completed? (PREVIOUS DEMENTIA ENDPOINT: No)

- Yes - Completed at visit
- No - insufficient time in visit
- No - participant declined to complete assessment
- No - participant unable to complete assessment (see SOP for details)
- No - Phone call / MRO visit

**COWAT Assessment (Entered on Checklist AND Other Cogs eCRF) - N/A for XT01**

Has the COWAT assessment been completed? (PREVIOUS DEMENTIA ENDPOINT: No)

SECTION C2

_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Score COWAT

If COWAT assessment was not completed, please indicate the reason below:

- No - insufficient time in visit
- No - participant declined to complete assessment
- No - participant unable to complete assessment (see SOP for details)
- No - Phone call / MRO visit

007159 TSTEZ (Male)

DOB: 01 Jan 1940

Practice: BASS HOUSE SURGERY

**SDMT Assessment (Entered on Checklist eCRF) - N/A for XT01**

Has the SDMT assessment been completed? (PREVIOUS DEMENTIA ENDPOINT: No)

- Yes - Completed at visit by participant/staff
- No - insufficient time in visit
- No - participant declined to complete assessment
- No - participant unable to complete assessment (see SOP for details)
- No - Phone call / MRO visit

**Colour Trails Assessment (Entered on Checklist eCRF) - N/A for XT01**

Has the Colour Trails assessment been completed? (PREVIOUS DEMENTIA ENDPOINT: No)

- Yes - Completed at visit by participant/staff
- No - insufficient time in visit
- No - participant declined to complete assessment
- No - participant unable to complete assessment (see SOP for details)
- No - Phone call / MRO visit

**HVLT-R Assessment (Entered on Checklist eCRF) - N/A for XT01**

Has the HVLT-R assessment been completed? (PREVIOUS DEMENTIA ENDPOINT: No)

- Yes - Completed at visit by participant/staff
- No - insufficient time in visit
- No - participant declined to complete assessment
- No - participant unable to complete assessment (see SOP for details)
- No - Phone call / MRO visit

**LIFESTYLE (Entered on Checklist eCRF)**

Has the Lifestyle questionnaire been completed?

- Yes - Complete prior to visit by participant
- Yes - Completed at visit by participant/staff
- Yes - Complete by proxy (see SOP for details)
- No - insufficient time in visit - participant has taken assessment home (or been posted) to complete and mail back
- No - participant declined to complete assessment
- No - MRO visit

**LIFE Disability (Entered on Checklist eCRF)**

Has the LIFE Disability been completed?

- Yes - Complete prior to visit by participant
- Yes - Completed at visit by participant/staff
- Yes - Complete by proxy (see SOP for details)
- No - insufficient time in visit - participant has taken assessment home (or been posted) to complete and mail back
- No - participant declined to complete assessment
- No - MRO visit

007159 TSTEZ (Male)

DOB: 01 Jan 1940

Practice: BASS HOUSE SURGERY

**SF-12 (Entered on Checklist eCRF)**

Has the SF-12 questionnaire been completed?

- Yes - Complete prior to visit by participant
- Yes - Completed at visit by participant/staff
- No - insufficient time in visit - participant has taken assessment home (or been posted) to complete and mail back
- No - participant declined to complete assessment
- No - participant unable to complete assessment (see SOP for details)
- No - MRO visit

**PMHU (Entered on Checklist eCRF)**

Has the PMHU been completed?

- Yes - Complete prior to visit by participant
- Yes - Completed at visit by participant/staff
- Yes - Complete by proxy (see SOP for details)
- No - insufficient time in visit - participant has taken assessment home (or been posted) to complete and mail back
- No - participant declined to complete assessment

**HFOR (Entered on Checklist eCRF)**

Has the HFOR been completed?

- Yes - Complete prior to visit by participant
- Yes - Completed at visit by participant/staff
- Yes - Complete by proxy (see SOP for details)
- No - insufficient time in visit - participant has taken assessment home (or been posted) to complete and mail back
- No - participant declined to complete assessment

**PARTICIPANT RECENT MEDICAL SCREENING (Entered on Checklist eCRF)**

Has the Participant Recent Medical Screening been completed?

- Yes - Complete prior to visit by participant
- Yes - Completed at visit by participant/staff
- Yes - Complete by proxy (see SOP for details)
- No - insufficient time in visit - participant has taken assessment home (or been posted) to complete and mail back
- No - participant declined to complete assessment
- No - MRO visit

**FAMILY CANCER HISTORY UPDATE (Entered on Checklist AND Family History eCRF)**Mother deceased, do not collect dataFather deceased, do not collect data**Siblings - Recent Cancer History**

In the last 12 months, have any siblings been diagnosed with cancer?

Yes  No / Unsure / Adopted 

If yes, complete the following for primary cancer site:

Siblings - Cancer Type

	<50	50+
Bladder		
Blood		
Brain		
Breast		
Cervical		
Colon / Rectum		

	<50	50+
Gallbladder / Bile Ducts		
Kidney		
Liver		
Lung		
Melanoma		
Ovarian / Endometrium		

	<50	50+
Pancreas		
Prostate		
Stomach / Oesophagael		
Thyroid		
Unknown		
Other		
Specify:		

Are your siblings still living?Yes  No / Adopted **Children - Recent Cancer History**

In the last 12 months, have any children been diagnosed with cancer?

Yes  No / Unsure / Adopted 

If yes, complete the following for primary cancer site:

Children - Cancer Type

	<50	50+
Bladder		
Blood		
Brain		
Breast		
Cervical		
Colon / Rectum		

	<50	50+
Gallbladder / Bile Ducts		
Kidney		
Liver		
Lung		
Melanoma		
Ovarian / Endometrium		

	<50	50+
Pancreas		
Prostate		
Stomach / Oesophagael		
Thyroid		
Unknown		
Other		
Specify:		

Are your children still living?Yes  No / Adopted If **Family Cancer History** update was not completed, please indicate the reason below:

- No - Insufficient time in visit
- No - Participant declined to complete assessment
- No - participant unable to complete assessment (see SOP for details)
- No - MRO visit



POWER OF ATTORNEY

Have you appointed someone to make medical treatment decisions for you (e.g. a Medical Enduring Power of Attorney or equivalent)?

<HV 1R

If Yes, are you willing to provide the contact details for this person to ASPREE?

<HV 1R 8QDEOH WR SURYLGH GHWDLOV

If Yes, is this person one of your NOK contacts?

<HV 1R

If Yes, what is his/her name?

767 (=2

If No, please complete details

Update NOT required

Title:

Surname:

Firstname:

Preferred Firstname:

Home Phone:

Mobile Phone:

Email:

Address:

Relationship:

'RHV WKH SDUWLFLSDQW ZDQW KLV KHU 32\$ WR UHFHLYH VWXG\ LQIRUPDWLRQ LQ WKH HYHQW RI WKHLU GHDWK" <HV 1R

If Power of Attorney section was not completed, please indicate the reason below:

- No - Insufficient time in visit
 No - Participant declined to complete assessment
 No - MRO visit

PATHOLOGY (Entered on Pathology eCRF)

Have pathology been requested?

FBE: 5HTXHVVWHG

- 1RW UHTXHVVWHG +LVWRULFDO UHVXOW FROOHFWHG
 1RW UHTXHVVWHG \*3 3&3 3W UHIXVHG WR DXWKRULVH
 1RW UHTXHVVWHG 052 YLVLW

Creatinine 5HTXHVVWHG

- (blood): 1RW UHTXHVVWHG +LVWRULFDO UHVXOW FROOHFWHG
1RW UHTXHVVWHG \*3 3&3 3W UHIXVHG WR DXWKRULVH
1RW UHTXHVVWHG 052 YLVLW

HbA1c: 5HTXHVVWHG

- 1RW UHTXHVVWHG +LVWRULFDO UHVXOW FROOHFWHG
 1RW UHTXHVVWHG \*3 3&3 3W UHIXVHG WR DXWKRULVH
 1RW UHTXHVVWHG 052 YLVLW

Urine ACR: 5HTXHVVWHG

- 1RW UHTXHVVWHG +LVWRULFDO UHVXOW FROOHFWHG
1RW UHTXHVVWHG \*3 3&3 3W UHIXVHG WR DXWKRULVH
1RW UHTXHVVWHG 052 YLVLW

Pathology 0HOERXUQH 3DWKRORJA

'RUHYLWFK

6W 9LQFHQW V

1 : 3DWKRORJA

Provider: 6W -RKQ RI \*RG

\*LSSVODQG 3DWKRORJA

/DXQFHVVWRQ 3DWKRORJA

\$XVWUDOLDQ &QLQLFDO /DEV

+REDUW 3DWKRORJA

&DSLWDO 3DWKRORJA

&DEULQL

\*RXOEXUQ 9DOOH\ +HDOWK

\$&7 3DWKRORJA

\$XVWLQ 3DWKRORJA

%HQGLJR +HDOWK

6RXWKHUQ ,O/

6\$ 3DWKRORJA

\$GHODLGH 3DWKRORJA

%RUGHU 3DWKRORJA

<DUUD 5DQJHV 3DWKRORJA

3DWKFDUH

3DWKRORJA 2QH

%DUUDW 6PLWK

2WKHU BBBB BBBB BBBB

**PHYSICAL TESTS (Entered on Checklist and Physical Tests eCRF)**

SECTION D1

**Grip strength**

**Grip Strength Test RIGHT Hand**

Dynamometer Unit Number:

Grip Strength Test 1 (RH)   Kg  
[RightGrip1](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

Grip Strength Test 2 (RH)   Kg  
[RightGrip2](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

Grip Strength Test 3 (RH)   Kg  
[RightGrip3](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

**Grip Strength Test LEFT Hand**

Grip Strength Test 1 (LH)   Kg  
[LeftGrip1](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

Grip Strength Test 2 (LH)   Kg  
[LeftGrip2](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

Grip Strength Test 3 (LH)   Kg  
[LeftGrip3](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

**Gait speed**

Gait Speed Test 1   .   secs  
[Gait1](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

Gait Speed Test 2   .   secs  
[Gait2](#)

3DUWLFLSDQW GHFOLQHG (TXLSPHQW HUURU ,QVXIILFLHQW WLPH

Identify if any item was used as an aid during the execution of the Gait Speed Test:

- None [GaitWalkAid](#)
- Cane
- Walking frame
- Other (please specify): \_\_\_\_\_

If **Physical Performance tests** were not completed, please indicate the reason below:

- No - Insufficient time in visit
- No - Participant declined to complete assessment
- No - Participant unable to complete assessment (see SOP for details)
- No - Phone call / MRO visit

**END OF DATA COLLECTION**

Staff Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

# ASPREE-XT Color Trails

Participant ID

Participant Acrostic

Date of Assessment  /  /   
DD MMM (eg. JAN) YYYY

Visit Type  X  T

Staff ID

## SECTION C2

**\*\*Note: Only if participant exceeds 4 minutes (240 seconds) BUT completed the trail:**

Color Trails Test	Raw score
Color Trails 1 Time [Stopwatch time: _____]	CT1secs (in secs)
Color Trails 1 Errors	CT1Errs
Color Trails Near-Misses	CT1NM
Color Trails 1 Prompts	CT1Prpts
Color Trails 2 Time [Stopwatch time: _____]	CT2secs (in secs)
Color Trails 2 Color Errors	CT2ColErrs
Color Trails 2 Number Errors	CT2NoErrs
Color Trails 2 Near-Misses	CT2NM
Color Trails 2 Prompts	CT2Prpts

**Color Trails 1**  
 Write total time taken to complete the trail in the stopwatch field.  
  
 Circle reached at 4 minutes (240 sec) mark: \_\_\_\_\_  
 (Record total time and circle reached in visit comments )

**Color Trails 2:**  
 Write total time taken to complete the trail in the stopwatch field.  
  
 Circle reached at 4 minutes (240 sec) mark: \_\_\_\_\_  
 (Record total time and circle reached in visit comments )

Participant refused to complete Color Trails 1\*\*

Participant refused to complete Color Trails 2\*\*

\*\*Note: do not check this box if the participant simply runs out of time (i.e. this is for refusals only).

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Staff Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print in BLOCK LETTERS

# ASPREE-XT LIFE Disability Questionnaire

Participant ID

Participant Acrostic

Visit type  X  T

Date of Visit   /    /

Staff ID

DD MMM (eg. JAN) YYYY

## SECTION E1

PLEASE COMPLETE USING BLOCK LETTERS OR CROSS A BOX LIKE THIS:

1 How was the interview completed?  By the participant  By telephone  By proxy \*This variable is derived, please see data dictionary for categories  
[InterviewCmp\\*](#)

2 In the past **two** weeks, have you done any walking outside the home?  Yes  No  Don't Know / Refused  
[WalkOutside](#)  
If **YES**, complete question 3 and question 4.

If **NO**, go straight to question 5.

3 When you walked in the past two weeks, what is the longest amount of time that you walked without sitting down to rest?  
[WalkTime](#)

Less than 10 minutes	10 to 15 minutes	16 to 30 minutes	More than 30 minutes	Don't know / Refused
<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> -1

4 When you walked in the past two weeks, what is the farthest distance you walked at one time without sitting down to rest?  
[WalkDistance](#)

	Less than ¼ mile (about 2-3 blocks)	1/4 to ½ mile (about 3-6 blocks)	More than 1/2 to 1 mile (about 7-12 blocks)	More than 1 mile (over 12 blocks)	Don't know / Refused
Australian participants: 1 mile = (1.6km)	(<400m)	(400-800m)	(800m-1.6km)	(>1.6km)	
	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> -1

5 Because of a health or physical problem, do you have any difficulty walking a distance of one mile, which is about 8 to 12 blocks (or 1.6km)?  Yes  No  Don't know / Refused  
[WalkDifficult](#)

6 Could you walk up and down every aisle in a grocery store without sitting down to rest or leaning on a cart?  Yes  No  Don't know / Refused  
[WalkGrocery](#)

7 Could you walk ¼ mile, that is about 3-4 blocks (or 400 metres), without sitting down to rest?  Yes  No  Don't know / Refused  
[WalkQmile](#)

During the past month, how much difficulty have you had...

No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	Don't know / refused
---------------	---------------------	-----------------	---------------------	---------------------------	------------------------------	----------------------

8 Walking for a quarter of a mile, which is about 3 or 4 blocks (or 400 metres), because of your health?  1  2  3  4  5  6  -1  
[WalkQmileHealth](#)



# ASPREE-XT LIFE Disability Questionnaire

Participant ID

Visit type

Date of Visit   /     /

DD / MMM (eg. JAN) / YYYY

**BLOCK LETTERS** Cross box like this:

During the past month, how much difficulty have you had...

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	<i>Don't know refused</i>
<b>9</b> Walking across a small room because of your health? <a href="#">Katz1_Walking</a>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**a.** Do you usually receive help from **another person** when you walk across a small room? [Katz1\\_Help](#)

Yes  No  Don't know / Refused

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	<i>Don't know refused</i>
<b>10</b> Bathing or showering because of your health? <a href="#">Katz2_Bathing</a>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**a.** Do you usually receive help from **another person** when you bathe or shower? [Katz2\\_Help](#)

Yes  No  Don't know / Refused

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	<i>Don't know refused</i>
<b>11</b> Moving in and out of a chair or bed because of your health? <a href="#">Katz3_Chair</a>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**a.** Do you usually receive help from **another person** when you move in or out of a chair or bed? [Katz3\\_Help](#)

Yes  No  Don't know / Refused

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	<i>Don't know refused</i>
<b>12</b> Using the toilet because of your health? <a href="#">Katz4_Toilet</a>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**a.** Do you usually receive help from **another person** when you use the toilet? [Katz4\\_Help](#)

Yes  No  Don't know / Refused

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	<i>Don't know refused</i>
<b>13</b> Dressing yourself because of your health? <a href="#">Katz5_Dressing</a>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**a.** Do you usually receive help from **another person** when you get dressed? [Katz5\\_Help](#)

Yes  No  Don't know / Refused

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	<i>Don't know refused</i>
<b>14</b> Feeding yourself because of your health? <a href="#">Katz6_Feeding</a>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**a.** Do you usually receive help from **another person** when you feed yourself? [Katz6\\_Help](#)

Yes  No  Don't know / Refused

**15** Do you have to use a cane, walker, crutches or special equipment to help you get around? [WalkAid](#)

Yes  No  Don't know / Refused

# ASPREE-XT LIFE Disability Questionnaire

Participant ID

Visit type

of Visit Date   /    /

DD                      MMM (eg. JAN)                      YYYY

**BLOCK LETTERS** Cross box like this:

During the past month, how much difficulty have you had...

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to do the activity	Did not do for other reasons	Don't know refused
16 Doing light housework because of your health? <i>Housework</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17 Walking several blocks because of your health? <i>WalkBlocks</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18 Lifting heavy objects because of your health? <i>Lifting</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19 Preparing your own meals because of your health? <i>PrepMeals</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20 Participating in community activities because of your health? <i>CommunityAct</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 Walking 1 block because of your health? <i>Walk1Block</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22 Lifting or carrying something as heavy as 10 pounds (i.e., a bag of groceries) because of your health? <i>Lift10pounds</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23 Managing your money because of your health? <i>MngMoney</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24 Visiting with relatives or friends because of your health? <i>Visiting</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25 Gripping with your hands because of your health? <i>Gripping</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26 Using the telephone because of your health? <i>Telephone</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27 Getting in and out of a car because of your health? <i>GetInCar</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28 Taking care of a family member because of your health? <i>FamilyCare</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29 Raising your arms above your head because of your health? <i>RaiseArms</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30 Doing errands because of your health? <i>Errands</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31 Climbing 1 flight of stairs because of your health? <i>ClimbStairs</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Staff Name: \_\_\_\_\_ Staff Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# ASPREE-XT Lifestyle Questionnaire

Participant ID

Participant Acrostic

Visit type  X  T

Staff ID

**Staff Use Only**

Date of Visit   /    /      
DD MMM (eg. JAN) YYYY

## 1. Assistance

Cross box like this:

1.1 Do you currently require assistance with personal care (e.g. washing, dressing) or meals where you live?

- Yes - Require assistance from someone living with me at home
- Yes - Require assistance from a service or a person who does not live with me at home

(e.g. meals on wheels, district nursing).

**NOTE:** please select this response if you receive assistance from an external service, regardless of whether you also receive assistance from someone living with you at home or not.

- No - I do not require assistance with personal care or meals
- Prefer not to say

## 2. Current aspirin use

**SECTION G3**

2.1 Are you currently taking aspirin?  1 Yes  0 No (go to question 3)  9 Prefer not to say (go to question 3)

If **YES**, please answer the following:

2.1 a What dosage of aspirin do you take per day (total amount)? (please select one only)

- 1 100mg or less (baby dose)  4 150mg  2 300-325mg  3 500mg or more  -1 Unknown  9 Other Dosage

2.1 b How often do you take aspirin? (please select one only)

- 1 One or less per week  2 2-5 days per week  3 6-7 days per week

2.1 c What time of day do you usually take aspirin? (please select one only)

NOTE: if taken at differing times of the day, please select the option that best represents the most frequent time taken overall.

- 1 On waking  2 Morning  3 Afternoon  4 Evening (not bedtime)  5 Bedtime
- 6 Multiple times per day (divided dose)

2.1 d Are you taking aspirin by personal choice or due to a doctor's recommendation? (select one only)

- 1 Personal choice  2 Doctor's recommendation

2.1 e Why do you take aspirin? (select Yes OR No/Unsure for each reason, must select Yes for at least one reason)

- |  |   |
|--|---|
| (i) To prevent heart attacks <input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No/Unsure | (iv) For pain/fever <input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No/Unsure     |
| (ii) To prevent strokes <input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No/Unsure      | (v) For other reason(s) <input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No/Unsure |
| (iii) To prevent cancer <input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No/Unsure      |   |

2.1 f How do you usually take aspirin? (select one only)

- 1 Before meal  2 After (or during) meal  3 Anytime (sometimes before, sometimes after)

**PLEASE TURN OVER**

# ASPREE-XT Lifestyle Questionnaire

Participant ID Visit type  X  T **Staff Use Only**Date of Visit   /    /      
DD MMM (eg. JAN) YYYY

### 3. Smoking status

**SECTION A2****SmkStatus**3.1 Do you currently smoke?  1 Yes  0 No (go to question 4)  -1 Prefer not to say (go to question 4)**SmkNo**If YES, average number of cigarettes/cigars/pipes a day:  

### 4. Alcohol use

**AlcDrinker**4.1 Do you currently drink alcohol?  1 Yes  0 No  -1 Prefer not to say

If YES, current drinker, then:

**AlcDays**

4.1a How often do you usually drink alcohol? (please select one only)

 1 < once per week  2 1-2 days per week  3 3-4 days per week  4 5-6 days/week 5 every day**AlcNo**

4.1b On a day that you drink alcohol, how many standard drinks\* would you usually have? (please select one only)

 1 < 1-2 drinks  2 3-4 drinks  3 5-8 drinks  4 9-12 drinks 5 13-20 drinks  6 > 20 drinks**AlcWknd**4.1c Do you drink more on the weekends?  1 Yes  0 No

**AUS\*** One standard drink is defined as one pot/half a pint (285ml) of full strength (4.8%) beer OR one 30ml shot of 40% strength spirit. Alternatively, a standard bar/pub wine-glass serve (150ml) of 12.5% strength wine is 1.5 standard drinks.

**US\*** One standard drink is defined as one 12oz can or bottle of beer, one 6oz glass of wine, one shot of liquor.

**5. Sleep Questions** - The time at which you go to sleep and the duration of sleep can impact the way your body metabolises medications. The following questions help us to work out your sleep cycle and duration.

5.1 What time do you **usually** fall asleep **in bed** at night? Please indicate the time and circle either AM or PM.

Here is an example of how to record your answer using the time boxes below (two boxes for hours and two boxes for minutes) - if you usually fall asleep in bed at night at 9pm, then record your answer as follows:

  :   AM /  PM  
Hours Minutes  :   AM / PM  
Hours Minutes5.2 What time do you **usually** wake up in the mornings? Please indicate the time and circle either AM or PM.  :   AM / PM  
Hours Minutes**END OF QUESTIONNAIRE - THANK YOU**

Staff Name: \_\_\_\_\_ Staff Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# ASPREE-XT Participant Recent

## Medical Screening Tests

Participant ID Visit type  X  T Participant Acrostic Staff ID 

Staff Use Only

### SECTION B3

**In the past 12 months, have you had any of the following screening tests:**

**For colorectal cancer:** (please tick all that apply)

Sigmoidoscopy.....	<b>Col_Sig</b> <input type="checkbox"/>	Barium enema.....	<b>Col_Bar</b> <input type="checkbox"/>
Colonoscopy.....	<b>Col_Sco</b> <input type="checkbox"/>	Biopsy.....	<b>Col_Bio</b> <input type="checkbox"/>
Virtual colonoscopy (CT colonoscopy)...	<b>Col_Ctc</b> <input type="checkbox"/>	Other test/Unsure.....	<b>Col_Oth</b> <input type="checkbox"/>
Stool based test.....	<input type="checkbox"/>	None of the above.....	<b>Col_None</b> <input type="checkbox"/>

If you have had a stool based test, please specify what type of test:

Fecal occult blood test (FBT).....	<b>Col_Fbt</b> <input type="checkbox"/>	DNA test.....	<b>Col_DNA</b> <input type="checkbox"/>
Fecal immunochemical test (FIT).....	<b>Col_Fit</b> <input type="checkbox"/>	Other test /Unsure.....	<b>Col_Sto</b> <input type="checkbox"/>

**For breast cancer:** (please tick all that apply)

Mammogram.....	<b>Bre_Mam</b> <input type="checkbox"/>	Biopsy.....	<b>Bre_Bio</b> <input type="checkbox"/>
Breast ultrasound.....	<b>Bre_Ult</b> <input type="checkbox"/>	Other test/Unsure.....	<b>Bre_Oth</b> <input type="checkbox"/>
MRI.....	<b>Bre_Mri</b> <input type="checkbox"/>	None of the above.....	<b>Bre_None</b> <input type="checkbox"/>
Physical exam by Healthcare provider. (clinical breast exam)	<b>Bre_Phy</b> <input type="checkbox"/>		

**For cervical cancer:** (please tick all that apply)

Not applicable.....	<input type="checkbox"/>	Biopsy.....	<b>Cer_Bio</b> <input type="checkbox"/>
Pap smear.....	<b>Cer_Pap</b> <input type="checkbox"/>	Other test/Unsure.....	<b>Cer_Oth</b> <input type="checkbox"/>
HPV/Cervical Screen Test (CST).....	<b>Cer_Hpv</b> <input type="checkbox"/>	None of the above.....	<b>Cer_None</b> <input type="checkbox"/>

**For prostate cancer:** (please tick all that apply)

Not applicable.....	<input type="checkbox"/>	Biopsy.....	<b>Pro_Bio</b> <input type="checkbox"/>
PSA (blood test).....	<b>Pro_Ant</b> <input type="checkbox"/>	Other test/Unsure.....	<b>Pro_Oth</b> <input type="checkbox"/>
Physical exam by Healthcare Provider (digital rectal exam)	<b>Pro_Phy</b> <input type="checkbox"/>	None of the above.....	<b>Pro_None</b> <input type="checkbox"/>

**For lung cancer:** (please tick all that apply)

Chest x-ray.....	<b>Lun_Xra</b> <input type="checkbox"/>	Other test/Unsure.....	<b>Lun_Oth</b> <input type="checkbox"/>
Chest CT scan.....	<b>Lun_Cts</b> <input type="checkbox"/>	None of the above.....	<b>Lun_None</b> <input type="checkbox"/>
Biopsy.....	<b>Lun_Bio</b> <input type="checkbox"/>		

**For skin cancer:** (please tick all that apply)

Photographic Mole Check.....	<b>Skn_Ph</b> <input type="checkbox"/>	Other test/Unsure.....	<b>Skn_Oth</b> <input type="checkbox"/>
Physical exam by Healthcare Provider.....	<b>Skn_Phy</b> <input type="checkbox"/>	None of the above.....	<b>Skn_None</b> <input type="checkbox"/>
Biopsy.....	<b>Skn_Bio</b> <input type="checkbox"/>		

Staff Name: \_\_\_\_\_

Staff Signature: \_\_\_\_\_

Date: \_\_\_\_\_



# ASPREE-XT (Aus only) Participant

## Medical History Update

Participant ID Participant Acrostic Visit type  X  T Staff ID **Staff Use Only:** If collected by proxy, complete Part 1 only.

Name (print): \_\_\_\_\_ Date form completed: \_\_\_\_\_

Date of Birth:(Date) \_\_\_\_\_ (Month) \_\_\_\_\_ (Year) \_\_\_\_\_

BLOCK LETTERS Cross box like this: 

### 1a. In the past 6 months, or since we last spoke, have you been diagnosed with, or treated for, **CANCER**?

Part 1

Yes  **\*\* (if 2 different cancer types, please also complete question 1d on next page)** No/Unsure (go to question 2, page 3) **↳ \*\* If Yes: Please specify type by ticking the box:**

Bladder	<input type="checkbox"/>	Oesophagus	<input type="checkbox"/>	Pancreas	<input type="checkbox"/>
Blood*	<input type="checkbox"/>	Gallbladder or bile duct	<input type="checkbox"/>	Prostate	<input type="checkbox"/>
Brain	<input type="checkbox"/>	Kidney	<input type="checkbox"/>	Stomach	<input type="checkbox"/>
Breast	<input type="checkbox"/>	Liver (primary cancer)	<input type="checkbox"/>	Basal Cell Carcinoma (skin)	<input type="checkbox"/>
Cervix	<input type="checkbox"/>	Lung	<input type="checkbox"/>	Squamous Cell Carcinoma	<input type="checkbox"/>
Colon#/Rectum #(bowel)	<input type="checkbox"/>	Melanoma	<input type="checkbox"/>	Thyroid	<input type="checkbox"/>
		Ovary	<input type="checkbox"/>	Uterus (endometrium)	<input type="checkbox"/>

Other (please specify): \_\_\_\_\_

\*e.g. leukemia, myeloma, lymphoma

**\*\* If Yes:** Were you A) hospitalised or did you attend a day centre? Yes  No/Unsure   
B) did you receive treatment at home? Yes  No/Unsure **\*\* If Yes:** Date of hospital admission/attendance^: Month \_\_\_\_\_ Year \_\_\_\_\_

^If you are unsure, please provide an approximate month and year

Name of Hospital/Cancer Day Care Centre: \_\_\_\_\_

Referred to a specialist?: Yes  Name (if known): \_\_\_\_\_ No/Unsure 

### 1b. Is this a **NEW CANCER**? Yes No/Unsure

**If Yes:** How was this cancer diagnosed? Screening  Symptoms  Due to chance **If Yes:** How is your cancer **currently** being managed (tick only one):Active treatment (e.g. surgery, radio/chemo/immunotherapy) Observation (e.g. colonoscopies, CT/MRI scans) Other  No treatment 

### 1c. Is this a cancer that has '**COME BACK**' or **SPREAD**? Yes No/Unsure

**If Yes:** Where has the cancer come back, or spread to:Same location?  The lymph nodes?  Spread to another organ or bone?

## ASPREE-XT (Aus only) Participant

## Medical History Update

Visit type  X  T 

Staff Use Only

**1d. In the past 6 months, or since we last spoke, have you been diagnosed or treated for a SECOND CANCER TYPE?**

Yes  No/Unsure (go to question 2 - page 3)

↳ **\*\* If Yes:** Please specify this cancer type by ticking the box:

Bladder	<input type="checkbox"/>	Oesophagus	<input type="checkbox"/>	Pancreas	<input type="checkbox"/>
Blood*	<input type="checkbox"/>	Gallbladder or bile duct	<input type="checkbox"/>	Prostate	<input type="checkbox"/>
Brain	<input type="checkbox"/>	Kidney	<input type="checkbox"/>	Stomach	<input type="checkbox"/>
Breast	<input type="checkbox"/>	Liver (primary cancer)	<input type="checkbox"/>	Basal Cell Carcinoma (skin)	<input type="checkbox"/>
Cervix	<input type="checkbox"/>	Lung	<input type="checkbox"/>	Squamous Cell Carcinoma	<input type="checkbox"/>
Colon#/Rectum	<input type="checkbox"/>	Melanoma	<input type="checkbox"/>	Thyroid	<input type="checkbox"/>
#(bowel)		Ovary	<input type="checkbox"/>	Uterus (endometrium)	<input type="checkbox"/>

Other (please specify): \_\_\_\_\_

\*e.g. leukemia, myeloma, lymphoma

**\*\*If Yes:** Were you A) hospitalised or did you attend a day centre? Yes  No/Unsure   
 B) did you receive treatment at home? Yes  No/Unsure

**\*\*If Yes:** Date of hospital admission/attendance<sup>^</sup>: Month \_\_\_\_\_ Year \_\_\_\_\_

<sup>^</sup>If you are unsure, please provide an approximate month and year

Name of Hospital/Cancer Day Care Centre: \_\_\_\_\_

Referred to a specialist?: Yes  Name (if known): \_\_\_\_\_ No/Unsure

**1e. Is this a NEW CANCER?**  Yes  No/Unsure

**If Yes:** How was this cancer diagnosed? Screening  Symptoms  Due to chance

**If Yes:** How is your cancer **currently** being managed (tick only one):

Active treatment (e.g. surgery, radio/chemo/immunotherapy)

Observation (e.g. colonoscopies, CT/MRI scans)

Other  No treatment

**If Yes:**  
Where has the cancer come back, or spread to:

**1f. Is this a cancer that has 'COME BACK' or SPREAD?** Yes

No/Unsure

Same location?

The lymph nodes?

Spread to another organ or bone?

## Medical History Update

Staff Use Only

### 2. In the past 6 months, or since we last spoke, have you had major **BLEEDING** episode?

Yes  No/Unsure  (go to question 3)↳ If Yes: Were you hospitalised for this bleeding episode? Yes  No/Unsure If Yes: Date of Hospital Admission<sup>^</sup>: Month \_\_\_\_\_ Year \_\_\_\_\_<sup>^</sup>If you are unsure, please provide an approximate month and yearName of Hospital (if known): \_\_\_\_\_ Did you require a blood transfusion to treat this bleeding? Yes  No/Unsure ~~Did you require surgery to stop this bleeding? Yes  No/Unsure~~ 

### 3. In the past 6 months, or since we last spoke, have you been diagnosed with **DEMENTIA** or **MEMORY AND THINKING PROBLEMS**?

Yes  No/Unsure  (go to question 4)↳ If Yes: Have you spoken to your GP/PCP about this? Yes  No/Unsure   
Have you been referred to a specialist? Yes  No/Unsure If Yes: Name of specialist: \_\_\_\_\_ Name Unknown Date of specialist consultation: Month \_\_\_\_\_ Year \_\_\_\_\_ Have you been referred to CDAMS\* or a memory clinic? Yes  No/Unsure 

If Yes: Name of clinic (if known): \_\_\_\_\_

~~Date of clinic appointment: Month \_\_\_\_\_ Year \_\_\_\_\_~~

\*Cognitive Dementia and Memory Service

### 4. In the past 6 months, or since we last spoke, have you been hospitalised for **DEPRESSION**?

Yes  No/Unsure  (go to question 5)↳ If Yes: Date of Hospital Admission<sup>^</sup>: Month \_\_\_\_\_ Year \_\_\_\_\_

Name of Hospital (if known): \_\_\_\_\_ (If you are unsure, please provide an approximate month and year)

### 5. In the past 6 months, or since we last spoke, have you been hospitalised for **HEART FAILURE**?

Yes  No/Unsure  (go to question 6)↳ If Yes: Date of Hospital Admission<sup>^</sup>: Month \_\_\_\_\_ Year \_\_\_\_\_

If you are unsure, please provide an approximate month and year  
Name of Hospital (if known): \_\_\_\_\_

## Medical History Update

Staff Use Only

Visit type

**6. In the past 6 months, or since we last spoke, have you had a MYOCARDIAL INFARCTION/HEART ATTACK, HEART/CHEST PAIN OR ANGINA?**

Yes  No/Unsure  (go to question 7)

↳ If Yes: Please specify what type of event you had:

Myocardial infarction/Heart attack

Heart/Chest pain

Angina

**Who treated you?**

General practitioner

Specialist (not in a hospital)

Hospital staff (including at the emergency department)

No treatment

**If treated in hospital:**

Name of hospital (if known): \_\_\_\_\_

When were you hospitalised? Month \_\_\_\_\_ Year \_\_\_\_\_

**7. Since we last spoke (past 6 months) have you had a STROKE, MINI-STROKE or TIA\*? Yes  No/Unsure**

↳ If Yes: Please specify what type of event you had:

Stroke  Mini-stroke  TIA (\*Transient ischaemic attack)

**Who treated you?**

General practitioner

Specialist (not in a hospital)

Hospital staff (including at the emergency department)

No treatment

**If treated in hospital:**

Name of Hospital (if known): \_\_\_\_\_

When were you hospitalised? Month \_\_\_\_\_ Year \_\_\_\_\_

**8. In the past 6 months, or since we spoke to you last, have you had an AGED CARE ASSESSMENT (or similar, e.g. MyCare Assessment / 75+ Health Assessment)?**

Yes  No/Unsure

↳ If Yes, were you seen at home

OR, did you need to travel to the appointment?

PLEASE TURN OVER

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X	T		
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## Other New Diagnoses/Health Events

Part 2

**In the past 6 months, or since we last saw or spoke to you, has a doctor diagnosed you with any of the following?**

1. Atrial Fibrillation (AF or irregular pulse)..... Yes No/Unsure

2. Bowel polyp (found at colonoscopy)..... Yes No/Unsure

**(If Yes):** Approximately how many polyps were found (if known)?....

3. Depression (treated but not hospitalised)..... Yes No/Unsure

Name or type of treatment? \_\_\_\_\_ None/Unsure

4. Diabetes..... Yes No/Unsure

5. Fall(s) that did NOT result in a broken bone(s):..... Yes No/Unsure

**If Yes**, did you attend a GP or hospital? .....Yes No/Unsure

6. Fractured or broken bone (whether or not from a fall)..... Yes No/Unsure

**(If Yes):** Did you go to hospital?..... Yes No/Unsure

How was the break managed (regardless of attending hospital or not)?  
Surgery  
Outpatient  
Observation

Which bone(s) did you break/fracture? \_\_\_\_\_

7. Gastro-Oesophageal Reflux Disease (GORD), gastritis or dyspepsia (stomach upset requiring treatment)..... Yes No/Unsure

8. Heart Failure - treated by a doctor ..... Yes No/Unsure

9. Kidney disease (excluding kidney stones, bladder infection or incontinence)..... Yes No/Unsure

**(If Yes):** Have you required dialysis treatment?..... Yes No/Unsure

10. **Minor** bleeding (e.g. nose bleeds, bruising, small amounts of blood in the urine, bowel, vagina or stool (i.e. tarry/black stools)).... Yes No/Unsure

# ASPREE-XT (Aus only) Participant

Participant ID

## Medical History Update

Participant  
Acrostic

Staff ID

Visit type

Staff Use Only: do not collect Part 2 by proxy or via MRR/MRO

11. Osteoarthritis.....Yes No/Unsure

**PLEASE TURN OVER**

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# ASPREE-XT (Aus only) Participant

## Medical History Update

Participant ID

Participant Acrostic

Staff ID

Visit type  X  T

**Staff Use Only:** do not collect Part 2 by proxy or via MRR/MRO

### Other New Diagnoses/Health Events cont'd

Part 2 cont'd

In the past **6 months**, or since we last saw or spoke to you, has a doctor **diagnosed** you with any of the following?

12. Parkinson's disease..... Yes  No/Unsure

13. Ulcer (gastric/duodenal)..... Yes  No/Unsure

14. Osteoporosis (bone density loss, weak bones).....Yes  No/Unsure

15. Episode(s) of diverticulitis requiring antibiotics and/or hospitalisation .....Yes  No/Unsure

If Yes, did you require surgery? .....Yes  No/Unsure

Did you have an abscess (collection of fluid) associated with this/these episode(s) .....Yes  No/Unsure

16. Inflammatory bowel disease (e.g. Crohn's disease, ulcerative, microscopic and other types of colitis, but EXCLUDING Irritable Bowel Syndrome)? .....Yes  No/Unsure

17. Chronic Respiratory Disease (any type?).....Yes  No/Unsure

If Yes, was this a diagnosis of:

- Chronic Obstructive Pulmonary Disease (COPD or emphysema) .....Yes  No/Unsure

- Pulmonary Fibrosis or Interstitial Lung Disease .....Yes  No/Unsure

- Asthma .....Yes  No/Unsure

- Other long-term lung disease (e.g. asbestosis).....Yes  No/Unsure

18. Episode(s) of Urinary tract infection/s which required antibiotics.....Yes  No/Unsure

If Yes, how many episodes have you had?  1  2

3 or more

**END OF QUESTIONNAIRE**



## **Appendix 4: Example Annual Visit Summary Report**

# Annual Visit Summary Report (AVSR)

Milestone visit

## PART 1: PARTICIPANT REGISTRATION DETAILS AND CURRENT STATUS

Review and confirm participant registration details below. If details have changed record the changes below and update the Participant Registration page.

Participant ID: **025478**

Date of Birth:

Site:

Practice:

GP:

Participant Status: **On Study Med**

ASPREE Consent Uploaded: **Yes**

ASPREE Consent Signed: **Version 17 (Monash)**

Biobank Consent Signed: **Yes**

Visit Due Date: **18 Jan 2017**

Pathology Window: **18 Jul 2016 - 18 Jul 2017**

MBS/PBS Consent Form: **Consented - Medicare & PBS**

Review and confirm participant and NOK contact details.

If details have changed record the changes below and update the Participant Registration page.

Title:

Address:

Home Phone:

Email:

Mobile Phone:

Best time to contact:

Medicare Number:

No: 1

### NOK Contact Details

Title:

Address:

Home Phone:

Email:

Mobile Phone:

Relationship: **Sibling**

### Sub-study involvement

Substudy	Action to be taken
Envision	Participant did not take part in Envision. No action.
Biobank	Biobank participant. Follow-up completed. No action.
ACES Sample	DO NOT collect ACES sample
SNORE	Participant did not take part in SNORE. No action.
AMD (RetCam)	AMD (RetCam) participant. F/U visit completed. No action.
Hearing	Participant did not take part in Hearing. No action.
Neuro	Participant did not take part in Neuro. No action.
Knee	Participant did not take part in Knee. No action.

**PART 3: NEW DATA COLLECTION**

Please review sections 3.1-3.3, record data in the appropriate sections and update the corresponding eCRFs for each.

**Section 3.1 Review of Notified AE/Endpoints**3.1a Review of Participant Medical History Update form (PMHU)

Review PMHU with the participant. If it has not been completed prior to the visit please provide a blank form to the participant now for completion. Discuss any questions raised and for any 'Unsure' responses you MUST clarify if these are either 'Yes' or 'No; and update the form (initial and date).

This form will require web entry via the AE/ENDPOINT Report eCRF.

NOTE- Once you have entered this form onto the web you must record the AE/Endpoint Report Form number in the 'Office Use Only' section of the PMHU.

3.1b Review of Communication Log notifications

(No AE were notified on Communication Log)

3.1c Participant Recent Medical Screening Tests

Review Part 3 of the PMHU: Recent Medical Screening Tests. Ensure all questions are answered. This data must be entered on the Participant Med Tests eCRF.

**Section 3.2 Family Cancer History Update****3.2.1 a Mother deceased, do not collect data****3.2.2 a Father deceased, do not collect data****3.2.3 a Siblings - Recent Cancer History**

In the last 12 months, have any siblings been diagnosed with cancer? Yes

No / Unsure / Adopted

If yes, complete the following for primary cancer site:

**3.2.3b Siblings - Cancer Type**

	<50	50+
Bladder		
Blood		
Brain		
Breast		
Cervical		
Colon / Rectum		

	<50	50+
Gallbladder / Bile Ducts		
Kidney		
Liver		
Lung		
Melanoma		
Ovarian / Endometrium		

	<50	50+
Pancreas		
Prostate		
Stomach / Oesophagael		
Thyroid		
Unknow n		
Other		
Specify:		

3.2.3c Are your siblings still living?

Yes

No / Adopted

**3.2.4a Children - Recent Cancer History**

In the last 12 months, have any children been diagnosed with cancer? Yes

No / Unsure / Adopted

If yes, complete the following for primary cancer site:

**3.2.4b Children - Cancer Type**

	<50	50+
Bladder		
Blood		
Brain		
Breast		
Cervical		
Colon / Rectum		

	<50	50+
Gallbladder / Bile Ducts		
Kidney		
Liver		
Lung		
Melanoma		
Ovarian / Endometrium		

	<50	50+
Pancreas		
Prostate		
Stomach / Oesophagael		
Thyroid		
Unknow n		
Other		
Specify:		

3.2.4 c Are your children still living?

Yes

No / Adopted

**Section 3.3 Con-Meds**

The following is a list of all current Con-meds. Please review and update i.e record Year stopped as appropriate and add ALL new prescription meds including SELF REPORTED indication. For existing medications where the indication field is blank confirm indication with the participant at annual visit. If indication is unknown please record this.

NOTE: Remember if aspirin or another anti-thrombotic has been commenced it MUST be entered on the Con-Meds eCRF.

	Drug Trade Name (Or Generic Name)	Year Started	Staff ID	Year Stopped	Staff ID	Indication (Self-reported)
001	lipitor	2001	0100			Hypercholesterolaemia
002	ymbicort	2011	0100	2016	0671	Asthma
003	xalatan	2013	0538			Glaucoma
004	PREDNISOLONE	2016	0671			Gout
005	ADVANTAN	2016	0671			skin
006	EFUDIX	2016	0671			skin
	<i>Space for new Meds to be added</i>					

**Section 3.4 Study Drug Log**

Refer to ASPREE Status and Action to be taken at Annual Visit field (page 1 AVSR) when discussing study medication with participant. Then complete the study drug log below and update the Drug Log eCRF.

3.4a Record details of study med RETURNED.

Log ID	Med No.	Batch No.	Expiry date	Returned date	Destruction date	Staff ID	Number of tablets
001	107702-1	CR00697/CR01013	31 May 2013	30 Jan 2013	30 Jan 2013	198	47
	<i>Dispensing details auto-generated</i>						
002	107702-2	CR05119/CR05122	30 Jun 2014	06 Feb 2014	06 Feb 2014	538	44
	<i>Space for comment</i>						
003	107702-3	CR08631/CR08684	30 Jun 2015	05 Feb 2015		530	15
	<i>Space for comment</i>						
004	107702-4	15058008/15058007	30 Apr 2016	09 Feb 2016		458	54
	<i>Space for comment</i>						
005	107702-5	15058017/15058018	31 May 2017	13 Feb 2017		671	86
	<i>Space for comment</i>						
006	107702-6	15058023/15058024	31 May 2018			708	-1
	<i>Space for comment</i>						

3.4b Record details of new study med DISPENSED.

Med No.	Batch No.	Expiry date	Receipt date	Dispensed by
<i>Space for comment</i>				

**PART 4: OUTSTANDING DATA FOR FOLLOW-UP****Section 4.1 ALSOP Status**

If time permits review participant ALSOP status and prompt questionnaire return if outstanding

Outstanding ALSOP Questionnaire	Sent date
Medical Year 5 Questionnaire	02 Dec 2016

This following sections 4.2 - 4.3 detail outstanding information to be collected following an annual visit while at the practice.

**Section 4.2 Outstanding Pathology**

(No Outstanding Pathology for this participant)

**Section 4.3 Outstanding AE/Endpoint documentation**

The following lists further information/documentation required to code ENDPOINTS. Please look for the outstanding documents in the practice database and upload relevant documents identified. If a supporting document cannot be found please record this on the AE/Endpoint Report Form eCRF.

AE No.	Endpoint Type	Endpoint Date	Self-reported Hospital Date	Supp Doc Status	Comment
06	Hospitalisation for other reason	01 Oct 2015	01 Oct 2015	Discharge Summary: Request	

**PART 5: ENDPOINTS ENTERED TO DATE**

This section is for your information only. For Endpoints NOT identified through the PMHU, use this section as a reference to ensure you do not enter DUPLICATES (the PMHU must be entered as written). You DO NOT need to take any actions regarding this section.

Endpoint Type	Onset date
CES-D 10 Depression	30 Jan 2013
CES-D 10 Depression	05 Feb 2015
CES-D 10 Depression	13 Feb 2017
Falls (not hospitalised)	
Gout	
Hospitalisation for other reason	01 Oct 2015
Osteoarthritis	
OTHER	

**PART 6: (AUS ONLY) COPY OF 6 MONTH PHONE CALL eCRF**

Please place in participant file.

Phone Call Staff 0708 - [REDACTED]

Date 21 Jul 2016

Type Year 4 - 6M Phone Call

**1. Compliance to study medication**On most days, are you taking your study medication daily, as directed? **Yes****2. Clinical Events****Have you had any of the following since your previous visit?**A Heart Attack (Myocardial Infarction) **No**B Stroke **No**C Hospitalization for Heart Failure **No**D Cancer (Excluding non-melanomatous skin cancer) **No**E Any bleeding that required hospitalisation (Clinically significant bleeding) **No**F Any other hospitalisations **No**

(Hospitalization for reason not already reported above - Record only those events that required a minimum of 24 hours OR a change of 2 calendar days or more)

G Has a doctor diagnosed you with any memory or thinking problems, such as dementia **No**

(Alzheimer's disease or other type of dementia) in the past 6 months? (Clinical diagnosis of Dementia)

**3. New disease**Have you been diagnosed with a new disease or condition? **Not Entered****4. Worsening disease**Have you experienced worsening of any disease that you currently have? **Not Entered**