Clinical

Demographics

Date of birth [D D] [M M] [Y Y Y Y]

Smoking Habits

Has the participant ever smoked? ☐ Yes ☐ No

If yes: ☐ Current Smoker (within the last month) ☐ Previous Smoker → If previous smoker, age stopped [ ][ ] Years

→ Age started [ ][ ] Years

→ Type of product smoked (tick all that apply)

- ☐ cigarettes
- ☐ cigars
- ☐ pipes
- ☐ other

→ If cigarettes, number of cigarettes per day [ ][ ]

Ethnic group

White

- ☐ British
- ☐ Irish
- ☐ Any other White background*

Mixed

- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Any other Mixed background*

*If any other background, please specify:

[ ]

Asian or Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Any other Asian background*

Black or British Black

- ☐ Caribbean
- ☐ African
- ☐ Any other African background*

Chinese or other ethnic

- ☐ Chinese
- ☐ Any other*

Conditions

Please indicate if the participant has (current), or has ever had (past), any of the following conditions. If so please provide the onset date (and resolution date for those 'past' conditions) on the conditions log page 25.

Condition	Current	Past	Never	Condition	Current	Past	Never
Diabetes Mellitus If current, controlled by: ☐ diet ☐ tablet ☐ insulin	☐	☐	☐	Low trauma fracture - of hip	☐	☐	☐
				- of spine	☐	☐	☐
				- of forearm	☐	☐	☐
Hypertension If current: ☐ on treatment ☐ not on treatment	☐	☐	☐	Other low trauma fracture:	☐	☐	☐
Angina	☐	☐	☐	Neoplasia, specify:	☐	☐	☐
Myocardial infarction	☐	☐	☐				
Heart failure	☐	☐	☐				

Previous and other current medical history ☐ Yes ☐ No

If Yes, Record any relevant medical history in the systems listed below, use the codes* to relate to the associated system. (Don't record the conditions listed in the table above).

Code*	Details	Onset date	Current?
		M M Y Y Y Y	☐ Yes ☐ No
		M M Y Y Y Y	☐ Yes ☐ No
		M M Y Y Y Y	☐ Yes ☐ No
		M M Y Y Y Y	☐ Yes ☐ No
		M M Y Y Y Y	☐ Yes ☐ No

*Codes

CV: Cardiovascular R: Respiratory HB: Hepato-biliary GI: Gastro-intestinal GU: Genito-urinary End: Endocrine K: Renal	Hm: Haematological LM: Locomotor Neo: Neoplasia Nrl: Neurological Psy: Psychological Imm: Immunological Drm: Dermatological	All: Drug allergies ENT: Eyes, ear, nose, throat IA: Inflammatory arthritis SLE: Systemic lupus erythematosus IBD: Inflammatory bowel disease	OID: Other inflammatory disease GCA: Giant cell arteritis PMR: Polymyalgia rheumatica SSV: Any form of vasculitis Oth: Other

Please tick here if medical history is continued on another page (download additional pages from the TABUL website: https://weblearn.ox.ac.uk) ☐

Presenting symptoms - pre steroids

Has the participant started a course of high dose steroids within the last 7 days? ☐ Yes ☐ No If no, please go to page 4

If yes, steroid start date D D / M M / Y Y Y Y

If yes, please indicate if each group of symptoms was absent or present before starting high dose steroids, by selecting yes (if present) or no (if absent). If present please tick all symptoms that were present and complete the symptoms log on page 26.

Symptom			
General?	☐ Yes	☐ No	**If yes, tick all that apply:**
☐ Development of symptoms or findings beginning at age 50 or older*			
☐ Anorexia			
☐ Fatigue			
☐ Symptoms of fever or night sweats			
☐ New onset of bilateral shoulder pain			
☐ New onset of early morning stiffness > 1 hour			
☐ New onset of bilateral hip stiffness or pain			
Pain in or around the head?	☐ Yes	☐ No	**If yes, tick all that apply:**
☐ New onset or new type of localised pain in the head*			
☐ New onset of generalised scalp tenderness			
☐ Swelling over temporal artery			
☐ Pain over temporal artery			
☐ Jaw claudication			
☐ Tongue claudication			
Visual?	☐ Yes	☐ No	**If yes, tick all that apply:**
☐ New symptom of reduced or lost vision in either eye			
☐ Double vision			
☐ Amaurosis fugax			
Any others?	☐ Yes	☐ No	**If yes, please specify:**
e.g. TIA, stroke			

*ACR Criterion for classification of GCA

Presenting symptoms - current

Have the presenting symptoms changed since the pre-steroid assessment? ☐ Yes ☐ No ☐ Not applicable (participant has not started steroids)

If no, go to page 5.

If yes or not applicable; please indicate if each group of symptoms is absent or present at the time of the visit, by selecting yes (if present) or no (if absent). If present please tick all symptoms that are present and complete the symptoms log on page 26. (If these current symptoms were also present before starting high dose steroids don't duplicate this information in the symptoms log. However, do provide the resolution dates for any symptoms which have resolved since the commencement of steroids on this log).

Symptom

General? ☐ Yes ☐ No **If yes, tick all that apply:**

- ☐ Development of symptoms or findings beginning at age 50 or older*
- ☐ Anorexia
- ☐ Fatigue
- ☐ Symptoms of fever or night sweats
- ☐ New onset of bilateral shoulder pain
- ☐ New onset of early morning stiffness > 1 hour
- ☐ New onset of bilateral hip stiffness or pain

Pain in or around the head? ☐ Yes ☐ No **If yes, tick all that apply:**

- ☐ New onset or new type of localised pain in the head*
- ☐ New onset of generalised scalp tenderness
- ☐ Swelling over temporal artery
- ☐ Pain over temporal artery
- ☐ Jaw claudication
- ☐ Tongue claudication

Visual? ☐ Yes ☐ No **If yes, tick all that apply:**

- ☐ New symptom of reduced or lost vision in either eye
- ☐ Double vision
- ☐ Amaurosis fugax

Any others? ☐ Yes ☐ No **If yes, please specify:**

e.g. TIA, stroke

____

____

____

*ACR Criterion for classification of GCA

Vital signs

Pulse rate ☐☐☐ bpm

Blood pressure ☐☐☐ / ☐☐☐ mm/Hg

Recorded weight ☐☐☐ Kg or ☐☐ st ☐☐ lbs

Specific physical examination

Right side			Feature, please remember to complete left and right	Left side		
Abnormal	Normal	Not Assessed		Abnormal	Normal	Not Assessed
☐	☐		Thickened Temporal Artery	☐	☐	
☐	☐		Tender Temporal Artery*	☐	☐	
☐	☐		Reduced or absent pulsation in temporal artery*	☐	☐	
☐	☐		Tender Axillary Artery	☐	☐	
☐	☐	☐	Anterior ischaemic optic neuropathy	☐	☐	☐
☐	☐	☐	Posterior ischaemic optic neuropathy	☐	☐	☐
☐	☐	☐	Relative afferent pupillary defect	☐	☐	☐
☐	☐	☐	III/IV/VI nerve palsy	☐	☐	☐
☐	☐	☐	Bruits	☐	☐	☐

Other features	Present	Absent	Not Assessed	
Stroke	☐	☐	☐	If present please specify:
Aneurysm	☐	☐	☐	If present please specify site of aneurysm:
Other, e.g. scalp necrosis tongue necrosis	☐	☐	☐	If present please specify:

*ACR Criterion for classification of GCA

Pre Steroid Results: ESR / CRP/ Plasma viscosity ☐ not available, or:

Date of test D D M M Y Y Y Y

ESR ☐☐☐ mm/hr or > ☐☐☐ mm/hr

Plasma viscosity ☐.☐☐ mPa.s

CRP ☐ in the normal range, or:

☐☐☐.☐☐ or > ☐☐☐.☐☐ ☐ mg/L ☐ mg/dL ☐ mmol/L

Baseline Results: ESR / CRP / Plasma viscosity

ESR ☐☐☐ mm/hr or > ☐☐☐ mm/hr

Plasma viscosity ☐.☐☐ mPa.s

CRP ☐ in the normal range, or:

☐☐☐.☐☐ or > ☐☐☐.☐☐ ☐ mg/L ☐ mg/dL ☐ mmol/L

Haematology ☐ not done ☐ pre steroid results ☐ baseline results

Haemoglobin ☐☐.☐ g/dL or ☐.☐☐ g/L or ☐☐.☐ mmol/L

Platelets ☐☐☐☐ $x10^9/L$ or ☐☐☐☐ $x10^3\mu L$

Total WBC ☐☐☐.☐ $x10^9/L$ or ☐☐☐.☐ $x10^3\mu L$

Neutrophils ☐☐☐.☐ $x10^9/L$ or ☐☐☐.☐ $x10^3\mu L$

ANCA ☐ not done ☐ pre steroid results ☐ baseline results

Immunofluorescence

Negative	P	C	Indeterminate

titre if known 1/ ☐☐☐☐

Please circle the result

ELISA MPO ☐☐☐.☐ IU/ml or > ☐☐☐.☐ IU/ml

ELISA PR3 ☐☐☐.☐ IU/ml or > ☐☐☐.☐ IU/ml

Urine dipstick ☐ not done ☐ pre steroid results ☐ baseline results

Blood	0	Trace	+	++	+++

Please circle the result

Protein	0	Trace	+	++	+++

Diagnosis

How certain are you of the diagnosis of GCA? ☐ definite ☐ probable ☐ possible

Steroids

Has the participant taken any steroids? ☐ Yes ☐ No

If yes, are these being given for: ☐ Suspected GCA ☐ Other condition
(tick all that apply)

Please record details below:

Name of Steroid	Route†	Dose (mg)*
Current steroids:		
Previous steroid preparations:		

Immunosuppressants

Is the participant currently taking any immunosuppressants? ☐ Yes ☐ No

If yes, are these being given for: ☐ Suspected GCA ☐ Other condition
(tick all that apply)

If yes, please record details below:

Name of current Immunosuppressant	Route†	Total daily dose - unit	Start date
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY

*Total daily dose in mg †e.g. PO=Oral, IV=intravenous, IM=intramuscular; IA=intraarticular

End of visit checklist

	Yes	No
Is the participant taking any other concomitant medications? If yes please complete the concomitant medications form on page 27.	☐	☐
Has the ultrasound appointment been made? The ultrasound appointment must take place before the biopsy.	☐	☐
Has the biopsy appointment been made? The biopsy appointment must take place after the ultrasound.	☐	☐
Has the participant completed the EQ5D? If yes please store the completed EQ5D in the participant's study file.	☐	☐
Will the participant continue? If no please complete the discontinuation form on page 28.	☐	☐
Has an appointment been made for visit two? Usually two weeks after baseline visit.	☐	☐

I certify that the data contained in the baseline CRF are complete and accurate.
(To be signed and dated by the investigator or authorised member of the investigator's staff)

Signature ______________ Date DD MM YYYY

Print name ______________

Visit date D D M M Y Y Y Y

If not two weeks please explain: ____

Biopsy

Has the biopsy been done? ☐ Yes ☐ No*

If yes: Has the biopsy site been defined in the surgical records? ☐ Yes ☐ No

Did the sample consist of artery? ☐ Yes ☐ No

If yes, please specify (tick all that apply)**:**

	Right	Left	Side not defined
common superficial temporal artery	☐	☐	☐
parietal ramus	☐	☐	☐
proximal frontal ramus (< 2cm)	☐	☐	☐
distal frontal ramus (> 2cm)	☐	☐	☐
section of artery not defined	☐	☐	

Is the biopsy report available to you? ☐ Yes ☐ No

If no report available, reason:

☐ not reported yet

☐ reported but result not made available

☐ other, specify: ____

Are the results consistent with GCA? ☐ Yes ☐ No

***If the biopsy has not been done, reason:**

☐ participant did not attend

☐ procedure cancelled

☐ participant refused to have biopsy

☐ participant medically unfit for biopsy

☐ other, specify: ____

Current conditions

For those conditions that were not current at the previous visit and have not occurred since, please tick 'not occurred since last visit'. No further details are required.
For those conditions that were not current at the previous visit but have occurred since the last visit, please tick 'occurred since last visit'.
NB it is possible that the condition has occurred and resolved since the last visit, in which case also tick 'resolved'.
For those conditions that were current at the prior visit please tick if they have resolved.
If they have not resolved please tick if they are better, worse or no change.

If more than one other type of low trauma fracture or neoplasia is recorded at the prior visit, please provide details for each separately.

Condition	If absent at prior visit:		Resolved	If present at prior visit and not resolved:		
	Not Occurred since last visit	Occurred since last visit		Better*	Worse**	No change
Diabetes Mellitus If present, now controlled by: ☐ diet ☐ tablet ☐ insulin	☐	☐	☐	☐	☐	☐
Hypertension If present, now: ☐ on treatment ☐ not on treatment	☐	☐	☐	☐	☐	☐
Angina	☐	☐	☐	☐	☐	☐
Heart failure	☐	☐	☐	☐	☐	☐
Myocardial infarction	☐	☐				
Low trauma fracture - of hip	☐	☐				
- of spine	☐	☐				
- of forearm	☐	☐				
Other low trauma fracture: ______ ______	☐	☐ ☐				
Neoplasia, specify: ______ ______	☐	☐ ☐				

* No deterioration since last visit, the condition has improved.
**General deterioration since last visit.

For any new conditions please document the onset date on the conditions log (page 25). For any resolved conditions please document the resolution date next to the corresponding onset date on the conditions log (page 25).

Current symptoms **Do Not leave any blank rows.**

For those conditions that have not occurred at the previous visit and have not occurred since, please tick 'not occurred since last visit'. No further details are required.
For those symptoms that were absent at the previous visit but have occurred since the last visit, please tick 'occurred since last visit'.
NB it is possible that the symptom has occurred and resolved since the last visit, in which case also tick 'resolved'. For those symptoms that were present at the prior visit please tick if they have resolved
If they have not resolved please tick if they are worse, better or no change.

Symptom	If absent at prior visit:		Resolved	If present at prior visit and not resolved:		
	Not Occurred since last visit	Occurred since last visit		Better*	Worse**	No change
Anorexia	☐	☐	☐	☐	☐	☐
Fatigue	☐	☐	☐	☐	☐	☐
Symptoms of fever or night sweats	☐	☐	☐	☐	☐	☐
Bilateral shoulder pain	☐	☐	☐	☐	☐	☐
Early morning stiffness > 1 hour	☐	☐	☐	☐	☐	☐
Bilateral hip stiffness or pain	☐	☐	☐	☐	☐	☐
Localised pain in the head	☐	☐	☐	☐	☐	☐
Generalised scalp tenderness	☐	☐	☐	☐	☐	☐
Swelling over temporal artery	☐	☐	☐	☐	☐	☐
Pain over temporal artery	☐	☐	☐	☐	☐	☐
Jaw claudication	☐	☐	☐	☐	☐	☐
Tongue claudication	☐	☐	☐	☐	☐	☐
Reduced or lost vision in either eye	☐	☐	☐	☐	☐	☐
Double vision	☐	☐	☐	☐	☐	☐
Amaurosis fugax	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐

* No deterioration since last visit, the condition has improved.
**General deterioration since last visit.

For any new symptoms please document the onset date on the symptoms log. For any resolved symptoms please document the resolution date next to the corresponding onset date on the symptoms log (page 26).

Vital signs

Pulse rate ☐☐☐ bpm

Blood pressure ☐☐☐ / ☐☐☐ mm/Hg

Recorded weight ☐☐☐ Kg or ☐☐ st ☐☐ lbs

Specific physical examination

Right side				Left side		
Abnormal	Normal	Not Assessed	Feature, please remember to complete left and right	Abnormal	Normal	Not Assessed
☐	☐		Thickened Temporal Artery	☐	☐	
☐	☐		Tender Temporal Artery*	☐	☐	
☐	☐		Reduced or absent pulsation in temporal artery*	☐	☐	
☐	☐		Tender Axillary Artery	☐	☐	
☐	☐	☐	Anterior ischaemic optic neuropathy	☐	☐	☐
☐	☐	☐	Posterior ischaemic optic neuropathy	☐	☐	☐
☐	☐	☐	Relative afferent pupillary defect	☐	☐	☐
☐	☐	☐	III/IV/VI nerve palsy	☐	☐	☐
☐	☐	☐	Bruits	☐	☐	☐

Other features	Present	Absent	Not Assessed	
Stroke	☐	☐	☐	If present please specify:
Aneurysm	☐	☐	☐	If present please specify site of aneurysm:
Other, e.g. scalp necrosis tongue necrosis	☐	☐	☐	If present please specify:

*ACR Criterion for classification of GCA

ESR / CRP / Plasma viscosity

ESR ☐☐☐ mm/hr or > ☐☐☐ mm/hr

Plasma viscosity ☐.☐☐ mPa.s

CRP ☐ in the normal range, or:

☐☐☐.☐☐ or > ☐☐☐.☐☐ ☐ mg/L ☐ mg/dL ☐ mmol/L

Haematology ☐ not done

Haemoglobin ☐☐.☐ g/dL or ☐.☐☐ g/L or ☐☐.☐ mmol/L

Platelets ☐☐☐☐ $x10^9/L$ or ☐☐☐☐ $x10^3/\mu L$

Total WBC ☐☐☐.☐ $x10^9/L$ or ☐☐☐.☐ $x10^3/\mu L$

Neutrophils ☐☐☐.☐ $x10^9/L$ or ☐☐☐.☐ $x10^3/\mu L$

ANCA ☐ not done

Please circle the result

Immunofluorescence | Negative | P | C | Indeterminate | titre if known 1/ ☐☐☐☐

ELISA MPO ☐☐☐.☐ IU/ml or > ☐☐☐.☐ IU/ml

ELISA PR3 ☐☐☐.☐ IU/ml or > ☐☐☐.☐ IU/ml

Urine dipstick ☐ not done

Blood | 0 | Trace | + | ++ | +++ |

Please circle the result

Protein | 0 | Trace | + | ++ | +++ |

Birmingham Vasculitis Activity Score (BVAS)

Tick an item only if attributable to active suspected GCA. If there are no abnormalities in a section, please tick 'No' for that organ-system. If there are abnormalities, tick yes and tick all items attributable to active suspected GCA.

General? ☐ Yes ☐ No

If yes:

- ☐ Myalgia
- ☐ Arthralgia / arthritis
- ☐ Fever ≥ 38°C
- ☐ Weight loss ≥ 2kg

Cutaneous? ☐ Yes ☐ No

If yes:

- ☐ Infarct
- ☐ Purpura
- ☐ Ulcer
- ☐ Gangrene
- ☐ Other skin vasculitis

Mucous membranes / eyes? ☐ Yes ☐ No

If yes:

- ☐ Mouth ulcers
- ☐ Genital ulcers
- ☐ Adnexal inflammation
- ☐ Significant proptosis
- ☐ Scleritis / Episcleritis
- ☐ Conjunctivitis / Blepharitis / Keratitis
- ☐ Blurred vision
- ☐ Sudden visual loss
- ☐ Uveitis
- ☐ Retinal changes (vasculitis / thrombosis / exudate / haemorrhage)

ENT? ☐ Yes ☐ No

If yes:

- ☐ Bloody nasal discharge / crusts / ulcers / granulomata
- ☐ Paranasal sinus involvement
- ☐ Subglottic stenosis
- ☐ Conductive hearing loss
- ☐ Sensorineural hearing loss

Chest? ☐ Yes ☐ No

If yes:

- ☐ Wheeze
- ☐ Nodules or cavities
- ☐ Pleural effusion / pleurisy
- ☐ Infiltrate
- ☐ Endobronchial involvement
- ☐ Massive haemoptysis / alveolar haemorrhage
- ☐ Respiratory failure

Cardiovascular? ☐ Yes ☐ No

If yes:

- ☐ Loss of pulses
- ☐ Vascular heart disease
- ☐ Pericarditis
- ☐ Ischaemic cardiac pain
- ☐ Cardiomyopathy
- ☐ Congestive cardiac failure

Abdominal? ☐ Yes ☐ No

If yes:

- ☐ Peritonitis
- ☐ Bloody diarrhoea
- ☐ Ischaemic abdominal pain

Renal? ☐ Yes ☐ No

If yes:

- ☐ Hypertension
- ☐ Proteinuria > 1+
- ☐ Haematuria ≥ 10 RBCs/hpf
- ☐ Serum creatinine 125-249 μmol/L*
- ☐ Serum creatinine 250-499 μmol/L*
- ☐ Serum creatinine ≥500 μmol/L*
- ☐ Rise in serum creatinine >30% or fall in creatinine clearance >25%

* Can only be scored on the first assessment

Nervous system? ☐ Yes ☐ No

If yes:

- ☐ Headache
- ☐ Meningitis
- ☐ Organic confusion
- ☐ Seizures (not hypertensive)
- ☐ Cerebrovascular accident
- ☐ Spinal cord lesion
- ☐ Cranial nerve palsy
- ☐ Sensory peripheral neuropathy
- ☐ Mononeuritis multiplex

Other? ☐ Yes ☐ No

If yes, specify:

☐ ____________________

PERSISTENT DISEASE ONLY*

☐ Tick if ALL abnormalities are due to persistent disease.

*Active suspected GCA which is not new / worse in the prior 4 weeks.

VASCULITIS DAMAGE INDEX (VDI)

This is for recording organ damage that has occurred in patients *since the onset of suspected GCA*
Patients often have co-morbidity before onset of suspected GCA, **which must not be scored**
Record features of active disease using the Birmingham Vasculitis Activity Score (BVAS)
A new patient should **usually have a VDI score of zero**, unless:
(a) they have had suspected GCA for more than three months and
(b) the damage has developed or become worse since the onset of suspected GCA

Musculoskeletal? ☐ Yes ☐ No

If yes:

- ☐ Significant muscle atrophy or weakness
- ☐ Deforming/erosive arthritis
- ☐ Osteoporosis/vertebral collapse
- ☐ Avascular necrosis
- ☐ Osteomyelitis

Skin/Mucous membranes? ☐ Yes ☐ No

If yes:

- ☐ Alopecia
- ☐ Cutaneous ulcers
- ☐ Mouth ulcers

Ocular? ☐ Yes ☐ No

If yes:

- ☐ Cataract
- ☐ Retinal change
- ☐ Optic atrophy
- ☐ Visual impairment/diplopia
- ☐ Blindness in one eye
- ☐ Blindness in second eye
- ☐ Orbital wall destruction

ENT? ☐ Yes ☐ No

If yes:

- ☐ Hearing loss
- ☐ Nasal blockage/chronic discharge/crusting
- ☐ Nasal bridge collapse/septal perforation
- ☐ Chronic sinusitis/radiological damage
- ☐ Subglottic stenosis (no surgery)
- ☐ Subglottic stenosis (with surgery)

Pulmonary? ☐ Yes ☐ No

If yes:

- ☐ Pulmonary hypertension
- ☐ Pulmonary fibrosis
- ☐ Pulmonary infarction
- ☐ Pleural fibrosis
- ☐ Chronic asthma
- ☐ Chronic breathlessness
- ☐ Impaired lung function

Cardiovascular? ☐ Yes ☐ No

If yes:

- ☐ Angina/angioplasty
- ☐ Myocardial infarction
- ☐ Subsequent myocardial infarction
- ☐ Cardiomyopathy
- ☐ Valvular disease
- ☐ Pericarditis $\geq$ 3 mths or pericardectomy
- ☐ Diastolic BP $\geq$ 95 or requiring antihypertensives

Peripheral vascular disease? ☐ Yes ☐ No

If yes:

- ☐ Absent pulses in one limb
- ☐ 2nd episode of absent pulses in one limb
- ☐ Major vessel stenosis
- ☐ Claudication >3 mths
- ☐ Minor tissue loss
- ☐ Major tissue loss
- ☐ Subsequent major tissue loss
- ☐ Complicated venous thrombosis

Gastrointestinal? ☐ Yes ☐ No

If yes:

- ☐ Gut infarction/resection
- ☐ Mesenteric insufficiency / pancreatitis
- ☐ Chronic peritonitis
- ☐ Oesophageal stricture/surgery

Renal? ☐ Yes ☐ No

If yes:

- ☐ Estimated/measured GFR < 50%
- ☐ Proteinuria > 0.5g/24hr
- ☐ End stage renal disease

Neuropsychiatric? ☐ Yes ☐ No

If yes:

- ☐ Cognitive impairment
- ☐ Major psychosis
- ☐ Seizures
- ☐ Cerebrovascular accident
- ☐ 2nd cerebrovascular accident
- ☐ Cranial nerve lesion
- ☐ Peripheral neuropathy
- ☐ Transverse myelitis

Other? ☐ Yes ☐ No

If yes:

- ☐ Gonadal failure
- ☐ Chemical cystitis
- ☐ Marrow failure
- ☐ Malignancy
- ☐ Diabetes
- ☐ Other

Total VDI Score*

☐ Record the number of positive items (1 point for each).

*The VDI score can either increase or remain the same over time. Remember to carry forward any previous items of damage

Diagnosis

Does the participant have features consistent with a diagnosis of GCA? ☐ Yes ☐ No

If yes, which of the following influenced your decision (tick all that apply):

☐ symptoms ☐ signs ☐ blood abnormalities

☐ biopsy report ☐ other, specify: ____________________

If no*, please give at least one alternative diagnosis:

- ☐ non specific headache
- ☐ migraine
- ☐ myofascial pain
- ☐ temperomandibular dysfunction
- ☐ cervical spondylosis
- ☐ fibromyalgia
- ☐ sinusitis
- ☐ orbital cellulitis
- ☐ shingles
- ☐ orbital pseudotumour
- ☐ metastatic disease (cancer)
- ☐ lymphoma
- ☐ Paget's disease
- ☐ Takayasu's arteritis
- ☐ large vessel vasculitis
- ☐ polyarteritis nodosa
- ☐ Granulomatosis with polyangiitis (GPA)
- ☐ microscopic polyangiitis
- ☐ Churg-Strauss syndrome
- ☐ cryoglobulinemic vasculitis
- ☐ Henoch-Schonlein purpura
- ☐ other vasculitis, specify: ____________________
- ☐ other, specify: ____________________

***WARNING, are you considering rapidly withdrawing steroids because the participant does not have features consistent with a clinical diagnosis of GCA?** ☐ Yes** ☐ No

****IF YES: please contact 01865 737221 or 01865 227326.**

Weekends only, please contact 07905 211359

If no, please specify why you are not considering withdrawing steroids given that you do not suspect GCA. ____________________

After contacting the team are you still going to rapidly withdraw steroids? ☐ Yes ☐ No

If no, have you changed your diagnosis to:

☐ GCA? ☐ other, specify: ____________________

Steroids

Has the participant taken any steroids? ☐ Yes ☐ No

If yes, are these being given for: (tick all that apply) ☐ Suspected GCA ☐ Other condition

Please record details below:

Name of Steroid	Route†	Dose (mg)*
Current steroids:		
Previous steroid preparations:		

Immunosuppressants

Is the participant currently taking any immunosuppressants? ☐ Yes ☐ No

If yes, are these being given for: (tick all that apply) ☐ Suspected GCA ☐ Other condition

If yes, please record details below:

Name of current Immunosuppressant	Route†	Total daily dose - unit	Start date
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY

*Total daily dose in mg †e.g. PO=Oral, IV=intravenous, IM=intramuscular; IA=intraarticular

End of visit checklist

	Yes	No
Has the participant taken any other concomitant medications? If yes please complete the concomitant medications form (page 27).	☐	☐
Has the participant had any adverse events? If yes please complete the adverse event form (separate pad).	☐	☐
Has the participant had any serious adverse events? If yes please complete the adverse event form (separate pad).	☐	☐
Has the participant completed the EQ5D? If yes please store the completed EQ5D in the participant's study file.	☐	☐
Will the participant continue? If no please complete the discontinuation form (page 28).	☐	☐
Has an appointment been made for visit three? Usually six months after baseline.	☐	☐

I certify that the data contained in the visit two CRF are complete and accurate.
(To be signed and dated by the investigator or authorised member of the investigator's staff)

Signature ____________ Date DD MM YYYY

Print name ____________

Visit date D D M M Y Y Y Y

Current conditions

For those conditions that were not current at the previous visit and have not occurred since, please tick 'not occurred since last visit'. No further details are required.
For those conditions that were not current at the previous visit but have occurred since the last visit, please tick 'occurred since last visit'.
NB it is possible that the condition has occurred and resolved since the last visit, in which case also tick 'resolved'.
For those conditions that were current at the prior visit please tick if they have resolved.
If they have not resolved please tick if they are better, worse or no change.

If more than one other type of low trauma fracture or neoplasia is recorded at the prior visit, please provide details for each separately.

Condition	If absent at prior visit:		Resolved	If present at prior visit and not resolved:		
	Not Occurred since last visit	Occurred since last visit		Better*	Worse**	No change
Diabetes Mellitus If present, now controlled by: ☐ diet ☐ tablet ☐ insulin	☐	☐	☐	☐	☐	☐
Hypertension ☐ on treatment ☐ not on treatment	☐	☐	☐	☐	☐	☐
Angina	☐	☐	☐	☐	☐	☐
Heart failure	☐	☐	☐	☐	☐	☐
Myocardial infarction	☐	☐				
Low trauma fracture - of hip	☐	☐				
- of spine	☐	☐				
- of forearm	☐	☐				
Other low trauma fracture: ________ ________	☐	☐ ☐				
Neoplasia, specify: ________ ________	☐	☐ ☐				

* No deterioration since last visit, the condition has improved.
**General deterioration since last visit.

For any new conditions please document the onset date on the conditions log (page 25). For any resolved conditions please document the resolution date next to the corresponding onset date on the conditions log (page 25).

Current symptoms **Do Not leave any blank rows.**

For those conditions that have not occurred at the previous visit and have not occurred since, please tick 'not occurred since last visit'. No further details are required.
For those symptoms that were absent at the previous visit but have occurred since the last visit, please tick 'occurred since last visit'.
NB it is possible that the symptom has occurred and resolved since the last visit, in which case also tick 'resolved'. For those symptoms that were present at the prior visit please tick if they have resolved
If they have not resolved please tick if they are worse, better or no change.

	If absent at prior visit:			If present at prior visit and not resolved:		
Symptom	Not Occurred since last visit	Occurred since last visit	Resolved	Better*	Worse**	No change
Anorexia	☐	☐	☐	☐	☐	☐
Fatigue	☐	☐	☐	☐	☐	☐
Symptoms of fever or night sweats	☐	☐	☐	☐	☐	☐
Bilateral shoulder pain	☐	☐	☐	☐	☐	☐
Early morning stiffness > 1 hour	☐	☐	☐	☐	☐	☐
Bilateral hip stiffness or pain	☐	☐	☐	☐	☐	☐
Localised pain in the head	☐	☐	☐	☐	☐	☐
Generalised scalp tenderness	☐	☐	☐	☐	☐	☐
Swelling over temporal artery	☐	☐	☐	☐	☐	☐
Pain over temporal artery	☐	☐	☐	☐	☐	☐
Jaw claudication	☐	☐	☐	☐	☐	☐
Tongue claudication	☐	☐	☐	☐	☐	☐
Reduced or lost vision in either eye	☐	☐	☐	☐	☐	☐
Double vision	☐	☐	☐	☐	☐	☐
Amaurosis fugax	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐

* No deterioration since last visit, the condition has improved.
**General deterioration since last visit.

For any new symptoms please document the onset date on the symptoms log. For any resolved symptoms please document the resolution date next to the corresponding onset date on the symptoms log (page 26).

Vital signs

Pulse rate ☐☐☐ bpm

Blood pressure ☐☐☐ / ☐☐☐ mm/Hg

Recorded weight ☐☐☐ Kg or ☐☐ st ☐☐ lbs

Specific physical examination

Right side				Left side		
Abnormal	Normal	Not Assessed	Feature, please remember to complete left and right	Abnormal	Normal	Not Assessed
☐	☐		Thickened Temporal Artery	☐	☐	
☐	☐		Tender Temporal Artery*	☐	☐	
☐	☐		Reduced or absent pulsation in temporal artery*	☐	☐	
☐	☐		Tender Axillary Artery	☐	☐	
☐	☐	☐	Anterior ischaemic optic neuropathy	☐	☐	☐
☐	☐	☐	Posterior ischaemic optic neuropathy	☐	☐	☐
☐	☐	☐	Relative afferent pupillary defect	☐	☐	☐
☐	☐	☐	III/IV/VI nerve palsy	☐	☐	☐
☐	☐	☐	Bruits	☐	☐	☐

Other features	Present	Absent	Not Assessed	
Stroke	☐	☐	☐	If present please specify:
Aneurysm	☐	☐	☐	If present please specify site of aneurysm:
Other, e.g. scalp necrosis tongue necrosis	☐	☐	☐	If present please specify:

*ACR Criterion for classification of GCA

ESR / CRP / Plasma viscosity

ESR ☐☐☐ mm/hr or > ☐☐☐ mm/hr

Plasma viscosity ☐.☐☐ mPa.s

CRP ☐ in the normal range, or:

☐☐☐.☐☐ or > ☐☐☐.☐☐ ☐ mg/L ☐ mg/dL ☐ mmol/L

Haematology ☐ not done

Haemoglobin ☐☐.☐ g/dL or ☐.☐☐ g/L or ☐☐.☐ mmol/L

Platelets ☐☐☐☐ $x10^9/L$ or ☐☐☐☐ $x10^3/\mu L$

Total WBC ☐☐☐.☐ $x10^9/L$ or ☐☐☐.☐ $x10^3/\mu L$

Neutrophils ☐☐☐.☐ $x10^9/L$ or ☐☐☐.☐ $x10^3/\mu L$

ANCA ☐ not done

Please circle the result

Immunofluorescence	Negative	P	C	Indeterminate

titre if known 1/ ☐☐☐☐

ELISA MPO ☐☐☐.☐ IU/ml or > ☐☐☐.☐ IU/ml

ELISA PR3 ☐☐☐.☐ IU/ml or > ☐☐☐.☐ IU/ml

Urine dipstick ☐ not done

Blood	0	Trace	+	++	+++

Please circle the result

Protein	0	Trace	+	++	+++

Birmingham Vasculitis Activity Score (BVAS)

Tick an item only if attributable to active suspected GCA. If there are no abnormalities in a section, please tick 'No' for that organ-system. If there are abnormalities, tick yes and tick all items attributable to active suspected GCA.

General? ☐ Yes ☐ No

If yes:
- ☐ Myalgia
- ☐ Arthralgia / arthritis
- ☐ Fever ≥ 38°C
- ☐ Weight loss ≥ 2kg

Cutaneous? ☐ Yes ☐ No

If yes:
- ☐ Infarct
- ☐ Purpura
- ☐ Ulcer
- ☐ Gangrene
- ☐ Other skin vasculitis

Mucous membranes / eyes? ☐ Yes ☐ No

If yes:
- ☐ Mouth ulcers
- ☐ Genital ulcers
- ☐ Adnexal inflammation
- ☐ Significant proptosis
- ☐ Scleritis / Episcleritis
- ☐ Conjunctivitis / Blepharitis / Keratitis
- ☐ Blurred vision
- ☐ Sudden visual loss
- ☐ Uveitis
- ☐ Retinal changes (vasculitis / thrombosis / exudate / haemorrhage)

ENT? ☐ Yes ☐ No

If yes:
- ☐ Bloody nasal discharge / crusts / ulcers / granulomata
- ☐ Paranasal sinus involvement
- ☐ Subglottic stenosis
- ☐ Conductive hearing loss
- ☐ Sensorineural hearing loss

Chest? ☐ Yes ☐ No

If yes:
- ☐ Wheeze
- ☐ Nodules or cavities
- ☐ Pleural effusion / pleurisy
- ☐ Infiltrate
- ☐ Endobronchial involvement
- ☐ Massive haemoptysis / alveolar haemorrhage
- ☐ Respiratory failure

Cardiovascular? ☐ Yes ☐ No

If yes:
- ☐ Loss of pulses
- ☐ Vascular heart disease
- ☐ Pericarditis
- ☐ Ischaemic cardiac pain
- ☐ Cardiomyopathy
- ☐ Congestive cardiac failure

Abdominal? ☐ Yes ☐ No

If yes:
- ☐ Peritonitis
- ☐ Bloody diarrhoea
- ☐ Ischaemic abdominal pain

Renal? ☐ Yes ☐ No

If yes:
- ☐ Hypertension
- ☐ Proteinuria > 1+
- ☐ Haematuria ≥ 10 RBCs/hpf
- ☐ Serum creatinine 125-249 μmol/L*
- ☐ Serum creatinine 250-499 μmol/L*
- ☐ Serum creatinine ≥500 μmol/L*
- ☐ Rise in serum creatinine >30% or fall in creatinine clearance >25%

* Can only be scored on the first assessment

Nervous system? ☐ Yes ☐ No

If yes:
- ☐ Headache
- ☐ Meningitis
- ☐ Organic confusion
- ☐ Seizures (not hypertensive)
- ☐ Cerebrovascular accident
- ☐ Spinal cord lesion
- ☐ Cranial nerve palsy
- ☐ Sensory peripheral neuropathy
- ☐ Mononeuritis multiplex

Other? ☐ Yes ☐ No

If yes, specify:

☐

PERSISTENT DISEASE ONLY*

☐ Tick if ALL abnormalities are due to persistent disease.

*Active suspected GCA which is not new / worse in the prior 4 weeks.

VASCULITIS DAMAGE INDEX (VDI)

This is for recording organ damage that has occurred in patients *since the onset of suspected GCA*
Patients often have co-morbidity before onset of suspected GCA, **which must not be scored**
Record features of active disease using the Birmingham Vasculitis Activity Score (BVAS)
A new patient should **usually have a VDI score of zero**, unless:
(a) they have had suspected GCA for more than three months **and**
(b) the damage has developed or become worse since the onset of suspected GCA

Musculoskeletal? ☐ Yes ☐ No

If yes:
- ☐ Significant muscle atrophy or weakness
- ☐ Deforming/erosive arthritis
- ☐ Osteoporosis/vertebral collapse
- ☐ Avascular necrosis
- ☐ Osteomyelitis

Skin/Mucous membranes? ☐ Yes ☐ No

If yes:
- ☐ Alopecia
- ☐ Cutaneous ulcers
- ☐ Mouth ulcers

Ocular? ☐ Yes ☐ No

If yes:
- ☐ Cataract
- ☐ Retinal change
- ☐ Optic atrophy
- ☐ Visual impairment/diplopia
- ☐ Blindness in one eye
- ☐ Blindness in second eye
- ☐ Orbital wall destruction

ENT? ☐ Yes ☐ No

If yes:
- ☐ Hearing loss
- ☐ Nasal blockage/chronic discharge/crusting
- ☐ Nasal bridge collapse/septal perforation
- ☐ Chronic sinusitis/radiological damage
- ☐ Subglottic stenosis (no surgery)
- ☐ Subglottic stenosis (with surgery)

Pulmonary? ☐ Yes ☐ No

If yes:
- ☐ Pulmonary hypertension
- ☐ Pulmonary fibrosis
- ☐ Pulmonary infarction
- ☐ Pleural fibrosis
- ☐ Chronic asthma
- ☐ Chronic breathlessness
- ☐ Impaired lung function

Cardiovascular? ☐ Yes ☐ No

If yes:
- ☐ Angina/angioplasty
- ☐ Myocardial infarction
- ☐ Subsequent myocardial infarction
- ☐ Cardiomyopathy
- ☐ Valvular disease
- ☐ Pericarditis $\geq$ 3 mths or pericardectomy
- ☐ Diastolic BP $\geq$ 95 or requiring antihypertensives

Peripheral vascular disease? ☐ Yes ☐ No

If yes:
- ☐ Absent pulses in one limb
- ☐ 2nd episode of absent pulses in one limb
- ☐ Major vessel stenosis
- ☐ Claudication >3 mths
- ☐ Minor tissue loss
- ☐ Major tissue loss
- ☐ Subsequent major tissue loss
- ☐ Complicated venous thrombosis

Gastrointestinal? ☐ Yes ☐ No

If yes:
- ☐ Gut infarction/resection
- ☐ Mesenteric insufficiency / pancreatitis
- ☐ Chronic peritonitis
- ☐ Oesophageal stricture/surgery

Renal? ☐ Yes ☐ No

If yes:
- ☐ Estimated/measured GFR < 50%
- ☐ Proteinuria > 0.5g/24hr
- ☐ End stage renal disease

Neuropsychiatric? ☐ Yes ☐ No

If yes:
- ☐ Cognitive impairment
- ☐ Major psychosis
- ☐ Seizures
- ☐ Cerebrovascular accident
- ☐ 2nd cerebrovascular accident
- ☐ Cranial nerve lesion
- ☐ Peripheral neuropathy
- ☐ Transverse myelitis

Other? ☐ Yes ☐ No

If yes:
- ☐ Gonadal failure
- ☐ Chemical cystitis
- ☐ Marrow failure
- ☐ Malignancy
- ☐ Diabetes
- ☐ Other

Total VDI Score*

☐ Record the number of positive items (1 point for each).

*The VDI score can either increase or remain the same over time. Remember to carry forward any previous items of damage

Diagnosis

Has the clinical diagnosis changed compared to visit 2? ☐ Yes ☐ No

If no, no further details are required on this page.

If yes:

Does the participant have features consistent with a diagnosis of GCA? ☐ Yes ☐ No

If yes, which of the following influenced your decision (tick all that apply):

☐ symptoms ☐ signs ☐ blood abnormalities

☐ biopsy report ☐ other, specify: ________

If no, please give at least one alternative diagnosis:

☐ non specific headache
☐ migraine
☐ myofascial pain
☐ temperomandibular dysfunction
☐ cervical spondylosis
☐ fibromyalgia
☐ sinusitis
☐ orbital cellulitis
☐ shingles
☐ orbital pseudotumour
☐ metastatic disease (cancer)
☐ lymphoma
☐ Paget's disease

☐ Takayasu's arteritis
☐ large vessel vasculitis
☐ polyarteritis nodosa
☐ Granulomatosis with polyangiitis (GPA)
☐ microscopic polyangiitis
☐ Churg-Strauss syndrome
☐ cryoglobulinemic vasculitis
☐ Henoch-Schonlein purpura
☐ other vasculitis, specify: ________
☐ other, specify: ________

Steroids

Has the participant taken any steroids? ☐ Yes ☐ No

If yes, are these being given for: ☐ Suspected GCA ☐ Other condition
(tick all that apply)

Please record details below:

Name of Steroid	Route†	Dose (mg)*
Current steroids:		
Previous steroid preparations:		

Immunosuppressants

Is the participant currently taking any immunosuppressants? ☐ Yes ☐ No

If yes, are these being given for: ☐ Suspected GCA ☐ Other condition
(tick all that apply)

If yes, please record details below:

Name of current Immunosuppressant	Route†	Total daily dose - unit	Start date
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY
		-	DD MM YY

*Total daily dose in mg †e.g. PO=Oral, IV=intravenous, IM=intramuscular; IA=intraarticular

End of visit checklist

	Yes	No
Has the participant taken any concomitant medications? If yes please complete the concomitant medications form (page 27).	☐	☐
Has the participant had any adverse events? If yes please complete the adverse event form (separate pad).	☐	☐
Has the participant had any serious adverse events? If yes please complete the adverse event form (separate pad).	☐	☐
Has the participant completed the EQ5D? If yes please store the completed EQ5D in the participant's study file.	☐	☐
Has the participant completed the study? If no please complete the discontinuation form (page 28).	☐	☐

I certify that the data contained in the visit three CRF and pages 25 to 27 are complete and accurate.
(To be signed and dated by the investigator or authorised member of the investigator's staff)

Signature ______________ Date DD MM YYYY

Print name ______________

Please indicate the onset and resolution dates of any of the specified conditions present at any time from baseline to the six month visit (recorded on pages 2, 9 and 17). Where possible specify the day, month and year; if day is unknown specify year and, if possible, month (please cross through any unknown days and / or months). For any conditions still present at the six month visit tick ongoing.

Condition*	Details (if required**)	Onset date	Ongoing, or:	Resolution date
		DD MM YYYY	☐	DD MM YYYY
		DD MM YYYY	☐	DD MM YYYY
		DD MM YYYY	☐	DD MM YYYY
		DD MM YYYY	☐	DD MM YYYY
		DD MM YYYY	☐	DD MM YYYY
		DD MM YYYY	☐	DD MM YYYY
		DD MM YYYY	☐	DD MM YYYY
		DD MM YYYY	☐	DD MM YYYY

*Please use abbreviation from the table below (conditions as defined on pages 2, 9 and 17)

DM: Diabetes Mellitus HT: Hypertension	Ang: Angina MI: Myocardial infarction CCF: Heart failure	LTFH: Low trauma fracture - of hip LTFS: - of spine LTFF: - of forearm LTFO: - other, specify**	Neo: Neoplasia, specify** ** If LTFO or Neo: Please specify in the details field.

Please tick here if conditions are continued on another page (download additional pages from the TABUL website: https://weblearn.ox.ac.uk) ☐

Please indicate the onset and resolution dates of any of the specified symptoms present at any time from baseline to the six month visit (recorded on pages 3, 4, 10 and 18). Where possible specify the day, month and year; if day is unknown specify year and, if possible, month (please cross through any unknown days and / or months). For any symptoms still present at the six month visit tick ongoing.

Symptom*	If 'Oth' please give details**	Onset date	Ongoing, or:	Resolution date
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y
		D D M M Y Y Y Y	☐	D D M M Y Y Y Y

*Please use abbreviation from the table below: (Symptoms as defined on pages 3, 4, 10 and 18)

An: Anorexia	EMS: Early morning stiffness > 1 hour	STA: Swelling over temporal artery	RLV: Reduced or lost vision in either eye
Ftg: Fatigue	BHS: Bilateral hip stiffness or pain	PTA: Pain over temporal artery	DV: Double vision
FNS: Fever or night sweats	LPH: Localized pain in the head	JC: Jaw claudication	AF: Amaurosis fugax
BSP: Bilateral shoulder pain	GST: Generalised scalp tenderness	TC: Tongue claudication	Oth: Other, specify**

Please tick here if symptoms are continued on another page (download additional pages from the TABUL website: https://weblearn.ox.ac.uk) ☐

Please provide details of any medications taken throughout the duration of the study (other than steroids and immunosuppressants given for suspected GCA). Where possible specify the start and end date of each medication (day, month and year if known; if day and month is unknown specify year (please cross through any unknown days and / or months). For any medications still being taken at the six month visit, tick continuing and leave the end date blank.

Medication name	Route*	Dose	Unit*	Frequency*	Reason	Start date	Continuing or end date
						DD MM YYYY	☐ DD MM YYYY
						DD MM YYYY	☐ DD MM YYYY
						DD MM YYYY	☐ DD MM YYYY
						DD MM YYYY	☐ DD MM YYYY
						DD MM YYYY	☐ DD MM YYYY
						DD MM YYYY	☐ DD MM YYYY
						DD MM YYYY	☐ DD MM YYYY
						DD MM YYYY	☐ DD MM YYYY

*Please use codes below if applicable

Route:
PO: Oral
inh: Inhaled
SC: Subcutaneous
IV: Intravenous
IM: Intramuscular
IA: Intraarticular
TD: Transdermal
nas: Intranasal
TOP: Topical
PR: Rectal
If other, specify

Unit:
mg: milligrams
g: gram
mcg: microgram
mg/kg: milligrams/kilogram
mg/m^2: milligrams/meter squared
cap: capsule
IU: International Units
l: litre
drops: drops
patch: patch
mls: millilitres
puffs: puffs
tab: tablet
If other, specify

Frequency:
OD: Once daily
BD: Twice daily
TDS: Three times a day
QDS: Four times daily
PRN: As required
Nocte: At night
Mane: Morning
Q4H: Every 4 hours
STAT: Once only
WKY: Once weekly
If other, specify

Please tick here if medications are continued on another page (download additional pages from the TABUL website: https://weblearn.ox.ac.uk) ☐

Study discontinuation

Last date of participation in study D D M M Y Y Y Y

Discontinuation reason
(tick all that apply)

- ☐ Patient withdrew consent
- ☐ Investigator discretion
- ☐ Patient lost to follow-up
- ☐ Biopsy not done
- ☐ Ultrasound scan not done
- ☐ Patient died
- ☐ Other

Details

I certify that the participant has discontinued.
(To be signed and dated by the investigator or authorised member of the investigator's staff)

Signature

Date D D M M Y Y Y Y

Print name