* 1. Have multiple brain CTs been performed? [ ]  Yes [ ]  No, single head CT
		1. If YES, how many have been performed? [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  >6
		2. If >6 specify:

Table for recording CT results

| Head CT | Date Performed | Age of affected | Where Performed |
| --- | --- | --- | --- |
| 1st | Data to be filled in by site | [derived field] | Data to be filled in by site |
| 2nd | Data to be filled in by site | [derived field] | Data to be filled in by site |
| 3rd | Data to be filled in by site | [derived field] | Data to be filled in by site |

**Technical Information**

1. Name of the scanner manufacturer:

**[ ]** GE **[ ]** Siemens **[ ]** Philips **[ ]** Toshiba **[ ]** Other, specify:

1. Imaging scanner model name:
2. Imaging scanner software name:
3. Imaging scanner software version number:
4. Image acquisition mode:

**[ ]** Helical **[ ]** Sequential

1. Pitch:
2. Image acquisition parameters: kVp:

mA:

1. Slice thickness: mm
2. Slice orientation:
3. Contrast used: [ ]  Yes [ ]  No
	1. If YES, name of the contrasts: dosage:
4. Clinical read of CTs
	1. Reader blinded to clinical data?[ ]  Yes [ ]  No
	2. Quality of images technically satisfactory?[ ]  Yes [ ]  No [ ]  Partially, specify:

**Findings**

1. Lesions found?[ ]  Yes [ ]  No
	1. If YES, type of lesion(s): [ ]  Hypodensity [ ]  Calcification [ ]  Infarct [ ]  Hemorrhage
2. If present, location of hypodensity: [ ]  Cortical [ ]  WM [ ]  Caudate [ ]  Putamen [ ]  Globus pallidus

 [ ]  Thalamic [ ]  Brainstem [ ]  Cerebellum [ ]  Other, specify:

1. White matter involvement
	1. White matter hypodensity: [ ]  Absent [ ]  Present
		1. If present, indicate location(s) (if diffuse mark all):

**[ ]**  Frontal

**[ ]** Parietal

**[ ]** Temporal

**[ ]**  Occipital

**[ ]** Subcortical

**[ ]** Periventricular

**[ ]** Deep

**[ ]** Cerebellar

1. Cavitation: [ ]  Yes [ ]  No
	* 1. If present, indicate location(s):

**[ ]**  Frontal

**[ ]** Parietal

**[ ]** Temporal

**[ ]**  Occipital

**[ ]** Periventricular

**[ ]** Deep WM

**[ ]** Cerebellar WM

**[ ]**  Diffuse

**[ ]**  Caudate

**[ ]**  Putamen

**[ ]**  Globus Pallidus

**[ ]**  Thalamic

[ ]  Brainstem

**[ ]** Other, specify:

1. Acute infarct(s) present:

[ ]  Definitely present

[ ]  Equivocal

[ ]  Definitely absent

1. Number of acute infarcts:
2. Location of acute infarct (Choose all that apply. N/A – Not present should be default response for each region):

Acute Infarcts Location Table

| Brain Region | Side |
| --- | --- |
| Frontal lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Parietal lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Temporal lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Occipital lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Insula | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Cerebellum | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Pons | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Midbrain | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Medulla | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Corona radiata | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Anterior limb IC | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Posterior limb IC | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Caudate | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Globus Pallidus | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Putamen | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Thalamus | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |

1. Chronic infarct(s):
	1. Present? [ ]  Yes [ ]  No
2. Number of chronic infarcts:
3. Location of chronic infarct (Choose all that apply. N/A – Not present should be default response for each region):

Chronic Infarcts Location Table

| Brain Region | Side |
| --- | --- |
| Frontal lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Parietal lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Temporal lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Occipital lobe | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Insula | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Cerebellum | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Pons | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Midbrain | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Medulla | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Corona radiata | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Anterior limb IC | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Posterior limb IC | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Caudate | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Globus Pallidus | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Putamen | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |
| Thalamus | [ ]  Right[ ]  Left[ ]  Bilateral[ ]  N/A – Not present |

1. If present, location of hemorrhage: [ ]  Lobar, specify: [ ]  Caudate [ ]  Putamen [ ]  Globus Pallidum

[ ]  Thalamus [ ]  Brainstem [ ]  Cerebellum [ ]  Other, specify:

1. Malformations
	1. Cortical malformations: [ ]  Yes [ ]  No
		1. If YES, indicate location and specify:

**[ ]**  Frontoparietal, specify: **[ ]** Temporal, specify: **[ ]** Occipital, specify:

* 1. Corpus callosum: [ ]  Normal [ ]  Abnormal
		1. If Abnormal, specify:
	2. Subependymal cysts: [ ]  Yes [ ]  No
		1. If YES, indicate location(s):

[ ]  Frontoparietal [ ]  Temporal [ ]  Occipital

* 1. Ventricles**:** [ ]  Normal [ ]  Abnormal
		1. If Abnormal**,** specify:

**[ ]** Dilation **[ ]**  Other, specify:

* 1. Brainstem: [ ]  Normal [ ]  Abnormal
		1. If Abnormal, specify:
	2. Cerebellum: [ ]  Normal [ ]  Abnormal
		1. If Abnormal, specify:
1. Atrophy: [ ]  Present [ ]  Absent
	* 1. If Present, indicate location(s):

[ ]  Frontoparietal [ ]  Temporal [ ]  Occipital [ ]  Cerebellum

1. Abnormal Enhancement: [ ]  Yes [ ]  No
	* 1. If Abnormal, indicate location(s):

[ ]  Cortex [ ]  White matter [ ]  Basal ganglia [ ]  Thalamus [ ]  Brainstem [ ]  Cerebellum

1. Eye abnormalities: [ ]  Yes [ ]  No
	1. If YES, specify:

**[ ]** Optic nerve abnormalities

**[ ]**  Microphthalmia

**[ ]**  Cataract

**[ ]**  Other, specify:

Recorder Signature: Date:

## General Instructions

This form contains data elements that are collected for head computed tomography. Responses to categories are obtained from health professionals performing the procedure.

Important note: All of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all mitochondrial disease clinical studies to collect).

Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Date/Date performed – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* Multiple CTs performed – Answer, only if head CT was performed.
* Head CT date performed – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Head CT age of affected – This is recorded for each brain CT performed. This is a derived element based on Date of Birth and Visit Date.
* Slice thickness – Answer should be recorded in millimeters (mm).
* Slice orientation – Orientation of the axial slices (e.g., parallel to the OML, parallel to the hard palate, etc.)
* Contrast used – Choose one. If YES, record the name of the contrast agent and its dosage.