### DATA SHARING AGREEMENT

### between

### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### and

### Abdurrahman Islim, Institute of Institute of Systems, Molecular and Integrative Biology, University of Liverpool, Liverpool, UK

*Drafting assumes that:*

* *The data being shared is not personal data, nor pseudonymised individual-level data, nor data that is already in the public domain.*
* *The Provider Institution wishes to ensure that the data is kept confidential and secure*

*The Recipient institution wishes to resume control over the data shared via an online REDCap database*

# DATA SHARING AGREEMENT

between

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and

Dr Abdurrahman Islim, Institute of Institute of Systems, Molecular and Integrative Biology, University of Liverpool, Liverpool, UK

hereinafter referred to as “the Parties” and each of them being “a Party”

# BACKGROUND

1. The Recipient Institution is conducting a research project entitled “**Incidental Meningioma: Prognostic Analysis Using Patient Comorbidity and MRI Tests**” as described in more detail at Schedule 1 (the “Research”) under the direction of Dr Abdurrahman Islim (“the Recipient Scientist”) and wishes to access and use the data specified in Schedule 2 (the “Data”) for the purpose of the Research.
2. The Provider Institution is willing to supply the Data via REDCap to the Recipient Institution and the Recipient Institution is willing to receive, use and store of the Data in accordance with the terms and conditions contained within this agreement (the “Agreement”).

# TERMS AND CONDITIONS

It is hereby agreed as follows:

## In this Agreement:

## the term “Data” includes Manipulated Data;

## the term “Manipulated Data” means any Data that:

## the Recipient Institution adapts or combines or aggregates (wholly or in part) with any other data or information; and which

## has not been manipulated by the Recipient Institution to such a degree that it can no longer be identified as originating from the Data nor used as a substitute for the Data; and

1. the term “Research” includes the publication (if any) of the results of the Research by the Recipient Institution in accordance with clause 4(c).

## In consideration of the obligations accepted by the Recipient Institution under this Agreement, the Provider Institution grants to the Recipient Institution for the terms of this Agreement an exclusive and non-transferable licence to use the Data for the Research.

## The Recipient Institution undertakes to the Provider Institution:

## to use the Data solely for Research;

1. to restrict access to the Data to the Recipient Scientist and those staff and students comprising the Recipient Scientist’s research team, and to ensure that those staff and students are aware of and comply with the terms of this Agreement;

## to keep the Data confidential and not sub-license, transfer, disclose or otherwise make available the Data in whole or part to any third party, during the period of Research;

1. to keep the Data secure by implementing organisational and technological measures appropriate to the nature and sensitivity of the data to prevent the unauthorised or accidental access, use or disclosure of the Data;
2. to notify the Provider Institution as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the Data, and to co-operate with any investigation made by the Provider Institution in connection with the unauthorised or accidental access, use or disclosure of the Data; and
3. to allow the Provider Institution, after completion of this Research, to utilise the Data or parts of it for other research projects, provided written or verbal consent is obtained from the Recipient Scientist.

## The Provider Institution undertakes to the Recipient Institution:

## to provide the Data ‘as is’, and makes no representation and gives no warranty of any kind, either express or implied, including but not limited to warranties of accuracy or

## fitness for a particular purpose;

1. to acknowledge that the results of the Research and Data shall belong to the Recipient Institution. The Recipient Institution shall procure that in relation to any publication reporting on the results of the Research, the Recipient Scientist acknowledges the Provider Institution as the source of the Data in the publication and that contributing members of the Provider Institution will be cited as collaborators. If the Provider Institution requests, the Recipient Institution shall provide a copy of such publication to the Provider Institution thirty (30) days in advance of submission for publication. The Provider Institution agrees not to disclose any results contained in such advance copy to any third party until published by the Recipient Institution; and

## to permit the Recipient Institution to deposit the Data into an open access repository such as the Liverpool Data Catalogue, with contributors from the Provider Institution cited as collaborators.

##

## Except to the extent prohibited by law, the Recipient Institution assumes all direct liability for damages which may arise from its receipt, use, storage or disposal of the Data. The Provider Institution will not be liable to the Recipient Institution for any use made of the Data, including any loss, claim or demand [made by the Recipient Institution or] made against the Recipient Institution by a third party, due to or arising from the use, storage or destruction of the Data by the Recipient Institution, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the Provider Institution.

## The Provider Institution will not be liable to the Recipient Institution for any loss, damage, claim or liability arising from any reliance placed on the Data by the Recipient Institution.

## Nothing in this Agreement limits or excludes either party’s liability for any fraud or for any sort of other liability which, by law, cannot be limited or excluded.

## Nothing in this Agreement grants the Recipient Institution any right to use, or permit the use of, any products or processes containing the Data for any profit-making or commercial purposes (“Commercial Use”). Should the Recipient Institution wish to make Commercial Use of the Data and should the Provider Institution be willing and able to grant a licence for such purposes, the Parties shall negotiate in good faith to agree an appropriate licence or revenue sharing agreement on fair and reasonable terms.

## The rights and obligations of the Parties are not personal and may not assigned at any time without the prior written consent of the other Party

## This Agreement shall be effective from 15 October 2020 and shall continue in force until conclusion of the Research [The term of this Agreement may be extended *by the mutual written* agreement of both Parties signed by their authorised signatories.]

## The Provider Institution may terminate this Agreement if the Recipient Institution is in breach of any of the terms of this Agreement and, where the breach is capable of remedy, the Recipient Institution has failed to remedy the same within twenty-eight (28) calendar days of service of a written notice from the Provider Institution specifying the breach and requiring it to be remedied.

## The Data is provided at no cost

## The Parties shall procure that in carrying out their obligations under this Agreement, they will comply with all applicable laws, regulations and statutes, including those relating to the Data Protection Act 2018. Non-compliance with this clause by a Party shall not be sufficient justification for another Party not to comply with its obligations under this Agreement.

## Notices

## The Provider Institution’s representative for the purpose of receiving notices shall until further notice be:

with a copy to

## The Recipient Institution’s representative for the purpose of receiving notices shall until further notice be:

## Dr Abdurrahman Islim

## with a copy to:

## Professor Michael Jenkinson

## This Agreement constitutes the entire agreement between the parties in respect of its subject matter and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement.

## This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by e-mailed portable document format file or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

IN WITNESS WHEREOF this Agreement is executed as follows:

|  |  |  |
| --- | --- | --- |
| for and on behalf of Insert full name of the Provider Institution |  | for and on behalf of University of Liverpool, Liverpool, UK |
| Signed: |  |  | Signed: |  |
| Name: |  |  | Name: | Abdurrahman Islim |
| Title: |  |  | Title: | Academic Foundation Doctor |
| Dated: |  |  | Dated: |  |

[I, the Recipient Scientist, have read and understood the terms of this Agreement:

|  |  |
| --- | --- |
| Signed: |  |
| Name: | Abdurrahman Islim |
| Dated: |  |

Schedule 1

**The Research**

The study protocol and objectives can be found using this link: <https://www.researchregistry.com/browse-the-registry#home/?view_2_search=meningioma&view_2_page=1>

Schedule 2

**The Data**

|  |  |
| --- | --- |
| **Characteristic**  | **Options** |
| **BASELINE CLINICAL CHARACTERISTICS (PAGE/SECTION 1)** |
| Age (years) | Free field  |
| Sex | Dropdown list/check box* Male
* Female
 |
| Ethnicity | Dropdown list/check box* White
* Mixed / Multiple ethnic groups
* Asian / Asian British
* Black / African / Caribbean / Black British
* Other ethnic group
* NA
 |
| Comorbidities  | Check box * Hypertension - systolic > 140 or diastolic > 90 and patients on medical treatment
* Previous myocardial infarction
* Congestive heart failure
* Peripheral vascular disease
* Previous stroke/TIA - If hemiplegia present, do not check
* Hemi/paraplegia
* Diabetes which requires medical treatment
* Diabetes with end-organ damage - if so, do not check diabetes that requires treatment
* COPD/Asthma
* Renal disease
* Mild liver disease - Hep B/C or cirrhosis without portal hypertension
* Moderate to severe liver disease - cirrhosis with portal hypertension, jaundice, ascites
* Peptic ulcer disease
* Cancer - excluding basal cell carcinoma
* Metastatic cancer - if so, do not check cancer
* Rheumatic or connective tissue disease
* HIV/AIDS
* Skin ulcers/cellulitis
* Depression
* Dementia
* On Warfarin
 |
| WHO Performance status  | Dropdown list/check box* 0
* 1
* 2
* 3
* 4
 |
| Indication for scan | Dropdown list/check box* Headache
* Cerebrovascular accident
* Head injury
* Audiovestibular symptoms
* Visual symptoms
* Psychiatric symptoms
* Cognitive symptoms
* Loss of consciousness
* Other
 |
| **NUMBER OF MENINGIOMAS ON 1ST DIAGNOSTIC SCAN (PAGE/SECTION 2)** |
| Initial scan date | DD/MM/YYYY |
| How many meningiomas?  | Check box* Single
* Multiple
 |
| **BASELINE IMAGING CHARACTERISTICS (SECTION/PAGE 3)** |
| Meningioma signal intensity on T2 | Dropdown list/check box* Hypointense
* Hyperintense
* Isointense
* NA
 |
| Meningioma signal intensity on FLAIR | Dropdown list/check box* Hypointense
* Hyperintense
* Isointense
* NA
 |
| Peritumoural signal intensity on T2 | Dropdown list/check box* 0-5%
* 6-33%
* 34-66%
* 67-100%
* NA
 |
| Peritumoural signal intensity on FLAIR | Dropdown list:* 0-5%
* 6-33%
* 34-66%
* 67-100%
* NA
 |
| Venous sinus nearby | Checkbox  |
| If yes, specify | Dropdown list/check box* Superior sagittal sinus
* Cavernous sinus
* Sigmoid sinus
* Transverse sinus
* Confluence of sinuses
 |
| Separate, direct contact or invaded? | Dropdown list/check box* Separate
* Direct contact
* Invaded
 |
| In contact with critical neuro-vascular structures? | Checkbox  |
| If yes, which | Dropdown list/check box* Internal carotid artery
* Basilar artery
* Vertebral artery
* Middle cerebral artery
* Anterior cerebral artery
* Posterior cerebral artery
* Optic apparatus (optic nerve and chiasm)
* Trigeminal nerve
* Facial nerve
* Vestibulo-cochlear nerve
* Other
 |
| Major axis (mm) | Free field  |
| Minor axis (mm) | Free field  |
| Cor/sag major axis  | Free field  |
| Location  | Dropdown list/Check box* Convexity
* Parasagittal
* Parafalcine
* Sphenoid wing
* Anterior midline
* Post fossa-midline
* Post fossa-lateral & posterior
* Tentorial
* Intraventricular
* Pineal region
 |
| Location subcategory  | Dropdown list/Check box* Anterior
* Posterior
* Falco-tentorial
* Lateral
* Medial (including ACP)
* Cribriform plate/olfactory groove
* Planum
* Tuberculum/diaphragma sellae
* Clival
* Petro-clival
* Anterior foramen magnum
* Petrous
* Squamous occipital
* Posterior foramen magnum
* Supratentorial
* Infratentorial
 |
| Side  | Dropdown list/check box * Right
* Left
* Midline
 |
| **MANAGEMENT DECISION (PAGE/SECTION 4)** |
| Decision  | Dropdown list/Check box* Active monitoring
* Surgery
* SRS
* *f*RT
* Discharge from outpatient care
* Lost to follow-up
* Dead
 |
| **ACTIVE MONITORING (SECTION/PAGE 5)** |
| Scan date | DD/MM/YYYY |
| Peritumoural signal intensity on T2 | Dropdown list/check box * 0-5%
* 6-33%
* 34-66%
* 67-100%
* NA
 |
| Peritumoural signal intensity on FLAIR | Dropdown list/check box * 0-5%
* 6-33%
* 34-66%
* 67-100%
* NA
 |
| Venous sinus nearby  | Checkbox  |
| If yes, specify  | Dropdown list/check box* Superior sagittal sinus
* Cavernous sinus
* Sigmoid sinus
* Transverse sinus
* Confluence of sinuses
 |
| Separate, direct contact or invaded? | Dropdown list/check box* Separate
* Direct contact
* Invaded
 |
| Any new meningioma-related symptoms? | Checkbox |
| If yes, specify domain | Dropdown list/check box * Seizure
* Headache
* Motor
* Sensory
* Language
* Cognitive
* Other
 |
| Major axis (mm) | Free field  |
| Minor axis (mm) | Free field  |
| Cor/sag major axis (mm) | Free field  |
| Outcome  | Dropdown list/check box* Resume follow-up (active monitoring)
* Surgery
* SRS
* *f*RT
* Discharge
* Lost to follow-up
* Dead
 |
| **SURGERY (SECTION/PAGE 6)** |
| Surgery date | DD/MM/YYYY |
| Indication for intervention  | Dropdown list/checkbox* Clinical-radiological
* Clinical
* Radiological
* Patient preference
 |
| Preoperative WHO PS | Dropdown list/checkbox* 0
* 1
* 2
* 3
* 4
 |
| Preoperative comorbidities  | Check box * Hypertension - systolic > 140 or diastolic > 90 and patients on medical treatment
* Previous myocardial infarction
* Congestive heart failure
* Peripheral vascular disease
* Previous stroke/TIA - If hemiplegia present, do not check
* Hemi/paraplegia
* Diabetes which requires medical treatment
* Diabetes with end-organ damage - if so, do not check diabetes that requires treatment
* COPD/Asthma
* Renal disease
* Mild liver disease - Hep B/C or cirrhosis without portal hypertension
* Moderate to severe liver disease - cirrhosis with portal hypertension, jaundice, ascites
* Peptic ulcer disease
* Cancer - excluding basal cell carcinoma
* Metastatic cancer - if so, do not check cancer
* Rheumatic or connective tissue disease
* HIV/AIDS
* Skin ulcers/cellulitis
* Depression
* Dementia
* On Warfarin
 |
| Simpson grade | Dropdown list/check box* 1-GTR
* 2-GTR
* 3-GTR
* 4-STR
* 5-STR
 |
| WHO grade at the time of surgery | Dropdown list/check box* 1
* 2
* 3
 |
| Microscopic brain invasion | Dropdown list/checkbox * Yes
* No
* Brain tissue absent
* NA
 |
| Updated WHO grade (2016) | Dropdown list/check box* 1
* 2
* 3
* NA
 |
| Postoperative surgical complications  | Checkbox  |
| Complication | Dropdown list/check box* Haemorrhage
* Hydrocephalus
* Surgical site infection - superficial and deep incisiona
* Surgical site infection - intracranial (meningitis, ventriculitis and abscess)
* Stroke
* CSF leak
* Other
 |
| New or worsening neurological impairment | Checkbox |
| Clinical manifestation | Dropdown list/checkbox* Seizure
* Headache
* Motor
* Sensory
* Language
* Cognitive
* Reduced GCS
* Other
 |
| Pharmacological intervention | Checkbox |
| Surgical intervention | Dropdown list/checkbox* No
* Without GA
* Under GA
 |
| ICU admission | Checkbox |
| Organ failure | Dropdown list/checkbox* None
* Single-organ
* Multi-organ
 |
| Persisted with no improvement beyond 30 days? | Checkbox |
| Postoperative medical complications | checkbox  |
| Complication | Dropdown list/check box* Myocardial infarction
* Arrhythmia
* Pneumonia
* Pulmonary embolism
* Deep venous thrombosis
* Urinary tract infection
* Acute kidney injury
* Other
 |
| Pharmacological intervention | Checkbox |
| Surgical intervention | Dropdown list/checkbox* No
* Without GA
* Under GA
 |
| ICU admission  | Checkbox |
| Organ failure | Dropdown list/checkbox* None
* Single-organ
* Multi-organ
 |
| Persisted with no improvement beyond 30 days? | Checkbox |
| Postoperative WHO PS | Dropdown list/checkbox* 0
* 1
* 2
* 3
* 4
* 5 (dead)
 |
| Recurrence | Checkbox |
| Scan date (at recurrence or last follow-up date if no recurrence) | DD/MM/YYYY |
| WHO PS at time of recurrence/last follow-up | Dropdown list/checkbox* 0
* 1
* 2
* 3
* 4
 |
| **SRS (SECTION/PAGE 7)** |
| Pre-radiation WHO PS | Dropdown list/check box* 0
* 1
* 2
* 3
* 4
 |
| Pre-radiation comorbidity  | Check box * Hypertension - systolic > 140 or diastolic > 90 and patients on medical treatment
* Previous myocardial infarction
* Congestive heart failure
* Peripheral vascular disease
* Previous stroke/TIA - If hemiplegia present, do not check
* Hemi/paraplegia
* Diabetes which requires medical treatment
* Diabetes with end-organ damage - if so, do not check diabetes that requires treatment
* COPD/Asthma
* Renal disease
* Mild liver disease - Hep B/C or cirrhosis without portal hypertension
* Moderate to severe liver disease - cirrhosis with portal hypertension, jaundice, ascites
* Peptic ulcer disease
* Cancer - excluding basal cell carcinoma
* Metastatic cancer - if so, do not check cancer
* Rheumatic or connective tissue disease
* HIV/AIDS
* Skin ulcers/cellulitis
* Depression
* Dementia
* On Warfarin
 |
| Dose  | Free field |
| Early CTCAE toxicity (≤3 months) | Checkbox  |
| Toxicity  | Free field |
| Late CTCAE toxicity  | Checkbox  |
| Toxicity  | Free field |
| Meningioma progression/regrowth  | Checkbox |
| Scan date (at progression or last follow-up date if no progression) | DD/MM/YYYY |
| WHO PS at time of progression/last follow-up | Dropdown list/checkbox* 0
* 1
* 2
* 3
* 4
* 5 (dead)
 |
| ***f*RT (SECTION/PAGE 8)** |
| Pre-radiation WHO PS | Dropdown list/check box* 0
* 1
* 2
* 3
* 4
 |
| Pre-radiation comorbidity  | Check box * Myocardial infarction
* Congestive heart failure
* Peripheral vascular disease
* Hemiplegia
* Cerebrovascular disease
* Pulmonary disease
* Diabetes
* Renal disease
* Liver disease
* Peptic ulcer disease
* Cancer
* Dementia
* Connective tissue disease
* AIDS
* Hypertension
* Skin ulcers/cellulitis
* Depression
* On Warfarin
 |
| Number of fractions  | Free field  |
| Fractionated dose | Free field |
| Total dose  | Free field |
| Early CTCAE toxicity (≤3 months) | Checkbox  |
| Toxicity  | Free field |
| Late CTCAE toxicity  | Checkbox  |
| Toxicity  | Free field |
| Meningioma progression/regrowth  | Checkbox |
| Scan date (at progression or last follow-up date if no progression) | DD/MM/YYYY |
| WHO PS at time of progression/last follow-up | Dropdown list/checkbox* 0
* 1
* 2
* 3
* 4
* 5 (dead)
 |
| **Discharge from outpatient care/Lost to follow-up (SECTION/PAGE 9)** |
| Date of data entry into the database  | DD/MM/YYYY |
| Rescanned during the time between discharge/loss to FU and the date of data entry | Checkbox |
| Date of scan | DD/MM/YYYY |
| Reason? | Dropdown list:* Seizure
* Headache
* Motor
* Sensory
* Language
* Cognitive
* Other
 |
| Peritumoural signal intensity on T2 | Dropdown list/check box* 0-5%
* 6-33%
* 34-66%
* 67-100%
* NA
 |
| Peritumoural signal intensity on FLAIR | Dropdown list:* 0-5%
* 6-33%
* 34-66%
* 67-100%
* NA
 |
| Venous sinus nearby | Checkbox* Superior sagittal sinus
* Cavernous sinus
* Sigmoid sinus
* Transverse sinus
* Confluence of sinuses
 |
| If yes, specify | Dropdown list/check box |
| Separate, direct contact or invaded? | Dropdown list/check box* Separate
* Direct contact
* Invaded
 |
| Major axis (mm) | Free field  |
| Minor axis (mm) | Free field  |
| Cor/sag major axis (mm) | Free field  |
| Verdict | Dropdown list/checkbox* Related
* Unrelated
 |
| Outcome | Dropdown list/Checkbox* Resume follow-up (active monitoring)
* Surgery
* SRS
* *f*RT
* Discharge
* Lost to follow-up
* Dead
 |
| Overall outcome | Dropdown list/Checkbox:* Dead
* Alive
 |
| **Mortality (SECTION/PAGE 10)** |
| Date of death  | DD/MM/YYYY |
| Cause of death | Dropdown list/checkbox* Meningioma-related
* Unrelated
 |