



Dementias
Platform^{UK}
Medical Research Council

DATA DEPOSIT AGREEMENT

RELATING TO DEMENTIAS PLATFORM UK

**THIS IS A SAMPLE DOCUMENT FOR
YOUR INFORMATION ONLY**

**BETWEEN
SWANSEA UNIVERSITY
AND
COHORT OWNER'S ORGANISATION**

VERSION 2, APRIL 2018

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THIS AGREEMENT is dated

PARTIES

- (1) **SWANSEA UNIVERSITY** an academic institution having a registered address of Singleton Park, Swansea, SA2 8PP (“**Swansea**”).
- (2) **[FULL NAME] [ADDRESS] (“Cohort Owner”)**.

BACKGROUND

- (A) Swansea is a signatory to a multiparty consortium agreement ‘Dementias Platform UK’ (the “Project”) dated 13 June 2014 (the “Consortium Agreement”)
- (B) Part of the work under the Consortium Agreement is to develop a new resource to help dementia researchers make the most of existing study data from over 30 well-established UK population, or cohort studies.
- (C) The Cohort Owner is entitled to deal with the copyright and any database rights in the Cohort Owner Data (as defined below) as set out in this agreement.
- (D) The Cohort Owner wishes to transfer data into Swansea’s ‘United Kingdom Secure eResearch Platform’ (“UKSeRP”). UKSeRP shall ring-fence the Cohort Owner Data (defined below) and create data linking opportunities for the Cohort Owner and, subject to an approved access request, other DPUK UKSeRP Users (defined below).
- (E) Subject to the relevant access request procedure being followed, in accordance with this agreement, the Cohort Owner wishes to license to Swansea the use of all copyright and database rights in its Cohort Owner Data (as defined below) to enable Swansea to perform the Purpose (defined below)

AGREED TERMS

1. INTERPRETATION

1.1 The following definitions and rules of interpretation apply in this agreement.

Background Intellectual Property: shall mean any Intellectual Property owned or controlled by a Party a) prior to commencement of this agreement or b) which the owning Party contributes or uses after the commencement of this agreement in the course of performing its obligations under this agreement. For the avoidance of doubt UKSeRP shall be deemed Background Intellectual Property of Swansea.

Commencement Date: means the date this agreement is executed.

Confidential Information: all confidential information (however recorded or preserved) disclosed by a party or its employees, officers, representatives, advisers or subcontractors involved in the provision or receipt of the Services who need to know the confidential information in question (Representatives) to the other party and that party's Representatives in connection with this agreement, which is either labelled as such or else which should reasonably be considered as confidential because of its nature and the manner of its disclosure.

Cohort Owner Data: the Data and any Personal Data (as defined below) comprised in the Cohort Owner Data details of which are captured in Schedule 4.

Data: any data or information, in whatever form.

Data Controller: shall have the meaning set out in Article 4 of GDPR.

Data Incorporation: standard transfer of Cohort Owner Data onto the dedicated UKSeRP, via a split-file process in order to a) standardise the format of data to enable future linkage and b) anonymise the Cohort Owner Data, where applicable.

Data Protection Legislation means while they remain in force, the Data Protection Act 1998, the European Data Protection Directive, the Regulation of Investigatory Powers Act 2000, the Telecommunications (Lawful Business Practice) (Interception of Communications) Regulations 2000, the Electronic Communications Data Protection Directive, the Privacy and Electronic Communications (EC Directive) Regulations, 2003, once it comes into force the Data Protection Act 2018 [subject to Royal Assent], European General Data Protection Regulation (GDPR), Law Enforcement Directive (Directive (EU) 2016/679) and any other laws and regulations relating to the processing of personal data and privacy which apply to a Party and, if applicable, the guidance and codes of practice issued by the Information Commissioner or other relevant data protection or supervisory authority;

Data Processor: shall have the meaning set out in Article 4 of GDPR.

DPUK Data Portal Management: the management and administration by Swansea of requests by third parties to access the Cohort Owner Data and other Data provided by third parties, held within UKSeRP.

DPUK UKSeRP Users: institutions whose applications for data access from UKSeRP in order to produce Interrogated Information TPR (defined below) have been approved by DPUK. For the avoidance of doubt, the Cohort Owner may also be a DPUK UKSeRP User if accessing data belonging to another Cohort Owner.

Study: means a distinct research project set out in any one application to DPUK.

Study Approvals Panel or “SAP”: a group/forum established to consider requests for Interrogated Information TPR (defined below), and having the terms of reference set out in Schedule 5. Such group shall include a representative of each cohort owner whose data is the subject of a request.

Intellectual Property Rights: patents, utility models, rights to inventions, copyright and neighbouring and related rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, database rights, and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

“Interrogated Information (OD)” means the reports generated by the Cohort Owner acting through its Permitted Person(s) using their Cohort Owner Data only (not linking or utilising any third party data) using the UKSeRP. (For the purpose of this definition, “OD” stands for “Own Data”)

“Interrogated Information (TPR)” means all reports which have been generated as a result of a third party DPUK UKSeRP User requesting access to the Cohort Owner Data (via the SAP-approval process) (For the purpose of this definition, “TPR” stands for “Third Party Request”).

Permitted Person(s): means [insert name or names] permitted access by the Cohort Owner to the Cohort Owner Data in order to create Interrogated Information (OD)

Personal Data: shall have the meaning set out in GDPR.

Project: means Dementias Platform UK.

Purpose: means to:

(a) Perform the Services; and

(b) In consideration of the Cohort Owner’s agreement to provide their Cohort Owner Data to UKSeRP, permit access of the Cohort Owner, acting through its Permitted Person, to UKSeRP to create Interrogated Information (OD).

Security Breach: any security breach relating to the Cohort Owner Data reasonably determined by Swansea to be sufficiently serious or substantial to justify notification to the Cohort Owner.

Security Feature: any security feature, including any key, PIN, password, token or smartcard.

Services: means the services detailed in Schedule 1.

Term: the period detailed in clause 8.

UKSeRP: means the United Kingdom Secure eResearch Platform developed by Swansea including its ancillary computer codes, algorithms, statistical scripts, tools, techniques, methods, and similar materials which will receive and store the Cohort Owner Data.

1.2 Data Subject, Personal Data, Processing and appropriate technical and organisational measures shall bear the meanings given to those terms respectively in the relevant Data Protection Legislation.

1.3 A **person** includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).

1.4 A reference to a company shall include any **company**, corporation or other body corporate, wherever and however incorporated or established.

1.5 Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.

1.6 Unless the context otherwise requires, a reference to one gender shall include a reference to the other genders.

1.7 A reference to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time.

1.8 A reference to a statute or statutory provision shall include all subordinate legislation made from time to time under that statute or statutory provision.

1.9 A reference to **writing** or **written** includes faxes but not e-mail.

1.10 Where the Cohort Owner is also party to the Consortium Agreement, should there be any inconsistency with between this agreement and the Consortium Agreement, the terms of the Consortium Agreement shall prevail.

2. SCOPE

2.1 During the Term Swansea shall supply the Services to the Cohort Owner.

2.2 Swansea shall process the Cohort Owner Data for the Purpose only and always in accordance with the access procedure outlined in clause 4 below.

2.3 The Cohort Owner acknowledges that Swansea is under no duty to investigate the completeness, accuracy or sufficiency of the Cohort Owner Data.

3. DATA INCORPORATION

With respect to Data Incorporation, the following terms shall apply

CONNECTION

3.1 The parties shall use reasonable efforts to establish connectivity between the Cohort Owner system and the UKSeRP on the Commencement Date.

3.2 Each party shall bear its own costs of establishing that connectivity.

3.3 The Cohort Owner may after the Commencement Date migrate their Cohort Owner Data from the Cohort Owner system to the UKSeRP in accordance with this agreement.

3.4 The Cohort Owner acting through its Permitted Person shall continue to have complete control over their Cohort Owner Data deposited in accordance with this agreement and, subject to clause 4.3, may at any time remove their Cohort Owner Data from the UKSeRP. Prior to removal the Cohort Owner shall provide Swansea with at least 7 days written notice of their intention to withdraw their Data.

ANONYMISATION

3.5 To the extent that the incorporation requires Swansea's handling of Personal Data:

(a) the terms of Schedule 2 shall apply; and

(b) without prejudice to clause 3.5 (a) or clause 10.1, the Cohort Owner hereby consents to Swansea sub-contracting with Velindre NHS Trust as host of NHS Wales Informatics Service of Tŷ Glan-yr-Afon, 21 Cowbridge Road East, Cardiff, CF11 9AD, in relation to the handling of such Personal Data.

SECURITY AND PASSWORDS

3.6 Swansea shall ensure that the Cohort Owner Data is kept secure by using the Security Features and in an encrypted form, and shall use all reasonable security practices and systems applicable to the use of the Cohort Owner Data to prevent, and take prompt and proper remedial action against, unauthorised access, copying, modification, storage, reproduction, display or distribution of the Cohort Owner Data.

3.7 Where Swansea uses Security Features in relation to the Services (wholly or in part), the Security Features must, unless Swansea notifies the Cohort Owner otherwise, be kept confidential and not lent, shared, transferred or otherwise misused by the Cohort Owner.

3.8 If either party:

(a) becomes aware of any unauthorised or unlawful processing of any Cohort Owner Data or that any Cohort Owner Data is lost or destroyed or has become damaged, corrupted or unusable;

(b) becomes aware of any Security Breach; or

(c) learns or suspects that any Security Feature has been revealed to or obtained by any unauthorised person,

that party shall promptly notify the other party and fully co-operate with the other party to remedy the issue as soon as reasonably practicable.

3.9 Swansea's obligations under clause 3.8 shall be performed at Swansea's reasonable expense, except to the extent that the Security Breach arose out of any negligence or wilful default of the Cohort Owner .

3.10 Swansea may change Security Features on notice to the Cohort Owner for security reasons.

DATA PROTECTION

3.11 The Parties acknowledge that in carrying out the Services under the terms of this Agreement, Personal Data may be collected and transferred between them. The Parties further acknowledge that they will be data controllers in respect of all data collected by them but may also become data processors when dealing with data passed to them by another Party.

3.12 The Parties agrees that where they are in possession of such personal data they shall:

3.12.1. only process such Personal Data as is necessary to perform the services and will make no independent use of data received from another Party unless expressly permitted by that Party by way of prior written consent;

3.12.2. only process such Personal Data with the explicit, informed consent of any individual to whom any data relates;

3.12.3. act at all times in accordance with the informed consent and with the disclosing party's reasonable instructions and requirements;

3.12.4. ensure that all Personal Data is kept securely and in accordance with the requirements of the Data Protection Legislation;

3.12.5. maintain all appropriate technical and organisational measures in place to guard against unauthorised or unlawful processing of Personal Data and against accidental loss, damage or destruction;

3.12.6. take all reasonable steps to ensure the reliability of its staff that will have access to such Personal Data including explicit confidentiality agreements with those staff;

3.12.7. not export any Personal Data outside of the European Economic Area without the consent of the subject

3.13. The Parties will ensure that if necessary data consent and information sheets issued in connection with the Services performed under this Agreement acknowledge all Parties as data controllers and contain appropriate information regarding the use and exchange of such data between the Parties.

3.14. Each Party shall indemnify the other Parties for any breach of the Data Protection Legislation which renders a Party or the Parties liable for any costs, fines, claims or expenses howsoever arising.

ADDITIONAL OBLIGATIONS ON SWANSEA

3.13 Swansea shall:

(a) take appropriate technical and organisational measures against unauthorised or unlawful processing of the Cohort Owner Data and against the accidental loss or destruction of, or damage to, the Cohort Owner Data;

(b) only make copies of the Cohort Owner Data to the extent reasonably necessary for the Purpose (which, for clarity, includes back-up, mirroring (and similar availability enhancement techniques), security, disaster recovery and testing of the Cohort Owner Data);

(c) not extract, re-utilise, use, exploit, redistribute, re-disseminate, copy or store the Cohort Owner Data other than for the Purpose; and

(d) not do anything that may damage the reputation of the Cohort Owner.

3.14 Swansea shall take reasonable steps to ensure the reliability of all its employees who have access to the Cohort Owner Data.

4. DPUK DATA PORTAL MANAGEMENT

With respect to DPUK Data Portal Management, the following terms shall apply:

STUDY APPROVALS PANEL (SAP)

4.1 The SAP shall hear, oversee, approve or reject all requests for Interrogated Information (TPR). The terms of reference for the SAP are attached at Schedule 5.

4.2 Swansea shall require any DPUK UKSeRP User that wishes to request Interrogated Information (TPR) to complete an expression of interest form and full study application.

Following receipt of the expression of interest and subject to the agreement of the SAP, Swansea shall require the requesting DPUK UKSeRP User to enter into a Data Access Agreement (“DAA”) before they are provided with Interrogated Information (TPR). The **DAA** is as appended at Schedule 3 hereto.

4.3 If the Cohort Owner acting through its Permitted Person(s) and the SAP has agreed a DPUK UKSeRP User to access all or part of their Cohort Owner Data (via Interrogated Information (TPR)), the Cohort Owner, shall not be entitled to withdraw their Cohort Owner Data until such time as that DPUK UKSeRP User has completed their analysis of the Interrogated Information (TPR) in accordance with the DAA covering their research project.

INTELLECTUAL PROPERTY RIGHTS

Background

4.4 Any Background Intellectual Property used in connection with this agreement shall remain the property of the Party introducing the same. No Party will make any representation or do any act which may be taken to indicate that it has any right, title or interest in or to the ownership or use of any of the Background Intellectual Property of the other parties except under the terms of this agreement. Each Party acknowledges and confirms that nothing contained in this agreement shall give it any right, title or interest in or to the Background Intellectual Property of the other Parties save as granted by this agreement.

UKSeRP Arising Intellectual Property:

4.5 Intellectual Property Rights that embody computer codes, algorithms, statistical scripts, tools, techniques, methods and similar materials developed in the performance of the Project (DPUK Infrastructure) for use on Cohort Owner Data and contained within the UKSeRP, whether wholly or partially (“**UKSeRP Arising IP**”) shall be owned by Swansea.

4.6 Swansea hereby grants a non-exclusive, royalty-free, fully paid up licence to the Cohort Owner to use any UKSeRP Arising IP for the purpose of obtaining and analysing Interrogated Information (OD).

Intellectual Property Rights in Cohort Owner Data and Interrogated Information (TPR/OD)

4.7 Swansea acknowledges that:

(a) all Intellectual Property Rights in the Cohort Owner Data will remain the property of the Cohort Owner or its licensors, as the case may be; and

(b) Swansea shall have no rights in or to the Cohort Owner Data other than the rights granted to it by the Cohort Owner under this agreement.

4.8 The Cohort Owner hereby grants to Swansea a royalty-free, non-exclusive licence to use any Intellectual Property Rights contained within the Cohort Owner Data for the Purpose. Such licence shall be sub-licensable to DPUK UKSeRP Users to the extent necessary for Swansea to perform the Purpose. Swansea shall only grant such sub-licences to DPUK UKSeRP Users subject to the SAP process in clause 4.1-4.3 being followed.

4.9 Swansea shall procure that Intellectual Property Rights contained within the Interrogated Information (OD) and (TPR) generated by UKSeRP shall vest at all times and for all purposes in the Cohort Owner whose data has been used to create the Interrogated Information (OD) and/or Interrogated Information (TPR).

4.10 For the avoidance of doubt DPUK UKSeRP Users provided access to UKSeRP to create Interrogated Information (TPR) shall not have Intellectual Property Rights in the Interrogated Information (TPR).

4.11 Swansea shall procure that DPUK UKSeRP Users will abide by the publication process as set out in Schedule 1 of the DAA.

4.12 Where a Cohort Owner receives a publication for review under the publication process set out in Schedule 1 of the DAA, the Cohort Owner agrees that:

(a) the Cohort Owner may object to or request a delay to a proposed publication for accuracy/patent reasons and/or require deletion of that Cohort Owners Confidential Information, provided the Cohort Owner submits such objection/request in writing to the SAP within twenty (20) days of receipt of the notification from the SAP; and

(b) if the Cohort Owner does request a delay on the submission of a publication, such delay shall not last longer than is absolutely necessary to seek the required approvals; and therefore shall not exceed three (3) months from the date of receipt of the proposed publication.

5. CONFIDENTIALITY

5.1 Swansea acknowledges that the Cohort Owner's Confidential Information includes any Cohort Owner Data.

5.2 The term Confidential Information does not include any information that:

(a) is or becomes generally available to the public (other than as a result of its disclosure by the receiving party or its Representatives in breach of this clause 5);

(b) was available to the receiving party on a non-confidential basis before disclosure by the disclosing party;

(c) was, is, or becomes, available to the receiving party on a non-confidential basis from a person who, to the receiving party's knowledge, is not bound by a confidentiality agreement with the disclosing party or otherwise prohibited from disclosing the information to the receiving party;

(d) was known to the receiving party before the information was disclosed to it by the disclosing party;

(e) the parties agree in writing is not confidential or may be disclosed; or

(f) is developed by or for the receiving party independently of the information disclosed by the disclosing party.

5.3 Each party shall keep the other party's Confidential Information confidential and shall not:

(a) use any Confidential Information except for the Purpose; or

(b) disclose any Confidential Information in whole or in part to any third party, except as expressly permitted by this clause 5.

5.4 A party may disclose the other party's Confidential Information to those of its Representatives who need to know that Confidential Information for the Purpose, provided that:

- (a) it informs those Representatives of the confidential nature of the Confidential Information before disclosure; and
- (b) at all times, it is responsible for the Representatives' compliance with the confidentiality obligations set out in this clause 5.

5.5 A party may disclose Confidential Information to the extent required by law, by any governmental or other regulatory authority, or by a court or other authority of competent jurisdiction provided that, as far as it is legally permitted to do so, it gives the other party as much notice of the disclosure as possible.

5.6 Each party reserves all rights in its Confidential Information. No rights or obligations in respect of a party's Confidential Information, other than those expressly stated in this agreement, are granted to the other party, or are to be implied from this agreement.

5.7 The provisions of this clause 5 shall continue to apply after termination of this agreement and continue for a period of five (5) years.

6. WARRANTIES

6.1 Where the Data Incorporation requires Swansea's handling of Personal Data, Swansea warrants that it will process the Cohort Owner Data in compliance with relevant Data Protection Legislation.

6.2 Swansea warrants and represents that it will,:

- (a) where the data incorporation requires Swansea's handling of Personal Data, ensure that Cohort Owner Data is anonymised prior to its incorporation into UKSeRP .
- (b) having regard to the state of technological development and the cost of implementing any measures, take appropriate technical and organisational measures against the unauthorised or unlawful processing of Cohort Owner Data and against the accidental loss or destruction of, or damage to, Cohort Owner Data to ensure a level of security appropriate to:
 - (i) the harm that might result from such unauthorised or unlawful processing or accidental loss, destruction or damage; and
 - (ii) the nature of the Data to be protected
- (c) take reasonable steps to ensure compliance with those measures; and
- (d) discharge its obligations under this agreement with all due skill, care and diligence.

6.3 The Cohort Owner warrants and represents that:

- (a) it has the right to transfer the Cohort Owner Data to UKSeRP for the Purpose;
- (b) the Cohort Owner Data contains nothing that is defamatory or indecent;
- (c) the transferring of the Cohort Owner Data has been carried out in accordance with Data Protection Legislation at all times;
- (d) it is not aware of any circumstances likely to give rise to breach of any of the Data

Protection Legislation in the future (including any Security Breach);

(e) It is not depositing Cohort Owner Data belonging to a Data Subject who has expressly declined the deposit of their Data;

(f) all Cohort Owner Data is necessary, accurate and up-to-date; and

(g) it is registered with all relevant data protection authorities.

6.4 Except as expressly stated in this agreement, all warranties, conditions and terms, whether express or implied by statute, common law or otherwise are hereby excluded to the extent permitted by law.

6.5 Without limiting the effect of clause 6.4, Swansea does not warrant that the Interrogated Information OD or TPR:

(a) is or are accurate, complete, reliable, secure, useful, fit for purpose or timely;

(b) has or have been tested for use by the Cohort Owner or any third party; or

7. LIMITATION OF LIABILITY

7.1 Neither party excludes or limits liability to the other party for:

(a) fraud or fraudulent misrepresentation;

(b) death or personal injury caused by negligence; or

(c) any matter for which it would be unlawful for the parties to exclude liability.

7.2 Subject to clause 7.1, Swansea shall not in any circumstances be liable whether in contract, tort (including for negligence and breach of statutory duty howsoever arising), misrepresentation (whether innocent or negligent), restitution or otherwise, for:

(a) any loss (whether direct or indirect) of profits, business, business opportunities, revenue, turnover, reputation or goodwill;

(b) any loss or liability (whether direct or indirect) under or in relation to any other contract.

7.3 Clause 7.2 shall not prevent claims, which fall within the scope of clause 7.4, for:

(a) direct financial loss that are not excluded under any of the categories set out in clause 7.2(a) to clause 7.2(b); or

(b) tangible property or physical damage.

7.4 Subject to clause 7.1, each party's total aggregate liability in contract, tort (including negligence and breach of statutory duty howsoever arising), misrepresentation (whether innocent or negligent), restitution or otherwise, arising in connection with the performance or contemplated performance of this agreement or any collateral contract shall in all circumstances be limited to £500,000.00.

7.5 Any dates quoted for delivery of the Services are approximate only, and the time of delivery is not of the essence. Swansea shall not be liable for any delay in delivery of the Services that is caused by an event, circumstance or cause within the scope of clause 9 or the Cohort Owner's failure to provide Swansea with adequate data that is necessary to the supply of the Services or the Cohort Owner's failure to comply with clauses 3 and 4.

7.6 The Cohort Owner acknowledges that the Services to be provided by Swansea are wholly reliant on the Cohort Owner transferring its Cohort Owner Data to Swansea.

7.7 If any third party makes a Claim against Swansea, or notifies an intention to make a Claim against Swansea, Swansea shall:

- (a) give written notice of the Claim against Swansea to the Cohort Owner as soon as reasonably practicable;
- (b) not make any admission of liability in relation to the Claim against Swansea without the prior written consent of the Cohort Owner;
- (c) at the Cohort Owner's request and expense, allow the Cohort Owner to conduct the defence of the Claim against Swansea including settlement;
- (d) at the Cohort Owner's expense, co-operate and assist to a reasonable extent with the Cohort Owner's defence of the Claim against Swansea;
- (e) take all reasonable steps to mitigate its loss in respect of such Claim against Swansea.

7.8 Where Swansea is required to handle Personal Data, the liability provisions found within Schedule 2 shall take precedence.

8. TERM AND TERMINATION

8.1 This agreement shall commence on the Commencement Date and shall continue until terminated by either party by giving the other 30 days' notice in writing.

8.2 Any provision of this agreement that expressly or by implication is intended to come into or continue in force on or after termination of this agreement shall remain in full force and effect.

8.3 Termination of this agreement, for any reason, shall not affect the accrued rights, remedies, obligations or liabilities of the parties existing at termination.

8.4 On any termination of this agreement for any reason each party shall as soon as reasonably practicable:

- (a) return or destroy (as directed in writing by the other party) all Data, information, software, and other materials provided to it by the other party in connection with this agreement including all materials containing or based on the other party's Confidential Information
- (b) if the Cohort Owner elects for destruction rather than return of the materials under clause 8.4, Swansea shall as soon as reasonably practicable ensure that all Cohort Owner Data is deleted from UKSeRP.

8.5 If the Cohort Owner elects for return rather than destruction of the materials under clause 8.4(a) and Swansea receives, no later than ten days after the effective date of the termination or expiry of this agreement, a written request for the delivery to the Cohort Owner of the most recent back-up of the Cohort Owner Data, Swansea shall use reasonable commercial efforts to fulfil such request within 30 days of its receipt. If the Cohort Owner makes no such election within that ten-day period, the Swansea may destroy or otherwise dispose of any of the Cohort Owner Data in its possession.

8.6 Each party shall provide written confirmation of compliance with clause 8.4 and, in the case of the Swansea only, clause 8.4(b) (in the form of a letter signed by its [RELEVANT OFFICER]) no later than 14 days after termination of this agreement.

8.7 If a party is required [or requested] by any law, regulation, or government or regulatory body to retain any documents or materials that it would otherwise be required to return or destroy under clause 8.4, it shall notify the other party in writing of that retention, giving details of the documents or materials that it must retain. That party shall not be in breach of clause 8.4 with respect to the retained documents or materials, but clause 5 shall continue to apply to them.

9. FORCE MAJEURE

Neither party shall be in breach of this agreement nor liable for delay in performing, or failure to perform, any of its obligations under this agreement if that delay or failure results from events, circumstances or causes beyond its reasonable control. In such circumstances, the affected party shall be entitled to a reasonable extension of the time for performing such obligations.

10. ASSIGNMENT

10.1 This agreement is personal to the Cohort Owner and Swansea and neither shall assign, transfer, mortgage, charge, subcontract, declare a trust of or deal in any other manner with any of its rights and obligations under this agreement without the prior written consent of the other (which is not to be unreasonably withheld or delayed). For the avoidance of doubt this clause is not intended to limit a party's right to deal with any Intellectual Property Rights in the manner set out in this agreement.

11. WAIVER

No failure or delay by a party to exercise any right or remedy provided under this agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of any right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

12. RIGHTS AND REMEDIES

Except as expressly provided in this agreement, the rights and remedies provided under this agreement are in addition to, and not exclusive of, any rights or remedies provided by law.

13. NOTICE

13.1 Any notice or other communication given to a party under or in connection with this agreement shall be in writing and shall be delivered by hand or by pre-paid first class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case).

13.2 A notice given under this agreement is not valid if sent by email.

14. ANNOUNCEMENTS

No party shall make, or permit any person to make, any public announcement concerning this agreement without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except as required by law, any governmental or regulatory authority (including any relevant securities exchange), any court or other authority of competent jurisdiction.

15. ENTIRE AGREEMENT

15.1 This agreement constitutes the entire agreement between the parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

15.2 Each party acknowledges that in entering into this agreement it does not rely on, and shall have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this agreement.

15.3 Each party agrees that it shall have no claim for innocent or negligent misrepresentation based on any statement in this agreement.

16. VARIATION

Except as expressly provided in this agreement, no variation of this agreement shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

17. SEVERANCE

17.1 If any provision or part-provision of this agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of this agreement.

17.2 If any provision or part-provision of this agreement is invalid, illegal or unenforceable, the parties shall negotiate in good faith to amend such provision so that, as amended, it is legal, valid and enforceable, and, to the greatest extent possible, achieves the intended commercial result of the original provision.

18. NO PARTNERSHIP OR AGENCY

Nothing in this agreement is intended to, or shall be deemed to, establish any partnership or joint venture between any of the parties, constitute any party the agent of another party, nor authorise any party to make or enter into any commitments for or on behalf of any other party.

19. THIRD-PARTY RIGHTS

19.1 A person who is not a party to this agreement shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this agreement.

19.2 The rights of the parties to terminate, rescind or agree any variation, waiver or settlement under this agreement are not subject to the consent of any other person.

20. GOVERNING LAW

This agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

21. JURISDICTION

21.1 Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this agreement or its subject matter or formation (including non-contractual disputes or claims).

This agreement has been entered into on the date stated at the beginning of it.

SWANSEA UNIVERSITY

Signed: _____

Print: _____

Position: _____

Date: _____

COHORT OWNER

Signed: _____

Print: _____

Position: _____

Date: _____

SCHEDULES

SCHEDULE 1: THE SERVICES

DATA INCORPORATION

- Swansea will facilitate the transfer of Cohort Owner data as set out in Schedule 4.
- Cohort Owner data will be transferred onto the DPUK UKSeRP, where it will be housed in its own environment, readily accessible by the Cohort Owner's Permitted Person(s) and available for research access, subject to specific project approval.
- Incorporation of Cohort Owner Data will involve split-file anonymisation using a robust anonymisation process (where required) in conjunction with Swansea's trusted third party. Note this is a standard process which will be applied to all data incorporated, regardless of original format to enable linkability.
- Swansea will ring-fence the Cohort Owner Data once incorporated, housing it in a dedicated area of the UKSeRP awaiting creation of Interrogated Information (OD), or, subject to approval by SAP, Interrogated Information (TPR).

DPUK DATA PORTAL MANAGEMENT

- Swansea will manage Cohort Owner Data in accordance with the entirety of Clause 4.
- Swansea will provide access to the Permitted Person(s) nominated to the Cohort Owner Data.
- Swansea will create and manage user accounts within UKSeRP and their project permissions, from Permitted Person(s) to parties applying for access to Cohort Owner Data for the creation of Interrogated Information (TTP).
- Key services that will be provided include:
 - a) Processing of anonymised Cohort Owner Data to enable the creation of both Interrogated Information (OD) and Interrogated Information (TPR).
 - b) Ensure that Cohort Owner Data is sufficiently managed in accordance with SAP regulations before release for creation of Interrogated Information (TPR).
 - c) Follow an end-to-end project application and publications process in order to maintain the security and integrity of the Cohort Owner, their Data, DPUK and any other affiliated party.

SCHEDULE 2: SWANSEA: DATA PROCESSING PROCEDURES.

1. DATA PROCESSING PROCEDURES

1.1 The Cohort Owner and Swansea acknowledge that for the purposes of this Agreement, the Cohort Owner is the Data Controller and Swansea is the Data Processor of any Personal Data.

1.2 Swansea shall process the Personal Data

- (a) only to the extent, and in such a manner as is necessary for it to perform its obligations under this agreement, and not for any other purpose;
- (b) strictly in accordance with the Cohort Owner's instructions from time to time (including without limitation any request made by the Cohort Owner that Swansea amend, transfer or delete Personal Data, or to use or not use the Personal Data to communicate with Data Subjects in such terms and by such method as the Cohort Owner shall reasonably require); and
- (c) in compliance with the DPA and all other applicable laws, enactments, regulations, orders, standards and other similar instruments.

1.3 Swansea shall not:

- (a) disclose the Personal Data to any Data Subject or to a third party other than at the specific request of the Cohort Owner or as provided for in this Agreement; or
- (b) transfer the Personal Data outside the European Economic Area without the prior written consent of the Cohort Owner.

1.4 Swansea shall take appropriate technical and organisational measures against the unauthorised or unlawful processing of personal data and against the accidental loss or destruction of, or damage to, personal data to ensure the Cohort Owner's compliance with the seventh data protection principle.

1.5 Swansea shall notify the Cohort Owner immediately:

- (a) if any Personal Data is lost or destroyed or becomes damaged, corrupted, or unusable, in which case Swansea will arrange and bear the cost of restoring such Personal Data on the Cohort Owner's request and in accordance with the Cohort Owner's instructions; and/or
- (b) if Swansea becomes aware of any unauthorised or unlawful processing of the Personal Data, in which case Swansea will provide the Cohort Owner with full co-operation and assistance and comply with all the Cohort Owner's instructions in the handling thereof.

1.6 Swansea shall restrict access to the Personal Data to those of its employees who need access to the Personal Data to meet Swansea's obligations under this Agreement; and shall ensure that all such employees:

- (a) are informed of the confidential nature of the Personal Data;
- (b) have undertaken training in the laws relating to handling personal data; and
- (c) are aware both of Swansea's duties and their personal duties and obligations under such laws and this Agreement.

1.7 Swansea may only authorise a third party sub-contractor to process the Personal Data on its behalf:

(a) subject to the Cohort Owner's prior written consent where Swansea has supplied the Cohort Owner with full details of such sub-contractor; and

(b) provided that the sub-contractor's contract with Swansea:

(i) provides equivalent rights to the Cohort Owner against such sub-contractors and equivalent protections in relation to Personal Data as those set out in this clause 1 and

(ii) will terminate automatically on termination of this Agreement for any reason.

1.8 Swansea will keep a record of any processing of Personal Data it carries out on behalf of the Cohort Owner and shall:

(a) deal promptly and properly with all enquiries from the Cohort Owner concerning the Personal Data or its processing; and

(b) provide the Cohort Owner on request with a copy of all Personal Data held by it in the format and on the media reasonably specified by the Cohort Owner.

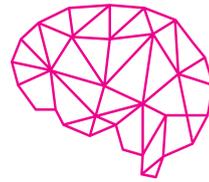
1.9 The Cohort Owner is entitled, on giving at least 14 days' notice (or, if the Cohort Owner believes that Swansea is in breach of any of its obligations under this clause 22, without notice) to Swansea, to inspect or appoint representatives to inspect all facilities, equipment, documents and electronic data relating to the processing of Personal Data by Swansea.

1.10 In the event of any complaint, notice or communication relating directly or indirectly to the processing of the Personal Data or to either party's compliance with the DPA (including without limitation a request from a Data Subject for access to that person's Personal Data) Swansea shall:

(a) immediately inform the Cohort Owner if any such complaint, notice or communication is received by Swansea from a third party; and

(b) provide the Cohort Owner with full co-operation and assistance and comply with all the Cohort Owner's instructions in the handling of any such complaint, notice or communication.

1.11 Swansea agrees to indemnify and keep indemnified the Cohort Owner against all costs, claims, damages or expenses incurred by the Cohort Owner or for which the Cohort Owner may become liable due to any failure by Swansea, its employees, agents or sub-contractors to comply with their obligations under this schedule or generally in relation to the processing of Personal Data.



Dementias
Platform^{UK}
Medical Research Council

DATA ACCESS AGREEMENT

VERSION 4, APRIL 2018

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THIS AGREEMENT is dated

BETWEEN

(1) **SWANSEA UNIVERSITY** an academic institution set up by royal charter having a registered address at Singleton Park, Swansea, SA2 8PP (“**Swansea**”)

(2) **[INSERT NAME]** of [address]

BACKGROUND

Dementias Platform UK (DPUK) brings together a number of universities and others in a common effort to build on existing national capabilities in order to implement a world-leading programme of research activity that will address the major burden of dementias associated with age-related neuro-degeneration.

The DPUK Data Portal is a data storage, analysis and linkage platform that is envisaged to be used as part of the DPUK project in order to integrate multiple cohorts for a comprehensive epidemiological research platform. The Portal will also aid the development of bio-informatics methods to support a large-scale experimental medicine platform and increase data linkage facilities. The DPUK Data Portal is hosted on an instance of UK Secure eResearch Platform at Swansea. Swansea manages the maintenance of and administration of access to the DPUK Data Portal on behalf of DPUK.

As a result of a successful Study application, Swansea is willing to grant access to certain data held within the DPUK Data Portal to the User[s] and User Institution[s] and this agreement governs the terms under which access will be granted.

In signing this agreement, You (defined below) are agreeing to be bound by the terms and conditions of access set out in this agreement.

For the sake of clarity, the terms of access set out in this agreement apply both to the User and the User’s Institution (as defined below). User Institution and User are referred to within the agreement as “**You**” and “**Your**” and shall be construed accordingly.

DEFINITIONS:

| | |
|-----------------------------|---|
| Anonymised | refers to the state of Data within the DPUK UKSeRP. Data provided will go through split-file anonymisation in order that Data is both robustly anonymised (double encryption between NHS Wales Informatics Service and Swansea) and standard in format. |
| Application | means the application made by the User attached at Appendix 2. |
| Bona Fide Research | means research that can be considered to be as follows: <ol style="list-style-type: none">1. An intention to generate new knowledge and understanding using rigorous scientific methods. (This includes discovery research, development and validation of methodology and technology, validating and challenging previous findings, and pilot research).2. An intention to publish the research findings and share the derived data in the scientific community, without restrictions and with minimal delay, for wider scientific and eventual public benefit. (Recognised constraints include a short prepublication delay to ensure proper management of intellectual property).3. The intended activities are not inconsistent with legal and ethical requirements or widely recognised good research practice. |
| Bona Fide Researcher | means any one researcher who should have the professional expertise to conduct bona fide research; and who has a formal relationship with a bona fide research organisation that requires compliance with appropriate research governance and management systems (MRC definition). |
| Cohort | means a group of Participants who share a common characteristic. |
| Data | means Anonymised data derived from a Cohort being used as part of a Study (defined below) including Interrogated Information. |
| Data Provider | means the organisation(s) that has/have agreed to share with DPUK its/their Data that is routinely collected within the organisation. |

| | |
|---------------------------------|---|
| DPUK | means the Dementias Platform UK Consortium – the overarching project with the aim of building a platform for experimental medicine that is used by scientists and industry by providing an environment that is optimal for translational research. |
| DPUK Data Portal | means the database that contains all the data obtained for use as part of the DPUK project, containing data linkage infrastructure and governance system provided by the UK Secure eResearch Platform; this also pertains to the virtual desktop infrastructure used to access DPUK Data. |
| Interrogated Information | means all reports which have been generated as a result of a User being afforded access to Data (via the SAP approval process). |
| Publication Process | means the process attached at Appendix 1. |
| Study | means the description of the research set out in the Application. |
| SAP | means the Study Approvals Panel, responsible for the governance review of DPUK projects, publications and outputs. The SAP will comprise Principal Investigators Representatives from each DPUK member whose Data has been approved for use in a Study, and representatives from any other Data Provider involved in a Study. |
| Study Period | [as set out in the DPUK study approval.] |
| User | means a researcher whose User Institution who is aware of and accepts the terms of this Data Access Agreement, and are party to this Data Access Agreement under the terms of signature. |
| User Institution | means the organisation at which the User is employed, affiliated or enrolled. |

TERMS AND CONDITIONS

Following your successful Study request to DPUK and in consideration of being afforded access to the Data relating to the Study defined within the Application, You agree as follows:

1. The Data that you have been afforded access to will be only the Data listed within the said Application, to include any amendments, whether this pertains to the addition or removal of Data from the Application. Updated versions including such amendments shall be appended at Appendix 2.
2. You are part of a DPUK Study that has adhered to the DPUK study application process and are requesting access to the study area and/or study specific DPUK data.
3. You agree to use the Data only for the purpose of performing the Study. You will not use the Data for any other purpose.
4. You agree that any amendments to the Study must be approved by SAP before You may use the Data for such amended purposes.
5. You agree to follow the Publication Process attached at Appendix 1 and the DPUK Publication Policy
6. This agreement shall be construed, interpreted and governed by the laws of England and Wales and shall be subject to the exclusive jurisdiction of the English courts.
7. You agree to:
 - use the Cohort Data entrusted to You for the public good and only as approved by the DPUK. -
 - acknowledge in any resulting publications the origins of the Cohort Data and the use of the DPUK Data Portal for access and analysis.
 - never make public the results of Your analysis that in Your reasonable option might result in an individual, or small groups of individuals, being identified.
 - abide by all relevant laws and codes of practice current at the time.
 - treat the Data You may view as strictly confidential; and use responsibly and take proper precautions with regard to the security of the Data.
8. You agree that if You suspect that the availability, integrity or security of the DPUK Data Portal is compromised in any way You will immediately notify Swansea.
9. You will not attempt to establish the identity of any individual to which the Data relates.
10. You understand and acknowledge that use of the Data granted under this Agreement should not be construed as conferring ownership of the Data, which are protected by copyright and other intellectual property rights.
11. You understand that no Data may be copied or electronically distributed, by any means and for any purposes, from the DPUK Data Portal; also that it may not be accessed for any purpose other than for the performance of a study that has been approved by the SAP and then only used as approved by the SAP
12. Swansea, the institutions comprising DPUK, the Data Provider(s) or guardians, depositors or copyright holders, or the funders of the collection of the Data shall not be liable for the use of the Data under this agreement. For the purposes of clause 20 the benefit conferred

by this clause 12 is intended to be enforceable by the persons referred to in it.

13. Swansea shall a) bear no legal responsibility for the accuracy or comprehensiveness of the Data; and b) accept no liability for indirect, consequential, or incidental, damages or losses arising from the unavailability of, or break in access to, the Data for whatever reason.

14. You agree that You will submit a report to the SAP, if requested, on completion of the [Study] and shall mark the report as “confidential information of [name of User Institution] communicated by Swansea University within the framework of the DPUK Programme” so that the members of DPUK are notified to treat the report and all information, data, results, and conclusions contained within such report as confidential information belonging to the User Institution.

15. You accept that the user account created for You will be used by Yourself only and no other individual.

16. You agree that any Data printed out for internal meetings shall be disposed of securely, for example by shredding, once it is no longer required. You will ensure that the person who printed Data ensures that all copies are disposed of. All printed Data must be kept for the minimum possible time and stored securely while not in use.

17. You agree to ensure that Your computer operating system, used to access the DPUK Data Portal, is, as far as possible, updated with the latest security patches, and that You will run reliable, effective and up-to-date anti-virus software. Failure to do this will result in Your (User) access privileges being revoked.

18. This agreement expires at the end of the Study Period. This agreement may be terminated by either party for any material or persistent breach of the obligations set out in this agreement, by giving thirty (30) days’ written notice to the other of its intention to terminate. The notice shall include a detailed statement describing the nature of the breach. If the breach is capable of being remedied and is remedied within the thirty-day notice period, then the termination shall not take effect. If the breach is of a nature such that it can be fully remedied but not within the thirty day notice period, then termination shall also not be effective if the party involved begins to remedy the breach within that period, and then continues diligently to remedy the breach until it is remedied fully. If the breach is incapable of remedy, then the termination shall take effect at the end of the thirty day notice period in any event. Confidentiality obligations shall continue to apply after termination and continue for 5 years beginning on the date of the termination or expiry.

19. These terms may only be varied by written agreement of the parties to this Agreement.

20. No one except a party to this agreement has any right to prevent the amendment of this agreement or its termination, and no one except a party to this agreement may enforce any benefit conferred by this agreement, unless this agreement expressly provides otherwise.

This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales. Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this agreement or its subject matter or formation (including non-contractual disputes or claims), except that an application for interim relief may be made to any court of competent jurisdiction.

APPENDIX 1 (DATA ACCESS AGREEMENT)

PUBLICATION PROCESS

Users wishing to publish results, Data (which may include Interrogated Information) and/or other information acquired/generated from their use of the DPUK Data Portal will inform the Swansea with prior written notice (including a reasonable summary of the proposed publication) at least thirty (30) days prior to submission of any such publication. Swansea will notify all the relevant Data Provider(s) in writing of the planned publication and information will be marked by You in accordance with clause 14.

The Data Provider will also be notified that they may object to or request a delay to a proposed publication for accuracy/patent reasons and/or require deletion of that Data Providers Confidential Information, provided such objection/request is submitted in writing to DPUK within twenty (20) days of receipt of the notification from DPUK. If this objection is upheld by DPUK the User will: (a) modify or delay the publication as reasonably requested; and/or (b) delete such Confidential Information from the intended Publication.

The Data Provider will also be notified that if they do request a delay on the submission of a publication, such delay shall not last longer than is absolutely necessary to seek the required approvals; and therefore shall not exceed there (3) months from the date of receipt of the proposed publication.

All approved publications arising from the use of the DPUK Data Portal shall give due credit to the Parties involved and shall also acknowledge the participation of the Data Provider, unless requested to the contrary by the Data Provider.

APPENDIX 2 (DATA ACCESS AGREEMENT)

APPLICATION

DATA ACCESS AGREEMENT

I have read the terms and conditions set out in the Dementias Platform UK Data Access Agreement version 1.4 and agree to be bound by them. I declare that I am not currently being investigated under data protection legislation applicable in the UK or in the past been found to be in breach of such legislation.

Researcher

Name: _____

Job Title: _____

Organisation: _____

Signature: _____

Date: _____

Institution Authorised Signatory

I confirm for and on behalf of my Organisation that the Organisation is liable also for any breach of these terms and conditions.

Name: _____

Job Title: _____

Organisation: _____

Signature: _____

Date: _____

**SCHEDULE 4:
COHORT OWNER DATA**

SCHEDULE 5: STUDY APPROVALS PANEL (SAP) REMIT

The SAP shall ensure that a DPUK UKSeRP User shall not be permitted access to Cohort Owner Data where such a request will result in, in the SAP's opinion, a sufficiently low level of data that could result in the DPUK UKSeRP User identifying an individual through the access of other external data.

Further considerations will be made on analytic methodology, ethical approvals and funding, however approvals are fully at the discretion of the study-specific SAP members.

The SAP will be comprised of relevant Principal Investigator's from Cohort Owner's whose Cohort Owner Data has been requested, supported by Swansea. In most cases, represented cohorts will have their own information governance committee, who will consider applications for Cohort Owner Data for the creation of Interrogated Information (TPR).

In situations where the cohort does not have an information governance committee, the study applications will be considered at the discretion of the cohort principal investigator(s) directly.



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