COLLABORATION DATA SHARING AGREEMENT

THIS AGREEMENT dated is made **BETWEEN**:

(1) **UNIVERSITY OF KEELE,** a university established by the University of Keele Act 1962 (10 &11 Eliz. 2 Ch Xv) and the granting of a Royal Charter in 1962, of Keele, Staffordshire ST5 5BG; ("**Keele**");

(2) **INSERT FULL PARTNER NAME,** whose administrative offices are at [please complete] **("the Data Provider")**.

each a "Party" and collectively "the Parties".

RECITALS

A. Keele, on behalf of North Staffordshire CCG, is the Lead Organisation for a research project called "Maximising outcome for patients with shoulder pain: using optimal diagnostic and prognostic information to target treatment (PANDA-S)", which is funded by the National Institute for Health Research and Arthritis Research UK; and

B. The Research Programme includes an Individual Participant Data (IPD) meta-analysis of randomised clinical trials, as detailed in Schedule 1; and

C. To complete the IPD meta-analysis, other organisations are requested to send data from previous randomised clinical trials to Keele; and

D. The Partner has relevant data from one or more randomised clinical trials and is willing to share it with Keele for the completion of the PANDA-S IPD meta-analysis; and

E. Keele now wishes to put in place an agreement with the Partner to define the rights and obligations with respect to the data transfer.

It is agreed by the Parties:

1. DEFINITIONS

1.1. The following expressions shall have the following meanings in this Agreement including its recitals, unless the context requires otherwise:

"Agreement"	means this collaboration data sharing agreement and the schedules annexed to and forming part of this agreement;

"Analysis Outputs"	the data and other material generated through analysis and/or manipulation of the Input Data provided by the Data Provider as well as equivalent data provided by other participating organisations;
"Application"	means the application made by the Parties to the Funder in relation to the Research and as incorporated in the Main Contract "Maximising outcome for patients with shoulder pain: using optimal diagnostic and prognostic information to target treatment (PANDA-S)" as set out in Schedule 2;
"Associate Investigator"	means the lead investigator responsible for the design, conduct and delivery of the PANDA-S IPD meta-analysis;
"Background Intellectual Property"	means any Intellectual Property excluding Foreground Intellectual Property owned or controlled by any Party prior to commencement of, or independently from the Research Programme, and which the owning Party contributes or uses in the course of performing the Research;
"Confidential Information"	means information of any form, however conveyed and irrespective of the media on which it is stored that is: a) information which has been designated as confidential by a Party; or b) information that reasonably ought to be considered as confidential including information which relates to the business, affairs, properties, assets, trading practices, goods/services, developments, trade secrets, Intellectual Property, know-how, personnel, customers and suppliers and commercially sensitive information of a Party; or c) Personal Data and Sensitive Personal Data within the meaning of the Data Protection Legislation, as amended from time to time;
"Data Protection Legislation"	means the Data Protection Act 1998 and, from the date it comes in to force, the General Data Protection Regulation (EU) 216/67 in addition to any other applicable laws relating to the processing of personal data and privacy;
"Data Provider"	means the organisation providing the individual patient data from previous randomised clinical trials to Keele;
"Foreground Intellectual Property"	means any Intellectual Property which is generated or first reduced to practice by any Party or Parties directly as a result of the work undertaken in accordance with this Agreement;

"Input Data"	means anonymised digital individual patient data resulting from clinical trials provided by the Partner;
"Intellectual Property"	means any intellectual property rights of any description including but not limited to patents, copyright, design rights, trade marks, data rights, database rights, know-how, trade secrets, and related rights whether registerable or not and including any applications and all similar rights in inventions, computer programs, designs, semiconductor topography rights, and any other intellectual property rights;
"Lead Organisation"	means the University of Keele;
"Output Data"	means the data and other material generated through analysis and/or manipulation of the Input Data provided by the Data Provider as well as equivalent data provided by other participating organisations;
"Permitted Users"	means those who are authorised by the Programme Steering Committee to access and use the IPD, including, but not limited to, the Chief Investigator, study statisticians, and members of the Programme Steering Committee.
"Programme Steering Committee"	means the oversight committee for the Research Programme as more particularly described in Schedule 2;
"Study Team"	means the Associate Investigator, statisticians, database manager, and coordinators who are responsible for collecting, handling, analysing and archiving Input Data, reporting and disseminating results of the PANDA-S IPD meta-analysis, as detailed in Schedule 1.

In this Agreement, references to Clauses and Schedules refer to clauses and schedules of this Agreement; and the singular form of any word includes the plural, and vice versa, as required by the context.

THE PARTIES HEREBY AGREE:

2. DATA TRANSFER FROM DATA PROVIDER TO KEELE

2.1 The Data Provider shall transfer non-identifiable data from one or more randomised clinical trials, as per Schedule 3, to Keele to allow the use and processing of such Input Data for further statistical and research analysis by the Permitted Users in accordance with the protocol detailed in Schedule 1.

2.2 The Study Team will process any data comprised within the Input Data only for such purposes as are reasonably necessary in accordance with this Agreement. Keele will use best endeavours to ensure that it has in place and will maintain appropriate technical and

organisational measures against unauthorised or unlawful processing of the Input Data and against accidental loss or destruction of or damage to the Input Data.

2.3 The Data Provider acknowledges that Input Data will be integrated with data provided by other participating organisations in order to enable Permitted Users to conduct further research in accordance with Schedule 1, and to create Output Data.

2.4 If additional analyses, not listed in Schedule 1, are required then a contract Variation Agreement will be sent to the Data Provider in accordance with clause 13.7 of this Agreement.

2.5 The Data Provider warrants and undertakes that the Input Data are the result of one or more randomised clinical trials conducted in accordance with the principles of Good Clinical Practice and Academic Standards, in accordance with the laws and procedures as to the direction and conduct of medical studies involving patients applicable in the country where the clinical trial is performed, in particular in accordance with the rules and regulations regarding patient's informed consent. These Standards, Procedures and Laws are considered compliant with the requirements of the Declaration of Helsinki (amended by the 59th WMA General Assembly, Seoul, October 2008) on the subject of Clinical Trials.

2.6 The Data Provider warrants and undertakes that it has complied with and shall continue to comply with all relevant legislation, regulations, codes of practices, guidance and other requirements of any relevant government or governmental agency as may apply to the Data Provider's possession and disclosure of the Input Data to Keele.

2.7 The Data Provider warrants that it has the authority to enter into this Agreement and that the processing of the Input Data by Keele in the manner envisaged by this Agreement does not and shall not breach any provision of any applicable legislation or agreement or understanding with other parties or individuals.

2.8 The Data Provider shall indemnify and hold harmless Keele against any and all loss, claim or expense suffered by Keele as a result of the Data Provider's breach of clause 2 of this Agreement.

3. PAYMENT

3.1 There will be no financial payment for the provision of the Input Data.

4. CONFIDENTIALITY

4.1 Subject to the remainder of this clause 4, each Party undertakes to keep secret and strictly confidential any Confidential Information and not disclose to any third party any Confidential Information nor use for any purpose except as expressly permitted by this Agreement, of any other Party.

4.2 The obligation in clause 4.1 shall survive termination of this Agreement for five (5) years, but will not apply to information which:

4.2.1 is known to the receiving Party before the start of this Agreement, and not impressed already with any obligation of confidentiality to the disclosing Party; or

4.2.2 is or becomes publicly known without the fault of the receiving Party; or

4.3.3 is obtained by the receiving Party from a third party in circumstances where the receiving Party has no reason to believe that there has been a breach of an obligation of confidentiality owed to the disclosing Party; or

4.2.4 is independently developed by the receiving Party; or

4.2.5 is approved for release in writing by an authorised representative of the disclosing Party; or

4.2.6 the receiving Party is specifically required to disclose in order to fulfil an order of any Court of competent jurisdiction, or is required to disclose by law or regulatory authority provided that, in the case of a disclosure under the Freedom of Information Act 2000, none of the exemptions in that Act applies to the Confidential Information.

4.3 If any Party receives a request under the Freedom of Information Act 2000 ("FOIA") and the Environmental Information Regulations 2004 ("EIR") to disclose any Confidential Information, it will notify and consult with the other Parties whose Confidential Information may be threatened with the disclosure. The other Parties will respond within five (5) working days after receiving notice if the notice requests assistance in determining whether or not an exemption in the EIR and/or FOIA applies. The final decision as to whether any Confidential Information shall be disclosed in response to a request under EIR or FOIA rests with the party in receipt of the request.

4.4 Each Party shall defend, fully indemnify and keep indemnified each of the other Parties, its officers, employees and agents from and against any and all liabilities, losses, costs, charges and expenses incurred (either directly or indirectly) as a result of any claims, demands, actions and proceedings made or brought against that other Party by any third party in respect of any loss or distress suffered by the loss or unauthorised disclosure of Personal Data, or Special Categories of Personal Data as defined in the Data Protection Legislation, or medical records by the indemnifying Party, or any employees, agents or person within its control.

5. PUBLICATIONS

5.1 Keele intends to publish the Output Data results of the analyses of the Input Data, in reputable scientific and medical journals and at scientific conferences via poster or oral presentations. Publications will be made in the name of all Partners, with one authorship being offered to the Principle Investigator (or other representative) of each Input Dataset.

5.2 Authorship and acknowledgements, of any publications relating to the IPD meta-analysis, shall follow the International Committee of Medical Journal Editors (ICMJE) criteria. According to these guidelines, authorship credit is based only on (i) substantial contribution to concept and design, or acquisition of data, or analysis and interpretation of data; and (ii) drafting or reviewing the manuscript for essential intellectual content; and (iii) approval of the final version to be published. All three aforementioned criteria must be fulfilled. Consistent with these and major journal guidelines, those individuals who meet all authorship criteria should be named as authors and those who do not should be acknowledged elsewhere, if appropriate.

5.3 In addition to clause 5.2, the Associate Investigator will be the first author for the main publication from the PANDA-S IPD meta-analysis.

5.4 Keele must notify the Funder prior to publication or dissemination (whether in oral, written or other form) of the Output Data. The Partner shall notify Keele of any publications that arise from the Output Data by sending one draft copy of the proposed publication to Keele seven (7) days prior to the date of submission for publication, or at least twenty eight (28) days before the intended publication date, whichever is earlier. Keele shall then forward the draft copy to the Funder at the same time as submission for publication, or at least twenty-eight (28) days before the intended publication date, whichever is earlier.

5.5 Any journal publication fees (or similar) shall be payable by the Party who at the time of publication is employing the lead author, unless the relevant Parties agree otherwise.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 For the avoidance of doubt all Background Intellectual Property used in connection with the Research Programme shall remain the property of the Party introducing the same (or its licensors). 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. The Parties agree that any improvements or modifications to a Party's Background Intellectual Property arising from the Research Programme which are not severable from that Background Intellectual Property will be deemed to form part of that Party's Background Intellectual Property.

6.2 The Data Provider grants Keele an irrevocable, royalty-free, non-exclusive licence for to use its Input Background Intellectual Property for the sole purpose of carrying out the IPD meta-analysis as part of the PANDA-S Research Programme. No Party may grant any sub-licence over or in respect of any other Party's Background Intellectual Property.

6.3 The Data Provider grants Keele an irrevocable, royalty-free, non-exclusive licence for to use its Input Background Intellectual Property for the sole purpose of carrying out the IPD meta-analysis as part of the PANDA-S Research Programme. No Party may grant any sub-licence over or in respect of any other Party's Background Intellectual Property.

7. ASSIGNMENT

7.1 No party will assign this Agreement without the prior written consent of the other Parties, such consent not to be unreasonably withheld, denied or delayed.

8. DURATION AND TERMINATION

8.1 This Agreement shall become effective on the date this Agreement is signed by the last Party and shall remain in force until termination in accordance with this clause.

8.2 Either Party ("the Withdrawing Party") may terminate its status as a Party to this Agreement on six (6) months' written notice to the other Party. The Withdrawing Party shall comply with any conditions that may be imposed by Keele which shall include (without limitation), unless otherwise agreed:

8.2.1 to the extent that exploitation by Keele of Foreground Intellectual Property is dependent upon the Withdrawing Party's Background Intellectual Property, then the Withdrawing Party shall, to the extent that it is free to do so, grant to Keele a non-exclusive licence to such Background Intellectual Property on fair and reasonable terms to be agreed;

8.3 In the event that a Party is in material breach of this Agreement (the "Breaching Party") then the other Party (the "Non-Breaching Party") may at any time serve notice on the Breaching Party to remedy the breach. If the breach is capable of remedy and the Breaching Party has not remedied or taken such steps as are reasonable in the circumstances to begin to remedy it within thirty (30) days of receiving written notice of such breach, then the Breaching Party's status as a party to the Agreement shall be terminated immediately;

8.4 In the event that a Party is in material breach of this Agreement (the "Breaching Party") then the other Party (the "Non-Breaching Party") may at any time serve notice on the Breaching Party to remedy the breach. If the breach is capable of remedy and the Breaching Party has not remedied or taken such steps as are reasonable in the circumstances to begin to remedy it within thirty (30) days of receiving written notice of such breach, then the Breaching Party's status as a party to the Agreement shall be terminated immediately.

8.5 In the event that Keele identifies serious and/or persistent non-compliance with the obligations outlined in clause 2.5 of this Agreement, Keele will have the right to terminate the Agreement with immediate effect and to remove the Input Data from the PANDA-S IPD meta-analysis.

8.6 In the event of termination, Input Data that have already been analysed and used to generate Output Data will be kept available by the Data Provider for monitoring and/or auditing purposes for a period of 15 years after termination.

8.7 Subject to earlier termination in accordance with its terms, this Agreement shall remain in force until the expiry of the Research Period whereupon it shall automatically terminate. Termination of this Agreement for whatever reason shall not affect the accrued rights of the Parties arising in any way out of this Agreement as at the date of termination, and any provisions which are expressly stated or impliedly understood to survive this Agreement shall remain in full force and effect including without limitation Clauses 2, 4 to 8. Clause 6.2 shall survive whilst the relevant Party remain owner of the relevant copyright.

9. LIMITATION OF LIABILITY

9.1 No Party makes any representation or warranty that the content or use of any materials, works or information provided in connection with the PANDA-S IPD meta-analysis, will not constitute or result in infringement of third-party rights.

9.2 Subject to Clause 9.3, no Party accepts any responsibility for any use which may be made of any work carried out under or pursuant to this Agreement, or of the results of the PANDA-S IPD meta-analysis, nor for any reliance which may be placed on such work or results, nor for advice or information given in connection with them.

9.3 The Parties undertake to make no claim in connection with this Agreement or its subject matter against any employees, students, agents or appointees of the other Parties (apart from claims based on fraud or wilful misconduct). This undertaking is intended to give protection to individual researchers: it does not prejudice any right which a Party might have to claim against any other Party.

9.4 The liability of any Party for any breach of this Agreement, or arising in any other way out of the subject-matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

9.5 In any event, except for the indemnities in clause 9.7, the maximum liability of either Party shall not exceed £ (one) 1 million GBP.

9.6 Nothing in this Agreement limits or excludes either Party's liability for:

9.6.1 death or personal injury resulting from negligence; or

9.6.2 wilful misconduct or fraud or fraudulent misrepresentation; or

9.6.3 any other liability which, by law, cannot be limited or excluded.

9.7 If any sub-clause of this Clause 9 is held to be invalid or unenforceable under any applicable statute or rule of law then it shall be deemed to be omitted, and if as a result any Party becomes liable for loss or damage which would otherwise have been excluded then such liability shall be subject to the remaining sub-clauses of this Clause 9.

10. NOTICES

Keele's representative for the purpose of receiving reports and other notices shall until further notice be:

Head of Legal and Compliance
Directorate of Research, Innovation and Engagement
Innovation Centre 2
Keele University Science & Innovation Park
Keele University
Staffordshire
ST5 5NH

The Data Provider's representatives for the purpose of receiving reports and other notices shall until further notice be:

[name/role]
[address]

11. FORCE MAJEURE

11.1 A Party shall not be liable for failure to perform its obligations under this Agreement, nor be liable to any claim for compensation or damage, nor be deemed to be in breach of this Agreement, if such failure arises from an occurrence or circumstances beyond the reasonable control of that Party (excluding an obligation to make payment).

12. EQUALITY, ANTI-BRIBERY AND MODERN SLAVERY

12.1 In carrying out its obligations under this Agreement each Party will:

12.1.1 comply with all laws, statutes, regulations, case law and regulatory guidance which apply to it or its activities and which relate to:

12.1.2 anti-bribery and anti-corruption, including the Bribery Act 2010;

12.1.3 equality, including the Equality Act 2010;

12.1.4 modern slavery, including the Modern Slavery Act 2015;

12.1.5 adopt, maintain and follow appropriate policies and procedures to secure such compliance; and

12.1.6 ensure that its employees, students, group companies, subcontractors, agents and their respective employees comply with the terms imposed by these provisions.

13. GENERAL

13.1 Clause headings are inserted in this Agreement for convenience only, and they shall not be taken into account in the interpretation of this Agreement.

13.2 Nothing in this Agreement shall create, imply or evidence any partnership or joint venture between the Parties or the relationship between them of principal and agent.

13.3 Each Party shall ensure that it has well defined arrangements for investigating and resolving allegations of research misconduct. Where an allegation of research misconduct arises in respect of the Partner's participation and leads to a subsequent formal investigation, the Partner shall inform Keele of the investigation and its outcome.

13.4 No Party shall use the name or any trade mark or logo of any other Party or the name of any of its staff or students in any press release or product advertising, or for any other commercial purpose, without the prior written consent of the Party(s).

13.5 Except as otherwise expressly provided for herein, the Parties confirm that nothing in this Agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this Agreement for the purposes of the Contracts (Rights of Parties) Act 1999.

13.6 The Parties shall procure that in carrying out the PANDA-S IPD meta-analysis they comply with the Data Protection Legislation.

13.7 This Agreement and its Schedules (which are incorporated into and made a part of this Agreement) constitute the entire agreement between the Parties for the transfer of Input Data for use in the PANDA-S IPD meta-analysis and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement. Any variation shall be in writing and signed by authorised signatories for each Party.

13.8 This Agreement shall be governed by English Law and the English Courts shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Agreement.

13.9 If any dispute arises out of this Agreement the Parties will first attempt to resolve the matter informally through designated senior representatives of each Party to the dispute, who are not otherwise involved with the IPD meta-analysis. If the Parties are not able to resolve the dispute informally within a reasonable time not exceeding two (2) months from the date the informal process is requested by notice in writing, they will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure.

13.10 If any one or more clauses or sub-clauses of this Agreement would result in this Agreement being prohibited pursuant to any applicable competition law, then it or they shall be deemed to be omitted. The Parties shall uphold the remainder of this Agreement, and shall negotiate an amendment which, as far as legally feasible, maintains the economic balance between the Parties.

13.11 This Agreement may be signed, including by exchange of document; or in portable document format (pdf) sent by email, in any number of counterparts, each of which will constitute an original of this Agreement, and all counterparts will together constitute the same agreement. No counterpart will be effective until each Party has executed at least one counterpart.

Agreed by the Parties through their authorised signatories:

SIGNED for and on behalf of **UNIVERSITY OF KEELE**

Name:

Position:

Signature:

SIGNED for and on behalf of **[INSERT PARTNER NAME HERE]**

Name:

Position:

Signature:

Schedules:

Schedule 1: IPD meta-analysis protocol including description of anonymous data provided by the Data Provider
Schedule 2: Programme Steering Committee details
Schedule 3: Data Protection Particulars

Schedule 1: IPD meta-analysis protocol including description of anonymous data provided by the Data Provider

protocol PANDA-S
IPD meta-analysis - v

Schedule 2: Programme Steering Committee (PSC)

The PANDA-S IPD meta-analysis is one of 4 components of the PANDA-S research programme ("Maximising outcome for patients with shoulder pain: using optimal diagnostic and prognostic information to target treatment", which is funded by the National Institute for Health Research and Arthritis Research UK. Oversight of the entire programme is provided by the PANDA-S Programme Steering Group.

The PSC includes an independent Chair (Dr D Hind, University of Sheffield), four independent members (one of whom is a statistician (professor Nicola Cooper, University of Leicester) and one of whom will represent the interests of patients and the public (Mr John Haines), and up to three members of the research team, including the CI, lead statistician, and Associate Investigator. Representatives of the Sponsor, Funder, and a representative of University of Oxford (collaborator) will be invited to all meetings. Additional members of the research team will attend meetings at the discretion of the PSC Chair

The PSC will:

- meet at least annually, and more frequently if judged necessary
- provide expert advice during the conduct of a programme that is independent of the Investigators, and supervise the overall Research Programme, on behalf of NIHR and the Sponsor
- monitor progress - against pre-agreed milestones (such as identification of relevant trials, requesting trial data, data analysis, and reporting and adherence to the agreed protocol. They will review any new evidence from the Research Programme or externally
- advise on proposed changes to the Research Programme's plans in light of new evidence or other unanticipated development
- provide written evidence to support any requests for additional funding or time extensions, indicating that all practical steps have been taken by the investigators to achieve targets and/or that changes to the planned work are fully justified
- encourage appropriate efforts to disseminate the Research Programme's findings

Schedule 3: Data Protection Particulars

The subject matter and duration of the Processing	This meta-analysis will test candidate treatment effect moderators by collating and synthesising Individual Participant Data (IPD) from multiple previously published randomised clinical trials of commonly used interventions (advice and pain relief, corticosteroid injection, exercise and/or mobilisation, or surgery) in patients with shoulder pain. The team at Keele will request anonymised IPD from each eligible trial (nationally and internationally), after their main results have been published in peer reviewed journals. Eligible trials have been identified from systematic searches of the literature (see IPD meta-analysis protocol). Data will be requested from trial teams (Partners) between March 2018 and June 2019. Data analysis will take place between July 2018 and December 2019. The trial teams will be represented in publications arising from this analysis.
The nature and purpose of the Processing	The Keele IPD meta-analysis team will request and only accept anonymised data (without any identifiable data such as name, address, date of birth, health insurance number); trial participants should have been allocated an individual participant code. Anonymising of data, if not already conducted as part of the primary analysis of the trial, will be done by the collaborator *prior to* transferring data to Keele University. Once data have been transferred to Keele, data will be checked for completeness and any queries will be discussed with the data provider. Collaborators will be notified immediately if personal (identifiable) data appear to have been transferred, and the dataset will immediately be removed from Keele drives. Data analysis using anonymised data by the Keele IPD meta-analysis team will include: (i) descriptive analysis of patient characteristics for each trial dataset to ensure Keele has received the correct dataset; (ii) harmonisation of data to allow meta-analysis; (iii) analysis of overall treatment effect within each trial dataset; (iv) analysis of treatment*moderator interactions within each trial dataset; (v) random effects meta-analysis combining estimates of interactions across datasets.
The type of Data being Processed	The Keele IPD meta-analysis team will request the following data: - All baseline characteristics, including participant code; demographic characteristics; clinical characteristics of the shoulder condition (e.g. previous episodes, duration,

	severity, impact on function and sleep, previous treatments, treatment preferences); coexisting neck pain; comorbidities; psychological or social characteristics; and any of the other candidate moderators listed in the protocol. - Randomisation code, indicating the type of treatment allocated to trial participants; (if available) variables indicating non-adherence to protocol during the treatment period (protocol deviations); duration of treatment and number of sessions where this varies between trial participants. - Data on pain and function (any scale), at baseline and at each follow-up time point. If existing multi-item scales have been used, also include the final scores. If scales are multi-dimensional, include subscales (e.g. pain and function subscale for SPADI). Datasets will be accepted in any form, provided that all data are anonymised and variables and categories are adequately labelled in English. Ideally the format will be a two-dimensional spreadsheet with one participant per row and variables listed in columns, and different time points on separate spreadsheets.
The categories of Data Subjects	The IPD meta-analysis will include all participants who provided informed consent to take part in the included trials, and were randomised. This concerns adult patients with general or non-specified shoulder pain; or diagnosed with (i) subacromial conditions, including rotator cuff tears, rotator cuff tendinopathy or subacromial bursitis; (ii) frozen shoulder or adhesive capsulitis; (iii) glenohumeral osteoarthritis; (iv) shoulder instability. The IPD meta-analysis will not include trials focusing on acute trauma (fractures, traumatic dislocations); inflammatory arthritis; shoulder pain resulting from cervical radiculopathy, or stroke-related shoulder pain.

Information Security

The data will not be used for any other research apart from that described in the data sharing agreement. Datasets will be accepted in any form, provided that all data are anonymised and variables and categories are adequately labelled in English. Ideally the format will be a two-dimensional spreadsheet with one participant per row and variables listed in columns, and different time points on separate spreadsheets.

Collaborators who have agreed to take part in the project and have signed the data sharing agreement will be invited to send their anonymised dataset as an encrypted file to Keele

University. They will be provided with guidance from Keele CTU regarding the use of 7-Zip to encrypt Files and Folders, and the Keele CTU working instructions for sending of encrypted data via email (used for non-identifiable data only). Prior to data transfer, there will be a process (including telephone / skype video call) to verify that the person receiving the data is the accurate and intended recipient for the data (CI: Danielle van der Windt) or one of the other members (Opeyemi Babatunde or Richard Riley) of the PANDA-S IPD meta-analysis project). Next, as stipulated in the Keele CTU working instruction, the encrypted zip archive file will be transferred to Keele via http://sendfile.keele.ac.uk. Once the file has been uploaded, the data receiver will be called to provide them with the password. (The pass word will not be communicated using the same medium as the data). Once the data receiver has downloaded the data, the collaborator will receive a confirmation email (sent by the send file application) informing the collaborator that the file has been downloaded. If the file is not downloaded within a set expiry time (e.g. 5 working days) the file will disintegrate.

Any additional processes or requirements for data transfer stipulated by collaborating institutions will be adhered to.

The data will be stored on a secure drive at Keele University, with access limited to the IPD Associate Investigator, meta-analysis statisticians, study coordinator, and CI.