

National COVID-19 Chest Image Database - Data Sharing Agreement

THIS AGREEMENT is made on [insert date]	
1	<p>Between: NHS England Covid Data Hub and organisations in the Enrollment Log.</p> <p>Organisations on the Enrollment Log referred to as “Company” throughout.</p>
2	<p>Definitions For definitions of purpose and datasets see DPIA.</p>
3	<p>Purpose, objectives of the information sharing:</p> <p>The data is shared with NHSX by the hospitals and Trusts wanting to participate in the National COVID-19 Chest Image Database.</p> <p>The data shared by each Party will be included in the National COVID-19 Chest Image Database (NCCID). The database will be used by researchers, radiologists and technology developers, to enable the validation and development of automated analysis technologies, and to promote research projects in response to the COVID-19 pandemic. Access to data will be granted and managed by NHSX. Each Party wanting to have access to the database will have to submit a request to NHSX. Upon approval, access will be permitted for free and via a bespoke platform (the “Platform”)</p> <p>The data will be solely used for analyses, research and for the development of technology tools (such as AI) to support healthcare staff in the response to the COVID-19 crisis.</p>
4	<p>Data Protection</p> <p>Although each of the Database Images is provided with the accompanying Related Data all Related Data is anonymised and no information or material is passed to the Company in any form that will or is likely to reveal the identity of the subjects of the Database Images or Related Data or any other individual. Company shall not, and shall procure that the Researchers shall not attempt to obtain any personal information, or in any other way take steps to identify the subjects of the Cases.</p> <p>In the event that Company obtains or otherwise becomes aware that it is in possession of personal information that may be used to identify the subject of any Database Images or Related Data, then it shall inform NHSX and Institution and cease all use of and return all such information to NHSX immediately.</p> <p>Company shall itself, and will procure that each Researcher shall, comply with all applicable laws relevant to the handling, storage and use of the Cases (including, among others, those relating to the storage, processing and use of the Cases arising under the Data Protection Act 2018 or General Data Protection Regulation, as amended from time to time, or equivalent provisions under local and national legislation no less onerous than those contained in such applicable laws).</p>

4	<p>Data Protection Impact Assessment (DPIA)</p> <p>Separate document available on request.</p>
5	<p>Legal powers for processing the data/information</p> <p>Drafting note: Under Article 5.1(a) of the GDPR Personal Data must be processed “lawfully”.</p> <p>Private sector organisations are able to do anything so long as it is not prohibited by legislation. This means that they can share and Process Personal Data, provided this does not breach the GDPR and other data protection laws.</p> <p>The same is not true for public bodies (like NHS England, local authorities, NHS Trusts, NHS Foundation Trusts, CCGs) that have been set up by legislation. Those organisations can only do what legislation empowers them to do, and they can only do things for the purpose given to them by legislation. So for the processing of Personal Data to be done “lawfully” by one of these public bodies the public body must:</p> <ul style="list-style-type: none"> • Have the “power” to Process and share Personal Data. <p>NHS England, CCGs and local authorities have the power under the NHS Act 2006, Schedule 1, paragraph 13(3) to obtain and analyse data.</p> <p>Other public bodies may not have a power that expressly mentions obtaining and analysing data but they often have the power to do anything that is “incidental” or “conductive” to carrying out the tasks given to them by legislation. The processing of Personal Data will usually come within this.</p> <p>The same is true of sharing information. There are some cases where public bodies are expressly given the power to disclose information in particular circumstances but these cases are not the norm. A power to do anything that is “incidental” or “conductive” to carrying out the tasks given to a public body by legislation will usually cover the sharing of Personal Data. Under section 2 of the NHS Act 2006, NHS England has the power to do anything calculated to facilitate, or that is conducive or incidental to the discharge of any of the tasks given to it by the NHS 2006 Act.</p> <ul style="list-style-type: none"> • Be processing the Personal Data for a purpose authorised by legislation. <p>Where a Party is a public body set up by legislation please specify (1) the powers and (2) statutory purpose that enables it to process data in the way set out in this Agreement.</p> <p>For the reasons outlined above, this section does not have to be completed for private sector organisations.</p> <p><u>Legal powers to receive, share and analyse data</u></p> <p><u>NHS England</u></p> <ul style="list-style-type: none"> • NHS Act 2006, Schedule 1, paragraph 13(3) to obtain and analyse data. • NHS Act 2006, Section 2 gives NHS England the power to do anything calculated to facilitate, or that is conducive or incidental to the discharge of any of the tasks given to it by the NHS 2006 Act. This includes sharing data when this is done for a proper purpose <p><u>Statutory purpose</u></p> <p><u>NHS England:</u></p> <p>COPI Regulation Notice:</p> <p>to require organisations to process confidential patient information for the purposes set out in Regulation 3(1) of COPI to support the Secretary of State’s response to Covid-19 (Covid-19 Purpose). “Processing” for these purposes is defined in Regulation 3(2) and includes dissemination of confidential patient information to persons and organisations permitted to process confidential patient information under Regulation 3(3) of COPI.</p>
6	<p>Data Controller(s)</p> <p>NHS England and the Department of Health are joint Data Controllers, supported by staff employed by any of the other Parties</p> <p>The Data Processors are:</p> <p>1) The Scientific Computing team of Royal Surrey County Hospital will be the data collector</p>

	<p>2) Faculty will provide the Platform environment to manage the data storage (on infrastructure owned by NHSX), enable data analysis, and allow for the testing and deployment of technology tools</p> <p>3) Third party technology developers will access the data and the Platform to create and validate software tools for the interpretation of chest X-Rays, CTs and MRIs of suspected COVID-19 patients</p> <p>4) Third party entities (including Faculty) will utilise the data and the Platform to audit technology tools (such as AI products) to ensure they are robust, safe and useful for COVID-19 response, they will be referred to as auditors.</p> <p><u>Due Diligence - Processors and Third Parties</u></p> <ul style="list-style-type: none"> • Royal Surrey County Hospital NHS Foundation Trust: IG Toolkit Compliant • Faculty: due diligence conducted previously during contract award 										
7	<p>Data items to be processed</p> <table border="1" data-bbox="347 745 1343 1223"> <thead> <tr> <th data-bbox="347 745 826 813">Data Item</th> <th data-bbox="826 745 1343 813">Justification</th> </tr> </thead> <tbody> <tr> <td data-bbox="347 813 826 913">CT imaging scans</td> <td data-bbox="826 813 1343 913">For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients</td> </tr> <tr> <td data-bbox="347 913 826 1014">X-Ray imaging scans</td> <td data-bbox="826 913 1343 1014">For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients</td> </tr> <tr> <td data-bbox="347 1014 826 1115">MR imaging scans</td> <td data-bbox="826 1014 1343 1115">For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients</td> </tr> <tr> <td data-bbox="347 1115 826 1223">List of clinical data points, see Appendix A</td> <td data-bbox="826 1115 1343 1223">For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients</td> </tr> </tbody> </table>	Data Item	Justification	CT imaging scans	For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients	X-Ray imaging scans	For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients	MR imaging scans	For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients	List of clinical data points, see Appendix A	For research and development of technology tools to support diagnosis, management and triaging of suspected COVID-19 patients
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8	<p>Article 6 condition – all Personal Data <u><i>Specify which Article 6 condition is met. You can rely on more than one condition.</i></u></p> <p>GDPR Article 6(1)(e) - The data processing is necessary for a task that is within NHSE’s remit as a public authority.</p> <p>GDPR Article 6(1)(d) - The data processing is necessary in an emergency situation to protect the life or safety of any person. Covid Purpose supported by COPI Reg’s Notice to identify Chest X-ray or CT or MR Image for inclusion.</p>										
9	<p>Article 9 condition – special categories of Personal Data</p> <p>The processing will involve data concerning health</p> <p>GDPR Article 9(2)(g) - The processing is necessary for reasons of substantial public interest , for the Covid-19 purpose</p> <p>GDPR Article 9(2)(h) - The processing is necessary for health or social care purposes, for the Covid-19 purpose</p> <p>GDPR Article 9(2)(i) - The processing is necessary for public health, for the Covid-19 purpose</p>										
10	<p>Article 10 – criminal offence data</p>										

	No criminal offence data will be processed
	<p>Compliance with confidentiality and privacy rights <u>Common law duty of confidentiality</u></p> <p>Patient identifiable data will be processed, and the grounds for doing so are: Other overriding public interest: the data will be used to accelerate research and development of technological tools to support the COVID-response. Permissive powers: COPI Notice CLDC, GDPR/DPA(18) and Public interest/Public Health legal cover</p> <p><u>Human Rights Act 1998 - Article 8</u> Is there any interference with Human Rights Article 8? No</p>
12	<p>How will the data sharing be carried out? <i>Drafting note: Document the arrangements for Processing the information. This should include:</i></p> <p>The mechanism by which the data will be shared by hospitals and Trusts, an explanation of why this is secure and which Party is responsible for ensuring security can be found in a detailed guidance document on data sharing processes, available on request.</p> <p>There will be records of what information has been shared by which hospital and with whom. The collection site keeps a record of the patient's information that has been sent to the NCCID. This is in the form of the spreadsheet submitted containing the clinical data points and Sectra Image Exchange Portal (IEP) logs showing which images were transferred. Furthermore, the data users will utilise the Platform, which logs all access instances and records what data has been used.</p> <p>We anticipate that some technology developers will need to process data outside of the EEA, in which case they will be bound by compliance with GDPR, and specific contract clauses as necessary.</p>
13	<p>Privacy notices – articles 13 & 14 <i>Drafting note: Set out here:</i></p> <p>Data subjects would not be directly informed of the processing of personal data about them. The Standard Covid Privacy Notice will cover.</p>
14	<p>Specify the procedures for dealing with the exercise of subject rights under Chapter III of the GDPR, FOIA access requests, or complaints or queries, from Data Subjects and members of the public <i>Drafting note: This is to ensure compliance with Chapter III of the GDPR. Chapter III covers subject access requests, right to have inaccurate data amended, right to have Personal Data deleted, right to restrict use of Personal Data, right to data portability, right to object, and the right to prevent automated decision-making/ profiling.</i> <i>If the organisations sharing information are Joint Controllers then this agreement must (under Article 26.1):</i></p> <ul style="list-style-type: none"> ● designate the contact point for Data Subjects; and ● determine the responsibility of each organisation for complying with Chapter III rights. <p><u>Data Subject Rights Protection</u></p> <p>All data subject rights will be protected via the Data Controller (NHS England and Department of Health are joint data controllers) standard procedures. these are covered and published in NHS E & I public web site, and Public Privacy Statement</p>

	<p>How will the organisations keep each other up to date about the amendment, erasure or restriction of use of Personal Data that has been shared under this agreement?</p> <p><i>Under the GDPR there is a new obligation on Controllers to pass on information about the amendment, erasure or restriction of use of Personal Data to any organisation with whom that Personal Data has been shared (Article 19).</i></p> <p>Data management and routine housekeeping process will be undertaken with usual procedure for data management between NHS E and Information Asset Owner.</p>
15	<p>Specify the retention period for the information to be shared</p> <p>Data will be made accessible to external entities to undertake specific research projects to address needs in the detection and stratification of COVID-19 that will benefit from combined clinical and imaging data. Any access to the data and licences to use will be limited to tools developed to support the COVID-19 pandemic, and will cease when the COVID-19 COPI (COVID-19 – Notice under Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002) ceases effect.</p>
16	<p>Specify the process for deleting/returning/safely destroying the information when it is no longer required (this should include provision for notification of such deletion/destruction)</p> <p>Upon expiry of this Agreement, or if this Agreement is terminated for any reason, all rights granted to Company in respect of the Database shall terminate immediately and Company shall cease all work on the Study and all use of, and further granting of access to the Database and delete or procure the deletion of all copies of the same from its computer or otherwise in its possession or in the possession of the Researchers. Certified evidence of deletion will be provided to NHSX.</p>
17	<p>Specify any particular obligations on <u>all</u> parties to the agreement:</p> <p><i>Drafting note:</i> <i>Some obligations will be applicable to <u>all</u> parties but where a specific organisation(s) has a particular task e.g. system security, reporting, this needs setting out in section 12. Ensure that, where a contract exists, these obligations do not conflict with it – amend the obligations as necessary. If it is agreed that a particular Party will take responsibility for any particular obligation it should be moved to section 14.</i></p> <p>Each organisation signed up to this Agreement will:</p> <ol style="list-style-type: none"> 1. comply with its obligations under the Data Protection Legislation, the Freedom of Information Act 2000 and the Environmental Information Regulations 2004 and comply with Data Guidance. The Parties acknowledge that once a Party has received data under this Agreement it will be responsible for ensuring that its own Processing of that data complies with this clause; 2. use the information shared solely for the purposes identified and shall not Process the information for any other purposes; 3. agree to treat the data received by them under the terms of this Agreement as confidential and shall safeguard it accordingly. Respect for the privacy of individuals will be afforded at all stages of Processing; 4. notify the other parties to this Agreement of any breach of this Agreement (in particular paragraph 17.1) connected to the sharing of information under this Agreement within 24 hours of first suspecting the breach. This obligation extends to breaches concerning the systems on which the data shared under this Agreement are held, even if the data shared under this Agreement is not directly affected; 5. notify the other parties to this Agreement of any complaint received from any person about the sharing of data under this agreement or any correspondence from the Information Commissioner or other regulator regarding the sharing of data under this Agreement; and

	<p>6. assist each other, in responding to requests made under the Freedom of Information Act 2000 or Environmental Information Regulations 2004 in relation to the information shared under this Agreement to ensure a co-ordinated and consistent response.</p>
18	<p>Specify any particular obligations on any individual Party: <i>Drafting note: E.g. co-ordination of incident reporting, co-ordination of responses to queries/complaints from individuals affected by the information sharing, conduct of Data Privacy Impact Assessments</i></p> <p>None additional</p>
19	<p>Data Protection Officers Each Party shall notify the other Parties of the name, email address, and direct dial telephone number of any Data Protection Officer and promptly notify the other Parties of any changes to those details.</p>
20	<p>Commencement of Agreement <i>Drafting note: Specify the date the Agreement will come into force.</i></p> <p>The agreement will be deemed to commence once the Information Asset Owner has received notification of acceptance from Company</p>
21	<p>Review of Agreement <i>Drafting note: Specify when the agreement will be reviewed.</i></p> <p>A review of this information sharing agreement shall take place every 3 (three) months during the Covid-19 emergence, or at the written request of any party. All parties to this Agreement agree to take part and fully cooperate in this review.</p>
22	<p>Persons responsible for the development and review of this Agreement <i>Drafting note: Specify Job Title and Organisation to enable relevant parties to be part of the review.</i></p> <p>Dr Mark Halling-Brown</p> <p>Head of Scientific Computing Royal Surrey County Hospital</p> <p>Guildford GU2 7XX Tel: +44(0)1483 571122 (Ext: 6876)</p> <p>Email: mhalling-brown@nhs.net</p>
23	<p>Dispute Resolution</p> <p>1. In the event of a dispute arising under this Agreement, authorised representatives of the Parties will meet to try to resolve the dispute within five Business Days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further ten Business Days.</p> <p>2. If the Parties are unable to settle the dispute by negotiation, they must, within 5 Business Days after the end of the ten Business Day period referred to above submit the dispute to an independent body or organisation agreed between the Parties. If the Parties are unable to agree on an independent body or organisation within that period then the dispute shall be submitted to the Centre for Effective Dispute Resolution (CEDR). The mediations will follow the mediation</p>

	<p>process of the independent body or organisation agreed by the parties or CEDR as appropriate.</p>
24	<p>Termination</p> <ol style="list-style-type: none"> 1. This Agreement shall commence on the date set out at clause 20. Unless terminated in accordance with this clause, this Agreement shall terminate concurrently with the repeal of the Covid-19 COPI Notice. 2. Any Party may withdraw from this Agreement at any time by notifying the other Parties in writing that it will no longer be sharing data under this Agreement . 3. Without affecting any other right or remedy available to it, each Party may immediately terminate this Agreement by notice in writing to the other Parties if any other Party commits a material breach of any provision of this Agreement or any other Party repeatedly breaches any of the provisions of this Agreement. 4. On termination of this Agreement: <ol style="list-style-type: none"> i.any rights, remedies, obligations or liabilities of the Parties that have accrued up to the date of termination, including the right to claim damages in respect of any breach of this Agreement which existed at or before the date of termination, shall not be affected; ii.the provisions of this Agreement which place obligations on the Parties in respect of the Processing of personal information shall continue in force and effect until such time as the Processing of the personal information received pursuant to this Agreement ceases; iii.without prejudice to the foregoing sub-clause, the provisions of this Agreement that expressly or by implication are intended to come into or continue in force on or after termination of this Agreement shall remain in full force and effect; and iv.each Party shall, at the request of any other Party, and promptly following that request, provide the other Parties of confirmation its compliance with sub-clause (ii)of this clause.
25	<p>Variation</p> <ol style="list-style-type: none"> 1.Any proposed changes to this Agreement, including the addition or removal of parties, the purposes of the information sharing, the nature or type of information shared or manner in which the information is to be Processed must be notified promptly to the Information Compliance/Governance leads so that the impact of the proposed changes can be assessed. 2.No variation of this Agreement shall be effective unless it is in writing and signed by all of the Parties to this Agreement.
26	<p>Remedies and no waiver</p> <ol style="list-style-type: none"> 1.Without affecting its liability for breach of any of its obligations under this Contract, a Controller will be liable to the other co-signees for, and must indemnify and keep the other co-signees indemnified against any fine that results from or arises out of the Controllers, or Processors engaged by the Controller, breach of Data Protection Law. 2.Each Party (“the Breaching Party”) shall indemnify, defend and hold harmless the other Parties (“the Non-Breaching Parties”) from and against all and any losses, claims, liabilities, costs, charges, expenses, awards and damages of any kind including any fines and legal and other professional fees and expenses (irrespective of whether they were reasonably foreseeable or avoidable) which it/they may suffer or incur as a result of, or arising out of or in connection with, any breach by the Breaching Party of any of its obligations in this Agreement. 3.The rights and remedies provided under this Agreement are in addition to, and not exclusive of, any rights or remedies provided by law or in equity. 4.A waiver of any right or remedy under this Agreement or by law or in equity is only effective if given in writing and signed on behalf of the Party giving it and any such

	<p>waiver so given shall not be deemed a waiver of any similar or subsequent breach or default.</p> <p>5.A failure or delay by a Party in exercising any right or remedy provided under this Agreement or by law or in equity shall not constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict any further exercise of that or any other right or remedy. No single or partial exercise of any right or remedy provided under this Agreement or by law or in equity shall prevent or restrict the further exercise of that or any other right or remedy.</p>
27	<p>Notices</p> <p>Any notice given to a Party under or in connection with this Agreement shall be in writing in the English language and shall be sent by email to the relevant address set out below.</p> <p>NHS England contact email: Indra Joshi, indra.joshi@nhsx.nhs.uk</p> <p>Faculty contact email: Alberto Favaro, alberto.f@faculty.ai</p> <p>Other parties: see Enrollment Log.</p> <p>Any notice validly given in accordance with the foregoing clause shall be deemed to have been received the following Business Day.</p> <p>This clause does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any mediation or other method of dispute resolution where any service may be made by any means permitted by law.</p>
28	<p>General</p> <ol style="list-style-type: none"> 1.No Party shall assign, transfer, mortgage, charge, subcontract, declare a trust over, or deal in any other manner with any or all of its rights and obligations under this Agreement. 2.This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement. No counterpart shall be effective until each Party has executed at least one counterpart. 3.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. 4.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), provided that nothing in this clause shall prevent a Party from enforcing any judgement obtained in the court of England and Wales in any other court with jurisdiction over the other Party.

Appendix A - Clinical Data Points collected

Hospital Name
NHS/CHI Number
Hospital (Internal) Number
Age
Sex
Smoking status
Pack year history
PMH hypertension
PMH CVS disease
PMH diabetes mellitus type II
PMH Lung disease (No = 0, COPD = 1, Fibrosis = 2, cystic fibrosis=3, asthma=4, other=5 please specify, 6=unknown)
PMH CKD (No = 0, Yes = 1, Unknown = 2)
If CKD, stage (2 / 3 / 4/ 5)
Current ACEi use (No = 0, Yes = 1, Unknown = 2)
Current Angiotension receptor blocker use (No = 0, Yes = 1, Unknown = 2)
Current NSAID used (No = 0, Yes = 1, Unknown = 2)
Date of admission
Duration of symptoms (days)
Respiratory rate on admission (breaths/min)
Heart rate on admission (beats/min)
PaO2 (% room air)
FiO2 (oxygen flow rate if on oxygen)
Systolic BP (mmHg)
Diastolic BP (mmHg)
Temperature on admission (oC)
NEWS2 score on arrival
WCC on admission (x109/L)
Lymphocyte count on admission (x109/L)
Platelet count on admission (x109/L)
CRP on admission (mg/L)
D-dimer on admission (mg/L)
Urea on admission (mmol/L)
Creatinine on admission (mmol/L)
Date of acquisition of 1st RT-PCR
Date of result of 1st RT-PCR
1st RT-PCR result (COVID-19 negative = 0, COVID-19 positive = 1)
Date of acquisition of 2nd RT-PCR
Date of result of 2nd RT-PCR
2nd RT-PCR result (COVID-19 negative = 0, COVID-19 positive = 1)
Date of 1st CXR

COVID CODE (Normal = 0, Classic/Probable = 1, Indeterminate = 2, Non-covid = 3)
CXR severity (Mild = 1, Moderate = 2, Severe = 3)
Date of 2nd CXR
COVID CODE (Normal = 0, Classic/Probable = 1, Indeterminate = 2, Non-covid = 3)2
CXR severity (Mild = 1, Moderate = 2, Severe = 3)3
ITU admission (Yes = 1, No = 0)
Date of ITU admission
APACHE score on ITU arrival
Intubation (Yes = 1, No = 0)
Date of intubation
Death (Yes = 1, No = 0)
Date of death
Date last known alive
Ethnicity