RECRUIT ONLINE GP ACCEPTANCE

OVERVIEW OF RECRUIT

PLEASE NOTE – THE SUMMARY INFORMATION IN THIS BOX HAS BEEN INCLUDED FOR INFORMATION PURPOSES ONLY AND DOES NOT FORM PART OF THE BELOW AGREEMENT:

Recruit

Recruit comprises the service set out in Schedule 2 of the terms and conditions (below). In summary there are two related stages to the service: (i) feasibility of clinical trials (Feasibility); and (ii) recruitment of patients for clinical trials (Recruitment).

Summary of the Feasibility and Recruitment Services

Stage 1 - Feasibility - From time to time, Optum may work, or explore potential opportunities, with research organisations and study sponsors (such as clinical research networks and life science companies) in relation to potential studies or topics of interest which may result in research studies relevant to primary care. By entering into the agreement, You appoint Optum to deliver the feasibility service to You.

The intended purpose of feasibility is to increase the number of active studies available to You (and by extension Your patients) – this is facilitated by Optum working with researchers at different stages of their study protocol development to refine and improve their study design.

Feasibility involves Optum running a search on behalf of the practices signed up to Recruit in order to identify whether the participating organisations have sufficient numbers of potentially relevant patients for a viable study to be run. The information provided to the potential sponsor will be limited to aggregate numbers of potentially relevant individuals and approximate locations (in order to determine where it might be best to place study centres). The data may need to be processed a number of times to optimise and refine the study design. This same information will be made available to the participating practices (though potentially not the identity of the potential sponsor(s)).

By way of example, a potential sponsor may have identified a new treatment for asthma that is focused on patients above a certain age and with certain comorbidities but is uncertain whether there will be sufficient individuals to justify running a study. We could, as part of the feasibility service, run a search against the participating practices' data and so determine that there are approximately 5,000 potentially relevant patients and that there are particular clusters around the East Midlands.

Stage 2 - Recruitment of Patients - Research organisations and study sponsors contract with Optum for Recruit so that they can make studies relevant to primary care available to GPs to help recruit potentially eligible patients for clinical trial(s). We will display relevant study details in Recruit (i.e., study name, sponsor (or relevant research organisation), therapeutic area, and practice income for each patient consent (in respect of patients who are contacted) recorded for the study). You can access Recruit from EMIS-X.

How You agree to sign up to Recruit

By accepting the agreement for Recruit You are authorising and instructing Optum to process the data we hold for You in EMIS Web: (i) for the purposes of delivering the feasibility service, including in order to ascertain study feasibility and/or validate cohort definitions (that may or may not then become listed); and (ii) subject to studies being approved and/or being validated successfully, to enable You to identify patients who might be eligible to participate in the studies listed.

You should only accept the agreement if You agree to the terms and conditions detailed below.

How we protect patient confidentiality and ask for patient consent

Patient consent and confidentiality is paramount. Optum will structure the searches to exclude certain patient types (for example those with a Type 1 opt out code, who are showing in the system as having recorded national data opt out (where NDOP is being applied as a filter for the relevant study), deceased

patients etc). It is therefore imperative that You keep information about patients accurate and up to date (including codes), as the accuracy of the data sets which are produced will be dependent on the information which You make available to us to analyse.

We'll provide You with a regular report of key feasibility searches and projects being worked on alongside information regarding recruitment of patients for clinical trials through Recruit.

Once You have indicated that Your practice wishes to participate in a trial we will provide You with a list of potentially suitable patients for that study that are registered with Your practice. The next step is for You to review that list to exclude any patients You do not wish to include.

Patient engagement is requested via a text message and/or e-mail which You send to Your list of suitable patients. We may also make automatic text and/or e-mail reminders available (where possible). The message can be sent straight from Recruit and we provide a preview of the text message and/or e-mail template used. The text message has a link through which patients can consent to their data being shared with the research study organisation for the purposes of recruitment to the study. If the patient provides consent, their contact details will be shared with the relevant study parties. Alternatively, the text message may direct the patient straight to the research organisation's study web page (or that of its intermediary).

The service also facilitates the sharing of patient summary care records with the research study organisation. This feature will only be available for specific research studies. Where it is available, each relevant patient will also be able to provide their consent to share their care record. Upon consent and, if applicable, subject to request by the research study organisation, you will need to review the pdf copy of the care record within Recruit after which you can decide to: a) share the record; b) decline to share the record; or c) redact the record before sharing with the research study organisation. It is your responsibility to ensure that only appropriate information is shared from each patient's record.

You are in control of patient contact

As their General Practitioner, You are in control of which patients are invited to a study from the list of patients we provide. As with any text message or e-mail You send, You are responsible for ensuring the message goes to the correct patient(s) and that they are happy to receive such messages. If You think that a patient should not receive a study invitation message, You can exclude them from the list of eligible patients shown in Recruit.

Patients can opt themselves out from their data being used for Recruit by contacting You. You will then need to add one of the current Opt Out Codes (as defined) into the relevant patient's medical record within EMIS Web. If a patient later wishes to opt back in, You will need to add one of the current Opt In Codes (as defined) into the relevant patient's medical record within EMIS Web. Please ensure you check the relevant Opt In Codes / Opt Out Codes regularly to ensure appropriate codes are applied to your patients' records. Where a patient has both an Opt Out Code and Opt In Code recorded against their medical record, we will rely upon the most recently added code for the purposes of including/excluding a patient for the purposes of Recruit.

Keeping patient data safe, secure and confidential

Whilst identifying patients suitable for the studies, no patient data is removed from the secure medical record environment.

For the feasibility service, no data will be shared with any third party other than high level aggregated statistical information, analytical insights and limited location data (i.e. the first 2 or 3 digits of a postcode).

For the recruitment service, only the data needed to validate a study's cohort definition and identify study feasibility/eligibility is processed and only anonymised, aggregated data may be shared with third party organisation(s). Only You can see the names of the patients identified as eligible for a study (unless or until those patients choose to opt in to participate in a particular study).

Record keeping

As a data controller of Your patient records under the UK GDPR, You must ensure that data about patients, including relevant codes, are up to date and accurate.

What do the patients see?

Patients will not see any of the outputs of any feasibility searches, which will only be made available to You.

In relation to patient recruitment for trials made available within Recruit to You, once You have sent the invitation via SMS and/or email the patient will receive a notification on their phone, consisting of a short message and a link. The link will either take the patient through for authentication by Optum or link away direct to the relevant research body (or its intermediary).

If coming via Optum, once the patient clicks the link, we check their identity by asking for their date of birth. If the phone number and date of birth match, authentication is successful, we will provide them with information about the study and two options as follows:

- Consent (to have their data shared with the research body); or
- Dissent (to have their data shared with the research body).

The individual's response will, once submitted, be automatically recorded in Recruit.

If patient care record functionality is available, patients will also be able to provide their consent to their record being shared, subject to your review and approval of the same (as described above).

Alternatively, if the invitation links the patient direct to the research body (or its intermediary), we may not undertake patient identity verification (which may instead be undertaken by such body) and in this scenario we may not be able to record a patient's consent in Recruit.

What happens if a patient consents?

If a patient confirms that they wish to take part in the relevant research opportunity, we will automatically share relevant details (e.g., name, NHS number, age, gender, phone number, email address and the name of their GP Practice) with the relevant research body, who may contact them directly about participating in the study. If a patient consents to sharing their electronic health record then, subject to your review and approval, this will also be shared with the relevant research body to assist such body in ascertaining the patient's potential eligibility for the trial. An individual can choose not to proceed at any time during the process (by informing the relevant research body), and if they do so, their data will no longer be used by the relevant research body for that study. The research body may record the opt-out and, subject to patient approval, You will be informed of the individual's choice via Recruit.

The only exception to the above is if the invitation links the patient directly to the research body (or its intermediary); under these circumstances we may or may not share data with such body depending upon the relevant trial. The relevant individual will still be able to choose not to proceed at any time during the process by informing the relevant research body (or its intermediary).

Your role as a Patient Identification Centre

When You choose to participate in the identification of potentially eligible patients for a particular trial (by accepting the relevant Study Terms and Conditions), You will be acting as a Patient Identification Centre. In accordance with the Health Research Authority's guidance, when You undertake these activities, You will be acting as a data processor (or sub-processor) for the relevant sponsor.

By accepting a relevant set of Study Terms and Conditions for a clinical trial, You are also accepting the Sponsor Processor Terms (see Schedule 5) which create a direct contract between You and the relevant named party (i.e. the Sponsor or CRO). The Services delivered through Recruit help You to fulfil Your role as a Patient Identification Centre.

AGREEMENT FOR RECRUIT

PLEASE READ CAREFULLY BEFORE PROCEEDING WITH THIS SERVICE:

This agreement is a legal agreement between you, the organisation, acting on behalf of itself and all its Authorised Users (as defined), using this service (**"You", "Your" or "Customer"**), and Egton Medical Information Systems Limited, trading as Optum, a company incorporated in England and Wales (company number 2117205) whose registered office is at Fulford Grange, Micklefield Lane, Leeds, LS19 6BA (**"Optum", "us" or "we"**). This Agreement relates to Your sharing of certain patient data with us, which we will use on Your behalf to deliver the Service (as defined below) to You.

IMPORTANT NOTICE TO ALL CUSTOMERS:

- BY CLICKING ON THE "ACCEPT" BUTTON, THE USER ACCEPTING THE TERMS OF THIS AGREEMENT REPRESENTS AND WARRANTS THAT THEY HAVE THE AUTHORITY TO BIND THE CUSTOMER AND THE CUSTOMER AGREES TO THE TERMS OF THIS AGREEMENT WHICH WILL BIND THE CUSTOMER AND ALL OF ITS AUTHORISED USERS. THE TERMS OF THIS AGREEMENT INCLUDE, IN PARTICULAR, LIMITATIONS ON LIABILITY IN CLAUSE 9 AND YOUR RESPONSIBILITIES IN SCHEDULE 1.

- IF YOU DO NOT AGREE TO THE TERMS OF THIS AGREEMENT, YOU SHOULD NOT SHARE THE DATA WITH US AND YOU MAY NOT RECEIVE THE SERVICE FROM US.

You should print a copy of this Agreement for future reference.

1. DEFINITIONS

1.1. In this Agreement, the following words shall have the following meanings:

Affiliate means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control with, that body corporate from time to time.

Agent means an agent authorised by You to undertake the Agent Activities.

Agent Activities means certain agreed rights that an Agent can exercise on Your behalf under the terms of this Agreement, as more particularly set out in paragraph 3 of Schedule 4.

Agreement means the clauses of this agreement as may be varied or amended from time to time in accordance with this agreement, including any Schedules attached hereto and any Appendices to such Schedules, along with any Study Terms and Conditions which the parties agree to from time to time in accordance with clause 3

Applicable Law means the laws of England and Wales and any other laws or regulations, regulatory policies, guidelines or industry codes which apply to the performance of the parties' respective obligations under this Agreement.

Authorised Users means the individual users (whether employed by the Customer or not) that use the Service under the terms of this Agreement through the Customer's account in accordance with clause 6.

Confidential Information means information (in any format) that falls within any of the following categories: (a) it relates to, includes or comprises the terms and conditions of this Agreement; (b) it is Customer Data; (c) it is marked as "confidential" (or similar); (d) it is of a nature that a reasonable person

would (in all the circumstances) consider confidential, including: (i) information concerning a party's business operations or affairs, including research and development efforts, inventions, drawings, models, trade secrets, know-how, products, processes, techniques, equipment, marketing, market opportunities, plans, intentions, relationships with customers and suppliers, finances, personnel, computer software, and algorithms; and/or (ii) similar information of third parties that a party maintains in confidence; or (e) any combination of the foregoing.

Control means the beneficial ownership of more than 50% of the issued share capital of a company or the legal power to direct or cause the direction of the general management of a party, and "Controls", "Controlled" and the expression "change of Control" shall be construed accordingly.

Customer Cause means anything which results directly or indirectly from Your: (a) breach of this Agreement; and/or (b) delay or failure in performing Your obligations under this Agreement (including those set out in clause 5 and Schedule 1), or in providing notices, arrangements, engagement, access, assistance or information to Optum in a sufficiently timely or accurate manner.

Customer Data means any Personal Data obtained by You or on Your behalf and shared with Optum via a relevant Optum solution (for example via EMIS Web) under this Agreement, as more particularly described in the Appendix to Schedule 3.

Data Controller has the meaning given under the Data Protection Laws.

Data Deliverables means any datasets produced by Optum in performing the Service, including the Patient Number Output and list of Potential Study Participants (each as defined in Schedule 2) but excluding any Metadata.

Data Processor has the meaning given under the Data Protection Laws.

Data Protection Laws means: (i) the Data Protection Act 2018, the General Data Protection Regulation ((EU) 2016/679) ("**GDPR**") as incorporated into domestic United Kingdom law by the European Union (Withdrawal Agreement) Act 2020 and amended by The Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2020 (the "**UK GDPR**"); (ii) the Privacy and Electronic Communications Regulations 2003; and (iii) any binding guidance or codes of conduct issued by the Data Protection Regulator from time to time.

Data Protection Regulator means the Information Commissioner's Office and any successor body from time to time.

Data Subject has the meaning given under the Data Protection Laws.

Disclosing Party has the meaning set out in clause 15.1.

Dispute has the meaning set out in clause 16.11.

Effective Date means the date upon which You accept the terms of this Agreement, including, by clicking on the 'Accept' button.

EHR means a pdf. copy of the relevant Patient's summary care record for the period between the Patient's birth and up to 48 hours before the Patient consents to share their EHR comprising (subject to: (i) removal of certain sensitive or third party information and/or (ii) any redaction or removal of information by you and/or (iii) availability within EMIS Web):

- Patient details: Name, NHS number, DOB, usual GP, patient type, registered, language, home telephone number, mobile number and e-mail address;
- Problem List: Active and Past Significant and Minor Problems, this may include associated freetext;
- Medications: Acute and Repeat prescriptions including date of prescription, number of issues and dosage instructions;
- Allergies: Details of any allergies recorded against the Patient's record;

- Health Status: Codes linked to patient health status including Alcohol, Smoking, Height, Weight, BMI, BP, Cervical Smear, Notes Summary;
- Immunisations: details of any immunisations recorded against the Patient's record;
- Planned Events: Details of any planned events recorded against the Patient's record;
- Consultations: consultation history for the Patient, this may include free text comments;
- Referrals: Details of historic and active referrals against the patients record; and
- Test Results: details of any test results recorded against the Patient's record.

EHR Feature means a feature of the Service that, when available on a particular Research Study, allows You to share Potential Study Participants EHRs with the Relevant Study Partner (subject to consent from the relevant Potential Study Participants to do so and Your review and approval of the EHR before sharing the same in accordance with the terms of this Agreement).

EMIS Web means Optum's proprietary electronic patient record system provided to GP's.

EMIS-X means Optum's proprietary application built on cloud technology and embedded directly into existing EMIS Web systems to enhance the EMIS Web clinical system both now and into the future.

Feasibility Reports means a summary of the key outputs of the Feasibility Service to be provided to You in accordance with the terms of this Agreement.

Feasibility Service means a service whereby we undertake searches on Your behalf in order to confirm whether a proposed study or opportunity appears to be viable with a view to increasing the number of Research Studies which are potentially available to You and Your patients via Recruit pursuant to (and as described in) paragraph 1 of Schedule 2. These searches are typically undertaken at an earlier stage of trial design than Study Validation Service.

Fees means the amounts Optum will pay to You under this Agreement on behalf of the Relevant Study Partner in accordance with clause 8, which may be based on the number of Potential Study Participants who consent to be contacted by the relevant Research Study team and/or the number of Potential Study Participants who are randomised to take part in the relevant Research Study and/or the number of EHRs shared, as specified in the relevant Study Terms and Conditions.

Intellectual Property Rights means all patents, rights to inventions, utility models, copyright and related rights, trade marks, service marks, trade, business and domain names, rights in trade dress or get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database right, topography rights, moral rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications for and renewals or extensions of such rights, and all similar or equivalent rights or forms of protection in any part of the world.

IRAS means the Integrated Research Application System being the collaborative single system created for applying for the permissions and approvals for health, social and community care research in the UK.

Metadata means the data described in clause 12.

Named Party means the Relevant Study Party named in the relevant Study Terms and Conditions as the contracting party with Optum and with whom You agree to enter into the relevant Sponsor Processor Terms.

Notice has the meaning set out in clause 16.11.

Opt In Code means the opt in codes as specified here: https://www.emisnow.com/csm?id=kb_article_view&sysparm_article=KB5003079 (as updated by Optum from time to time).

Opt Out Code(s) means the opt out codes as specified here: https://www.emisnow.com/csm?id=kb_article_view&sysparm_article=KB5003079 (as updated by Optum from time to time).

Optum Materials means Recruit, the invitations and any other materials provided by Optum pursuant to this Agreement or otherwise generated by Optum under this Agreement (but excluding the Data Deliverables).

Optum Referral means the process whereby Optum authenticates a Potential Study Participant's identity and facilitates the sharing of certain Customer Data with Relevant Study Parties (subject to the Potential Study Participant's consent), as more particularly described in Schedule 2.

Patient Access Referral means where a Potential Study Participant has consented to their data being shared with the sponsor of a relevant Research Study directly with Optum (including, through Optum's patient facing application (known as Patient Access)).

Patient Number Output has the meaning set out in paragraph 2 of Schedule 2.

Personal Data has the meaning set out under Data Protection Laws.

Personal Data Breach has the meaning set out under Data Protection Laws.

Potential Study Participants has the meaning set out in paragraph 2 of Schedule 2.

Privacy Notice means the notice containing the information required to be provided to a Data Subject by the Data Protection Laws.

Process has the meaning set out under Data Protection Laws (and "Processes" and "Processing" shall be construed accordingly).

Recipient Party has the meaning set out in clause 15.1.

Recruit means an application or feature which can be accessed via EMIS-X that enables You to receive the Service under this Agreement.

Research Study has the meaning set out in clause 3.

Relevant Study Party has the meaning set out in paragraph 3 of Schedule 1.

Relevant Study Party Referral means where a Potential Study Participant is sent (via a link) direct to the Relevant Study Party without Optum authenticating the identity of the Potential Study Participant or facilitating the sharing of Customer Data with the Relevant Study Party, as more particularly described in Schedule 2.

Service means the service to be delivered by Optum pursuant to this Agreement and as set out in Schedule 2 (Service Description).

Sponsor Processor Terms means the data processing agreement set out in Schedule 5 to be entered into between You and the relevant Named Party under the Study Terms and Conditions for the relevant Research Study.

Staff means in respect of either party, any staff engaged by such party (including employees as well as any agents and sub-contractors) in connection with this Agreement.

Study Terms and Conditions has the meaning set out in clause 3.

Study Validation Service means the service provided by Optum pursuant to (and as described in) paragraph 2 of Schedule 2.

VAT means applicable value added tax chargeable under English law for the time being (and any similar additional or replacement tax).

Working Days means any day between Monday and Friday (other than any public holiday in England and Wales).

Working Hours means 9am to 5pm local time on Working Days.

2. INTERPRETATION

2.1. Clause, attachment, schedule, appendix and paragraph headings shall not affect the interpretation of this Agreement.

2.2. A reference to: (i) a person includes an individual, corporate or unincorporated body (whether or not having separate legal personality) and that person's legal and personal representatives, successors or permitted assignees; (ii) a company shall include any company, corporation or other body corporate, wherever and however incorporated or established; (iii) words in the singular shall include the plural and vice versa; (iv) one gender shall include a reference to the other genders; and (v) a statute or statutory provision is a reference to it as it is in force for the time being, taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it; and (vi) writing or written includes e-mail, (provided that, in respect of correspondence sent from You to Optum, that the same is sent to uk.contracts@optum.com) but not faxes; and (vii) clauses and schedules are to the clauses and schedules of this Agreement; references to paragraphs are to paragraphs of the relevant schedule to this Agreement.

2.3. Any words following the terms ‘including’, ‘include’, ‘in particular’, ‘for example’ or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms.

3. STUDY TERMS AND CONDITIONS

3.1. From time to time, Optum may display to You within Recruit, details of upcoming clinical research studies “**Research Studies**” which are taking place, including details of the Relevant Study Party, a summary of what the study relates to, how Fees are calculated and other key details (each being the “**Study Terms and Conditions**”), and You will then have the option to participate in patient recruitment for each such Research Study. If You wish to participate in patient recruitment of a particular Research Study, You must accept the terms of the relevant Study Terms and Conditions, made available to You in Recruit. The Study Terms and Conditions will specify whether the Research Study is using the Optum Referral or Relevant Study Party Referral route.

3.2. Each relevant Study Terms and Conditions You accept from time to time in accordance with clause 3.1, forms part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes (as appropriate) any agreed Study Terms and Conditions (as amended in writing from time to time).

3.3. If there is any conflict or inconsistency between the terms in the various parts of this Agreement, the following order of priority shall prevail (unless explicitly stated otherwise in any agreed Study Terms and Conditions):

a) these clauses;

b) the Schedules; and

c) any agreed Study Terms and Conditions.

3.4. The clauses and the Schedules of this Agreement shall apply to any Study Terms and Conditions which are agreed between the parties from time to time.

3.5. For the avoidance of doubt, each agreed and signed Study Terms and Conditions will form part of this Agreement and shall not form a separate contract to it.

4. SERVICE AND DATA DELIVERABLES

4.1. Subject to Your compliance with this Agreement, in particular providing and obtaining the relevant consents, permissions and approvals set out in Schedule 1, Optum shall provide the Service to You in accordance with the terms of this Agreement, including (as appropriate) in accordance with the terms of each agreed Study Terms and Conditions.

4.2. Optum warrants that it shall:

a) provide the Service with reasonable care and skill; and

b) meet any performance dates specified in this Agreement, but any such dates shall be targets or estimates only and time shall not be of the essence in relation to the delivery of the Service.

4.3. Where such an arrangement is available to You, You may authorise an Agent in accordance with Schedule 4.

5. YOUR RESPONSIBILITIES

5.1. Without prejudice to Your other obligations set out under this Agreement, You shall:

a) provide Optum with the Customer Data; and

b) provide and obtain the relevant consents, permissions and approvals, and otherwise perform Your obligations set out in with Schedule 1 and as required by Applicable Law.

5.2. You agree and acknowledge that:

a) By entering into relevant Study Terms and Conditions and identifying Potential Study Participants through use of the Services, You are acting as a Participant Identification Centre ("**PIC**") for the purposes of the IRAS;

b) You will comply with all obligations and responsibilities expected of a PIC (if any) including the relevant Sponsor Processor Terms; and

c) Optum may provide a relevant Sponsor (and/or Named Party, if different) with details of Your practice in order to assist such Sponsor in its compliance with Applicable Laws and to ensure it has a record of Your acceptance of the relevant Sponsor Processor Terms.

5.3. You acknowledge that while the provision of the Services will assist with Your obligations as a PIC site, You remain ultimately responsible for ensuring that You comply with all relevant obligations of a PIC site.

6. AUTHORISED USER(S)

6.1. Subject to clause 6.3, upon acceptance of the Agreement by You, Optum shall use its reasonable endeavours to add the Service, and make the Service available to, all EMIS Web users at Your practice that have the following code against their user account: RBAC: B8029 (Manage Detailed Health Records) (the "**Permission**"). For the avoidance of doubt, You hereby authorise all relevant users at Your practice with the Permission to have access to, and to use, the Services on Your behalf and warrant that all such users have the relevant skill, expertise and knowledge to be able to use the Services.

6.2. You agree and acknowledge that:

a) You will not be able to revoke access, or add access, to the Services for any individual employees or contractors without adding or removing the Permission to such individuals EMIS Web account; and

b) Should you choose to make any such changes to a user's Permission, You do so at Your own discretion and Optum shall have no liability to You or any user in the event that such actions impacts the users access to EMIS Web and/or ability to carry out other functions at Your practice.

6.3. All Authorised Users need an existing EMIS Web user account and access to EMIS-X to be able to use the Services.

6.4. Optum may from time to time send communications to Authorised Users to let them know that the Service has been activated and added to their EMIS Web/EMIS-X account, to give them information about the Service and to inform them when new Research Studies are available to access in the Service.

6.5. In relation to the Authorised Users, You:

a) are, and shall at all times remain, responsible for the acts and omissions of all Authorised Users as if they were the acts and/or omissions of You yourself; and

b) must ensure that the terms of this Agreement are brought to the attention of all Authorised Users and that all Authorised Users comply with such terms.

6.6. Without prejudice to any other rights Optum may have under this Agreement, if any Authorised User breaches the terms of this Agreement, Optum shall be entitled to suspend such Authorised User's access to and/or use of the Service. Any suspension shall continue until a resolution to the relevant breach(es) has been achieved or as otherwise agreed with Optum.

7. INTELLECTUAL PROPERTY RIGHTS

Customer Data

7.1. In relation to Customer Data, the parties acknowledge that You and/or Your licensors, shall own all Intellectual Property Rights in and to the Customer Data.

7.2. You hereby grant to Optum, or shall procure the grant to Optum of, a non-exclusive, royalty-free, licence for the duration of this Agreement, to use the Customer Data for the purposes of Optum delivering the Service and performing its obligations under this Agreement.

Data Deliverables

7.3. In relation to the Data Deliverables, the parties acknowledge that You shall own all Intellectual Property Rights in and to the Data Deliverables.

7.4. You hereby grant to Optum, or shall procure the grant to Optum of, a non-exclusive, royalty-free, perpetual, sub-licensable licence, to use the Data Deliverables for the purposes of Optum delivering the Service and performing its obligations and exercising its rights under this Agreement.

7.5. Neither party shall do, or authorise any third party to do, any act which would or might invalidate or be inconsistent with any Intellectual Property Rights of the other party, and shall not omit or authorise any third party to omit to do any act which, by its omission, would have that effect or character.

7.6. Each party shall, for the duration of this Agreement, at the other party's expense, take all such steps as the other party may reasonably require to assist the other party in maintaining the validity and enforceability of any Intellectual Property Rights licensed and/or created by the other party under this Agreement.

Optum Materials

7.7. The parties agree that Optum (or its third party licensors) own all Intellectual Property Rights in and to the Optum Materials.

7.8. Optum hereby grants to You a non-exclusive, royalty-free, licence for the duration of this Agreement, to use the Optum Materials for the purposes of You performing Your obligations and exercising Your rights under this Agreement.

7.9. The parties acknowledge that any rights granted by Optum to You in respect of accessing and using EMIS-X for the purposes of this Agreement, are granted pursuant to, and subject to separate terms agreed between the parties. Accordingly, the licence restrictions relating to Your use of EMIS-X set out under the separate agreement between us, will also apply in relation to Your use of Recruit, the terms of which are incorporated herein by reference.

8. FEES

8.1. Subject to the terms of this clause 8, Optum shall pay the undisputed Fees to You, the details of which will be specified in the relevant Study Terms and Conditions or otherwise agreed in writing between the parties from time to time in respect of each Research Study.

8.2. For the avoidance of doubt all Fees are payable in GBP and are exclusive of VAT, which You shall add to Your invoices at the appropriate rate.

8.3. You shall raise an invoice for any relevant Fees at the end of each Research Study (as notified by Optum to You) and provided that Optum has first received its corresponding payment in full from the Relevant Study Party in respect of that Research Study, Optum shall pay each valid undisputed invoice in full and in cleared funds, within sixty (60) days of the date of receipt of such invoice to a bank account nominated in writing by You.

8.4. In the event of a dispute concerning Fees paid or payable under this Agreement, Optum shall, acting reasonably, investigate the disputed amount, taking into account information and evidence provided by both parties and shall, in its discretion determine the actual Fee due to You. You agree to accept our decision in this regard as final and binding.

8.5. If Optum fails to pay You on the due date, Your sole and exclusive remedy will be to charge interest on such sum from the due date for payment at the annual rate of two percent (2%) above the base lending rate from time to time of Barclays Bank plc, accruing on a daily basis and being compounded quarterly until payment is made, whether before or after any judgment.

9. LIMITATION OF LIABILITY

9.1. Nothing in this Agreement excludes or limits the liability of either party in respect of:

a) death or personal injury caused by its negligence;

b) any indemnity given in this Agreement;

c) fraud or fraudulent misrepresentation; and/or

d) any liability which may not otherwise be limited or excluded under Applicable Law.

9.2. Subject to clause 9.1, neither party shall under any circumstances whatsoever be liable to the other party, whether in contract, tort (including negligence or breach of statutory duty), misrepresentation, restitution or otherwise, for any:

a) loss (whether direct or indirect) of revenue or profits;

b) loss (whether direct or indirect) of business opportunity;

c) loss (whether direct or indirect) of goodwill or injury to reputation;

d) loss (whether direct or indirect) of anticipated savings; and/or

e) indirect, consequential or special loss or damage,

in each case arising out of or in connection with this Agreement.

9.3. Subject to clause 9.1 and clause 9.2, the aggregate liability of each party to the other arising out of or in connection with this Agreement whether arising from contract, tort, negligence or otherwise shall be limited to the greater of £10,000 (ten thousand pounds) or 120% of Fees paid to You in the 12 months preceding the relevant claim.

9.4. All warranties, conditions and other terms implied by statute or common law are, to the fullest extent permitted by law, excluded from this Agreement (including, any terms implied by sections 13 to 15 of

the Sale of Goods Act 1979 and the terms implied by sections 3 to 5 of the Supply of Goods and Services Act 1982).

9.5. Optum will not be in breach and will not be liable to You (and You shall not be entitled to terminate for breach or to exercise any other remedy under this Agreement) to the extent that Optum's performance of its obligations under this Agreement is delayed, prevented, impacted or otherwise affected by a Customer Cause.

9.6. Optum does not guarantee that access to and use of the Service will always be available or be uninterrupted. Optum will not be liable to You if for any reason the Service are unavailable at any time or for any period. The Service is provided by Optum on an 'as is' and 'as available' basis, with any and all faults as may be present.

9.7. Optum shall use its reasonable endeavours to ensure that each Potential Study Participant meets the relevant inclusion exclusion criteria for the Research Study (as set by the relevant sponsor and subject to limitations of clinical coding) however, it makes no representation or warranty that any such Potential Study Participant will be eligible for the relevant Research Study and/or that such individuals will be randomised for the Research Study.

9.8. You shall indemnify Optum, keep Optum indemnified and hold Optum harmless, against all claims, fines, actions and proceedings (to include, without limitation, legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) incurred by Optum due to a breach by You of Your obligations under the following provisions of this Agreement: clause 10 (Warranties and compliance with Applicable Law), clause 15 (Confidentiality) and/or Schedule 3 (Data Processing).

10. WARRANTIES AND COMPLIANCE WITH APPLICABLE LAW

10.1. You hereby warrant, represent and undertake that as of the Effective Date You have, and throughout the duration of this Agreement, shall continue to hold, all relevant approvals, rights, consents, permits and licences in relation to You performing Your obligations and exercising Your rights under this Agreement.

10.2. Both parties shall, in performing their respective obligations under this Agreement, comply with Applicable Law.

11. DATA PROCESSING

11.1. The parties acknowledge and agree that Schedule 3 (Data Processing) shall apply in relation to any Personal Data Processed by Optum on Your behalf in providing the Service under this Agreement.

11.2. The Sponsor Processor Terms shall apply between You and the relevant Named Party in respect of the relevant Research Study upon acceptance of the relevant Study Terms and Conditions.

12. METADATA

12.1. You agree that Optum can track usage information in respect of Your use of the Service and use such meta data as it deems appropriate (including providing the same to the relevant sponsor(s) of each Research Study). All data is tracked and presented in a fully anonymised form and is combined with the same data from all or some of the other participating practices in the relevant Research Study before being used and/or shared. No details about You or any of Your patients' details will be recorded or shared as part of this Metadata. Information that Optum may track includes:

a) the fact that You have activated Recruit;

b) the fact each Study Terms and Conditions have been made available to You to participate in (whether You decide to enter into it or not);

c) whether You accept each Study Terms and Conditions or not;

d) Data Deliverables;

e) the total number of patients You invite to participate in each Research Study You participate in through Recruit;

f) the total number of patients that consent to their details being shared with a sponsor for each Research Study You choose to participate in;

g) the total number of patients that consent to their EHR being shared with a sponsor for each Research Study You choose to participate in (where EHR sharing is available);

h) where patients provide such consent, the total number of EHRs (i) shared, (ii) not shared and (iii) downloaded by you for redaction before sharing or redacted within Recruit (when and if that functionality becomes available);

i) the average time taken by your practice between patient consent to share their EHR and you choosing one of the options mentioned in clause h);

j) usage tracking data; and

k) such other meta data as Optum deems relevant and appropriate.

13. TERMINATION

13.1. This Agreement shall commence on the Effective Date and shall continue unless and until terminated by either party in accordance with this clause 13. Each Study Terms and Conditions shall commence on the date upon which You agree to enter into that particular Research Study and shall expire upon completion of the relevant Research Study, unless terminated or suspended earlier in accordance with this clause 13.

13.2. You may terminate this Agreement for convenience immediately, at any time, by deactivating the data sharing setting on EMIS Web for Recruit.

13.3. This Agreement may be terminated with immediate effect by either party (the "**first party**") by written notice to the other in the event of one or more of the following:

a) if the other ceases to carry on business or goes into liquidation (other than voluntary liquidation for the purpose of a bona fide solvent reconstruction or amalgamation the terms of which have been approved in advance by the first party in writing) or is dissolved or struck off;

b) if the other is unable to pay its debts as they mature or suffers the appointment of a receiver, administrative receiver or administrator (or any similar official or process under the law of its domicile or place of incorporation) of the whole or any part of its assets or is the subject of any bankruptcy proceedings; and/or

c) if the other is in material breach of any provisions of this Agreement and fails to remedy such breach (where it is capable of being remedied) within 30 days of notice from the first party specifying such breach.

13.4. Optum may, without prejudice to its other rights and remedies, suspend or terminate this Agreement and/or any Study Terms and Conditions / Research Study in Recruit without liability to You at any time by giving notice to You. Examples of instances where Optum may choose to exercise this right include where Optum identifies a clinical or data protection issue/risk and/or where Optum, acting reasonably considers it is suffering or at risk of suffering reputational damage and/or where a Relevant Study Party suspends or terminates a Research Study.

13.5. Upon termination or expiry of this Agreement, all relevant Research Studies and Study Terms and Conditions shall also terminate with immediate effect. Suspension, termination or expiry of the relevant Study Terms and Conditions will not, unless the parties expressly agree otherwise in writing, result in the termination or expiry of the remainder of this Agreement.

14. EFFECT OF TERMINATION

14.1. Termination or expiry of this Agreement shall be without prejudice to any rights of either party which may have accrued up to the date of such termination.

14.2. Termination or expiry of this Agreement shall not affect any provision of this Agreement which is expressly or by implication intended to come into effect on, or to continue in effect after, such termination or expiry.

14.3. Without prejudice to the generality of clause 14.2, the provisions of clauses 1, 2, 33, 5, 8, 9, 11, 14, 15 and 16 shall survive any termination or expiry of this Agreement, howsoever arising.

14.4. Upon expiry or termination of this Agreement, howsoever caused:

a) all licences granted hereunder shall automatically terminate and You will no longer be able to use the Service;

b) any Agent authority given by You shall immediately cease (and You will notify any Agent accordingly). Optum may (also) notify the Agent of any such termination;

c) Optum shall decommission Your user account (please note that this may take up to 3 months to complete); and

d) each party shall, at the option of the other party, return or securely destroy all Confidential Information of the other party.

14.5. Upon termination of this Agreement by You in accordance with clause 13.2 or by us in accordance with clause 13.3, any due and undisputed Fees at the date of termination shall continue to be payable to You in accordance with clause 8 and/or to Your Agent in accordance with Schedule 4; however, no other Fees will be payable to You whatsoever.

14.6. Upon termination of this Agreement and/or any Study Terms and Conditions / Research Study by us in accordance with clause 13.4 or by You in accordance with clause 13.3, any undisputed Fees due, or that later become due to You (i.e. at the end of any Research Study You have recruited patients for under this Agreement), shall continue to be payable to You in accordance with clause 8.

15. CONFIDENTIALITY

15.1. Subject to clauses 15.2 and 15.3 and save as otherwise expressly provided in this Agreement, neither party shall during the term of this Agreement or thereafter for a period of 2 years, disclose to any person or use for any purpose any Confidential Information obtained by it (the "**Recipient Party**") from the other (the "**Disclosing Party**") in connection with this Agreement but the Recipient Party may:

a) disclose Confidential Information to such of its Staff or professional advisers (which shall include, lawyers, accountants and auditors) who require such disclosure where legitimately necessary for the proper performance of their duties; and/or

b) use Confidential Information in the proper exercise of its rights and the performance of its obligations under this Agreement.

15.2. The Recipient Party shall use its reasonable endeavours to minimise the risk of unauthorised disclosure or use and undertakes to take proper care and all reasonable measures to protect the confidentiality of the Confidential Information using not less than the standard of care as it applies to its own Confidential Information.

15.3. The restrictions on use and disclosure of Confidential Information under clause 15.1 shall not apply to any Confidential Information which:

a) was already known to the Recipient Party prior to its receipt thereof from the Disclosing Party;

b) was subsequently disclosed to the Recipient Party lawfully by a third party who did not obtain the same (whether directly or indirectly) from the Disclosing Party;

c) was in the public domain at the time of receipt by the Recipient Party or has subsequently entered into the public domain other than by reason of the breach of the provisions of this clause 15 or any obligations of confidence owed by the Recipient Party to the Disclosing Party; and/or

d) is required to be disclosed by Applicable Law.

15.4. Confidential Information shall be subject to the obligations of confidence in this clause 15, irrespective of whether communicated orally or in writing by the Disclosing Party or its representatives or obtained through observations made by representatives of the Recipient Party at the premises of the Disclosing Party.

15.5. Confidential Information shall not be exempted under clause 15.3 from restriction under this Agreement by reason only that:

a) some or all of its features (but not the combination and/or principle thereof) are or become public knowledge or are in the possession of or become available to the Recipient Party as mentioned in clause 15.3; or

b) such information could be derived or obtained from information which is or becomes public knowledge or is in the possession of or becomes available to the Recipient Party as mentioned in clause 15.3 if so to obtain or derive it would require substantial skill, labour or expense.

15.6. Nothing in this clause 15 shall prevent the Recipient Party from using any techniques, ideas or know-how gained during the performance of this Agreement in the course of its normal business to the extent that this use does not result in a disclosure of the Disclosing Party's Confidential Information or an infringement of its Intellectual Property Rights.

16. GENERAL TERMS

16.1. Publicity

You hereby agree that Optum and a Relevant Study Party (the identity of whom will be notified to You) shall both be permitted to publicise their respective involvement with You in relation to this Agreement / the relevant Research Study, provided that You shall have the right to review and approve or reject beforehand any proposed statement or release from Optum and or the Relevant Study Party.

16.2. Waiver

a) A waiver of any right under this Agreement is only effective if it is in writing and it applies only to the circumstances for which it is given. No failure or delay by a party in exercising any right or remedy under this Agreement or by law shall constitute a waiver of that (or any other) right or remedy, nor preclude or restrict its further exercise. No single or partial exercise of such right or remedy shall preclude or restrict the further exercise of that (or any other) right or remedy.

b) Unless specifically provided otherwise, rights arising under this Agreement are cumulative and do not exclude rights provided by law.

16.3. Force Majeure

Optum shall have no liability to the Customer under this Agreement if it is prevented from, or delayed in performing, its obligations under this Agreement or from carrying on its business by acts, events, omissions or accidents beyond its reasonable control, including: strikes, lock-outs or other industrial disputes (whether involving the workforce of Optum or any other party), failure of a utility service or transport network, act of God, war, riot, civil commotion, pandemic, epidemic, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood, storm or default of Optum or its subcontractors.

16.4. Relationship

Nothing in this Agreement creates a joint venture, relationship of partnership or agency between the parties. Accordingly, except as expressly authorised under this Agreement neither party has authority to pledge the credit of or make any representation or give any authority to contract on behalf of another party. No Staff of Optum shall be construed as being an employee of the Customer by virtue only of this Agreement or the performance of Optum's obligations under this Agreement.

16.5. Assignment and Sub-Contracting

a) Optum may assign or sub-contract any of its rights and/or obligations under this Agreement to any of its Affiliates or any other third parties. Optum will use reasonable endeavours to give You notice in writing in respect of any assignment.

b) Subject to clause 16.5a) and subject to Optum's right to appoint sub-contractors who are sub-processors pursuant to paragraph 1.5 of Schedule 3, neither party may assign or sub-contract any of its rights or obligations under this Agreement to any other third party without first obtaining the express written consent of the other party (such consent not to be unreasonably withheld or delayed).

16.6. Severability

Notwithstanding that the whole or any part of any provision of this Agreement may prove to be illegal or unenforceable, the other provisions of this Agreement and the remainder of the provision in question shall remain in full force and effect.

16.7. Variations

a) We reserve the right to amend the terms of this Agreement from time to time by giving You notice in writing either by (i) updating this Agreement online, (ii) in accordance with clause 16.8 and/or (iii) by posting an update on Optum Help Centre.

b) If any change to this Agreement would have a material effect on You, we will give not less than thirty days' notice in writing (in accordance with clause 16.8 and/or by posting an update to Optum Help Centre) of the relevant amendment. Where You do not accept such amendment to this Agreement, You may terminate this Agreement immediately, at any time up to the expiry of the notice, by deactivating the data sharing setting on EMIS Web and ceasing to use the Service.

c) If You continue to use the Service(s) following notification (or, as relevant, expiry of such notification) of any amendments made pursuant this clause 16.7, then You will be deemed to have accepted the same (and this Agreement is varied accordingly).

16.8. Notices

a) Subject to clause 16.7, any notice required under this Agreement shall be given in writing and in the English language and sent to the address of the party for which it is intended to be given, or such other address as shall have been notified to the other party in accordance with this clause and be sent by registered post or equivalent, courier or other electronic transmission; and

i. if posted, shall be deemed to have been received three Working Days after the date of posting or, in the case of a notice to an addressee not in the country of the sender, ten Working Days after the date of posting;

ii. in the case of email, upon confirmation of complete receipt being given by the intended recipient party (which in the case of Optum shall be sent to uk.contracts@optum.com marked for the attention of Legal Counsel); and/or

iii. if couriered, on delivery.

16.9. Third Party Rights

Save for any rights conferred on the Relevant Study Party (including the Named Party for the purposes of the Sponsor Processor Terms) and or any of Optum's Affiliates, this Agreement does not create or confer any rights or benefits enforceable by any person not a party to it (within the meaning of the Contracts (Rights of Third Parties) Act 1999).

16.10. Entire Agreement

This Agreement constitutes the entire agreement and understanding between the parties relating to the subject matter. Except as may be expressly stated in this Agreement, it supersedes and cancels all prior agreements, statements, representations, understandings, negotiations and discussions, whether oral or written, between the parties. Each of the parties acknowledges and agrees that in entering into this Agreement it has not relied on (nor has it been induced to enter into this Agreement by) any statement, representation, warranty or understanding made prior to this Agreement. Nothing in this clause shall exclude any liability in respect of any misrepresentations made fraudulently.

16.11. Dispute Resolution

a) Subject to clause 8.4, any dispute arising out of or in connection with this Agreement (each a "**Dispute**") shall be referred by either party first to the authorised representatives of each of the parties for resolution.

b) If the Dispute cannot be resolved by the authorised representatives of the parties within ten (10) Working Days after the Dispute has arisen, either party may give notice to the other party in writing (each a "**Notice**") that a Dispute has arisen.

c) Within ten (10) Working Days after the date of the Notice, the Dispute shall be referred to a senior executive of each of Optum and the Customer for resolution. If the Dispute is not resolved by agreement in writing between the parties within ten (10) Working Days after the date of the Notice, then each party shall be entitled to pursue such remedies as may be available to it under this Agreement or otherwise at law or in equity. This clause 16.11 is without prejudice to either party's right to seek interim relief against the other party (such as injunction) through local courts, as defined herein, to protect its rights and interests.

16.12. Applicable Law and Jurisdiction

a) This Agreement and any matters (whether contractual or non-contractual) arising out of or in connection with this Agreement shall be governed by and construed in accordance with the laws of England and Wales.

b) The parties submit and agree to the exclusive jurisdiction of the English Courts.

16.13. Counterparts

This Agreement may be executed in counterparts, all of which shall constitute one agreement between the parties.

Schedule 1

Your Responsibilities

1. Initial instructions and consents

By accepting these terms, You hereby instruct Optum (and confirm that You have obtained any necessary permissions) for Optum to anonymise and otherwise process the Customer Data to deliver the Service described in Schedule 2 and You hereby confirm that You will comply with all of Your responsibilities set out in this Schedule 1.

You hereby confirm that by providing Your instructions, approvals and consents set out herein, Optum is hereby instructed and fully authorised to perform each aspect of the Service set out in Schedule 2 without having to obtain any subsequent approvals or consents from You (and as a Data Processor, Optum is not required to obtain any consents from Data Subjects).

2. Keeping patient information accurate and up to date

It is Your responsibility to ensure that all patient information in EMIS Web is accurate and up to date, including in respect of relevant codes – the outputs generated by Optum pursuant to this Agreement will only be as accurate as the information which You make available to us. In particular, You must ensure that, before Optum performs its obligations pursuant to Schedule 2, the patient information in EMIS Web is updated to ensure that the following types of individuals are automatically excluded from participation in any Research Study:

a) patients who are registered on NDOP (National Data Opt Out) (when and if NDOP is being applied as more particularly described in paragraph 3 of Schedule 2) and Type 1 and 2 opt outs or who have the Opt Out Codes applied to their record (where not superseded by an Opt In Code). You agree and acknowledge that it can take up to 48 hours for any opt in or opt out codes to be reflected in your list of Potential Study Participants and it is Your responsibility to ensure you check the accuracy of this list before undertaking any actions. For the avoidance of doubt, an Opt In Code will not override a Type 1 or Type 2 opt out which can only be overridden by their corresponding withdrawal/consent codes;

b) deceased patients; and

c) patients who are no longer registered with You.

3. Other obligations

a) Where required pursuant to Schedule 2, You acknowledge that You are responsible for ensuring that invites are sent to the correct individuals – in particular, You should carefully review the list of Potential Study Participants to ensure that none of them have opted out, are deceased or have moved practice. You should let us know as soon as possible if any such individuals are on the list of Potential Study Participants.

b) You are responsible for ensuring that any patient who contacts You in order to opt out of future communications regarding clinical trials has an Opt Out Code recorded against the relevant patients record. Otherwise, such patients may still appear as a Potential Study Participant. Where a patient has both an Opt Out Code and Opt In Code applied to their medical record, Optum shall rely on the most recently added code for the purposes of whether the patient is included or excluded for Research Studies. It is Your responsibility to ensure that you check the applicable Opt In Codes and Opt Out Codes on a regular basis and apply them appropriately to your patients' records.

c) Whilst the parties acknowledge that Optum provides the Service to facilitate You achieving the following, You nonetheless bear primary and overall responsibility for:

   i. sending out specific invites to each Potential Study Participant, including details of the relevant Research Study, where relevant particularly in respect of Optum Referrals, asking for the Potential Study Participant to provide their express consent for their data (including, where relevant, their EHR) to be shared with the relevant academic institutions and other named third

party organisations sponsoring and/or running the Research Study, or third party intermediaries or agents acting on their behalf ("**Relevant Study Party**"); and

ii. where relevant, in particular in respect of Optum Referrals, obtaining and recording the consent or dissent of willing Potential Study Participants, to have their data shared (including their EHR) with the Relevant Study Parties for the purposes of the Potential Study Participant taking part in a specific Research Study (please see Selection and obtaining Consent Phase in paragraph 5 of Schedule 2); and

iii. in relation to the EHR Feature, deciding whether or not to share a Potential Study Participant's EHR with a Relevant Study Partner (where the patient has consented to the same) and what information is shared. In particular, You must ensure that only appropriate data about your patient is shared for the relevant Research Study, including removing any information that relates to third parties, or information that could cause serious harm to the patient or others if it were disclosed. To assist with your responsibilities, we have endeavoured to automatically redact codes that may contain sensitive or third-party information not required to assess study eligibility, however we do not guarantee that all such information has been fully removed, and you must ensure that the information is correct before sharing. You can find the full list of the codes we endeavour to remove here: https://www.emisnow.com/csm?id=kb_article_view&sysparm_article=KB5002053.

d) In Your capacity as a Data Processor (or sub-processor) for the Named Party, in respect of each Potential Study Participant who has consented to share their data using the Optum Referral process, You hereby instruct Optum to share the relevant Customer Data (as confirmed in the relevant Study Terms and Conditions, accepted by You) with the Relevant Study Parties.

e) A breach by Customer of its obligations under this Schedule 1 shall constitute a material breach incapable of remedy for the purposes of clause 13.3.

f) In relation to the EHR Feature, You agree and acknowledge that the:

i. EHR reflects the relevant information for the period between the Potential Study Participant's birth and the date falling up to 48 hours before the time the Potential Study Participant consented to share their EHR with the Relevant Study Partner; and

ii. Optum will not update the EHR after this time.

Schedule 2

Service Description

Subject strictly to You providing the necessary instructions, approvals and consents and otherwise fulfilling Your obligations set out in Schedule 1, Optum shall perform the following Service under Your instructions. This Service is essentially an enhancement of the processes which You would need to undertake manually in order to liaise with potential research organisations and/or sponsors to determine the feasibility of a potential study or opportunity and/or to recruit patients for a Research Study – Optum does this on Your behalf as part of the Service to create a more precise, scaled and efficient way for You to receive opportunities to take part in research studies and to recruit patients for clinical research studies. Each of the below services are an essential part of enabling Optum to deliver the overall Recruit service to You.

1. Stage 1 – Feasibility

a) Overview

From time to time, Optum works, or explores potential opportunities, with research organisations and study sponsors (such as clinical research networks and life science companies) in relation to potential studies or topics of interest which may result in studies which are relevant to primary care. By entering into this Agreement, You are appointing Optum to deliver the Feasibility Service to You.

The Feasibility Service involves us running a search on behalf of You (and any other participating organisations) in order to do one or more of the following:

i. identify whether the participating Recruit organisations have collectively sufficient numbers that it is feasible to recruit enough patients into a study; and/or

ii. optimise trial design to increase the chances of inception, success and completion of a study.

Any information provided to the potential sponsor or other relevant party (such as a CRO) will be limited to aggregate numbers of potentially relevant individuals, analytic insights, and approximate locations (in order to determine where it might be best to place study centres). This same information will be made available to You in the Feasibility Reports (though potentially not the identity of the potential sponsor where this is identified as being commercially sensitive).

b) Details of processing

As part of the Feasibility Service, You hereby instruct Optum to undertake the following processing of Customer Data:

i. running searches so as to determine, when viewed across the whole of the potential participating practices, whether the relevant study or opportunity appears to be potentially viable (and if it is, where it might be best located in broad terms); and/or

ii. running searches to optimise trial design to increase the chances of inception and success of a study. For example, by lowering or increasing age thresholds or by adding or removing a particular condition, are there more eligible patients without materially impacting on the purpose of the trial.

Optum will publish Feasibility Reports and make them available to You. Where it is permitted to do so, it will include details of the relevant sponsor/requestor. In addition, You hereby expressly permit us to (a) share this anonymised data along with any other anonymised data created through the provision of the Feasibility Service with the relevant potential sponsor/research organisation(s) in connection with the Feasibility Service and (b) otherwise use such anonymised data for our own internal and external business purposes (including making it available to third parties).

2. Stage 2 – Study Validation Service

a) Overview

The "**Study Validation Service**" involves Optum carrying out a series of checks and balances on each Research Study, necessary to help ensure that Research Studies made available to You are:

i. configured appropriately to work with the primary care data (i.e. Customer Data) in EMIS Web (so as to only identify those patients who may actually be eligible for the Research Study); and

ii. of genuine relevance to You i.e. Your practice is within the catchment area(s) for the Research Study sites and/or You have patients that are eligible.

This helps to safeguard the integrity of the Service being delivered to You, minimising the risk of You incorrectly contacting patients who are unlikely to be eligible (i.e. avoiding a situation where the cohort definition isn't optimised to identify patients who are more likely to be eligible) and tailoring the Research Studies You see in Recruit.

Optum's clinical and ethical sign-offs are designed to mean that Optum will endeavour only to present Research Studies to You that meet appropriate standards, with each Research Study reviewed on a case-by-case basis. If a Research Study does not pass through the Study Validation Service successfully, Optum will ensure that it is not made available to You within Recruit.

b) Details of processing

As part of the Study Validation Service, You hereby instruct Optum to undertake the following processing of Customer Data to ensure the viability of a Research Study:

i. review, test and, where relevant amend, the 'study cohort definition' (being the technical definition of who should be included in the Research Study – expressed in SNOMED / dm+d or other codes) for the Research Study, and validate this against Customer Data. This would be a first step before a Research Study can be surfaced to You in Recruit and is necessary to ensure that the cohort definition can and will work appropriately with Customer Data to identify eligible patients;

ii. establish the feasibility of a Research Study across all Recruit GP practices, using the refined study cohort definition, to help ensure that Research Studies are undertaken in areas where there are sufficient numbers of eligible patients to make the Research Study feasible and/or so we make Research Studies available to You in Recruit that are relevant to You. For example, seek to ensure You do not see studies that are taking place outside of Your catchment area and/or excluding Research Studies where You have very few or no eligible patients (however, for the avoidance of doubt, Optum will not share any Customer Data or Data Deliverables with other GP practices as part of this processing); and

iii. Data Deliverables – Create anonymised datasets that are necessary to demonstrate validation of the study cohort definition in accordance with paragraph 1(b)(i) and/or to show the number of patients who would potentially be eligible for participation in a particular Research Study (including by reference to key factors such as location). You hereby expressly permit us to: (a) share this anonymised data with Relevant Study Parties, including to demonstrate the efficacy and accuracy of the Study Validation Service; and (b) otherwise use such anonymised data for our own internal and external business purposes (including making it available to third parties).

For the avoidance of doubt, in the context of any processing undertaken by Optum in relation to the Study Validation Service, Optum may only use Customer Data as necessary to deliver the Service.

3. Determining Potential Study Participants

In relation to Research Studies that successfully pass through the Study Validation Service phase, You instruct Optum to use the Customer Data within EMIS Web to provide You with the following outputs:

a) the number of patients ("**Patient Number Output**") (with such number being visible to both parties); and

b) a list of patient names ("**Potential Study Participants**") (with such list only being visible to You and only once You have agreed to the relevant Study Terms and Conditions),

who might be eligible for participation in each Research Study.

Noting, in accordance with NHS Digital's guidance, that NDOP is not always applicable to a Research Study, Optum will either, at its discretion: i) automatically apply NDOP, ii) notify You in the relevant Study Terms and Conditions if NDOP is not being applied to that Research Study (at which point You can decide whether to participate in recruitment for the study or not); and/or iii) give You the option to apply/disapply NDOP with Recruit for the relevant Research Study.

4. Making the Data Deliverables available to You

Optum shall use its reasonable endeavours to make the Patient Number Output and the list of Potential Study Participants (in this instance, subject to Your acceptance of the relevant Study Terms and Conditions) available for You to view in Recruit, in respect of each Research Study.

Optum shall use its reasonable endeavours to provide relevant wording for the invites, which You can choose to send to Potential Study Participants in accordance with paragraph 3 of Schedule 1. You should satisfy Yourself that the wording in the invite is compliant with Applicable Law, particularly in relation to the validity of consents under Data Protection Laws and the law of confidentiality. If the wording of the invite requires any editing, You should inform us before the invite is sent.

5. Selection and Consent Phase

In order to assist Your compliance with paragraph 3 of Schedule 1, Optum shall, via functionality within Recruit, enable You to select all or individual patients from within the list of Potential Study Participants and send them an SMS and/or e-mail. At this stage, for Optum Referrals only, You will also be able to schedule a reminder SMS and/or e-mail to be sent to the Potential Study Participant(s). We'll show You the text of the reminder and confirm to You when the reminder will be sent. If You don't want to schedule a reminder, you'll need to toggle the reminder off before proceeding. If the Potential Study Participant responds to the initial SMS and/or e-mail, we won't send a reminder to them.

If a Potential Study Participant has opted out of receiving SMS and/or e-mail correspondence, this will be flagged in Recruit against the relevant patient. However, You can still select to send communications to such patients at Your discretion and subject always to Your compliance with this Agreement. Once You have submitted instructions to us to send the SMS and/or e-mail correspondence to the selected Potential Study Participant(s), the following steps in the remainder of this Schedule 2 will be followed by Optum (in each case, depending on whether it is an Optum Referral or a Relevant Study Party Referral):

a) Potential Study Participant Authentication

Once You have sent the invitation referred to above, the Potential Study Participant will receive a notification on their phone and/or in an email, consisting of a short message and a link. The link will either:

- **Optum Referral** – take the Potential Study Participant to an Optum landing page where Optum will check their identity by asking for their date of birth; or
- **Relevant Study Party Referral** – take the Potential Study Participant direct to the Relevant Study Party's landing page where the patient's identity and suitability for the Research Study will be validated direct by the Relevant Study Party. Any information (including Personal Data) shared by the Potential Study Participant at this stage will be subject to the contract and the privacy policy of the Relevant Study Party.

b) Post Authentication – Optum Referral

Stage 1 – Contact Details

If the Optum Referral authentication is successful, Optum will provide the patient with information about the Research Study and two options as follows:

- Consent to have their contact data shared with the Relevant Study Party; or

- Dissent to having their contact data shared with the Relevant Study Party.

At this stage, the Potential Study Participant will also be informed that if they wish to opt out of being contacted for research studies to contact You and we may also direct them to Your privacy policy. In order to be removed as a Potential Study Participant for any future Research Studies in Recruit, You will need to ensure that an Opt Out Code is recorded against the relevant patient's medical record within EMIS Web.

Stage 2 – EHR Feature

If the relevant Research Study includes the EHR Feature (as confirmed by the relevant Study Terms and Conditions), patients who consent at Stage 1 of the Optum Referral process will then be presented with two options regarding sharing their EHR with the Relevant Study Party:

- Consent to sharing their EHR with the Relevant Study Party. This consent, given by the patient to You, is to share their EHR with the Relevant Study Party subject to Your review and approval, it does not oblige You to share the EHR and this will not be automatically shared (see below for more details). The patient will be presented with a copy of the Relevant Study Partner's privacy policy and by providing consent will be agreeing that their EHR can be held and processed by the Relevant Study Partner in accordance with that policy upon the EHR being shared; or

- Dissent to share their EHR with the Relevant Study Party. Under these circumstances, the patient's contact details are still shared with the Relevant Study Party pursuant to the consent captured at Stage 1 above.

In each case, the individual's response will, once submitted, be automatically recorded in Recruit.

The EHR Feature can be enabled in two ways:

(a) Automatic review: this is where the EHR is immediately sent to You for review upon the patient consenting to share their EHR at Stage 1 of the Optum Referral process; or

(b) Sponsor triggered review: this is where the Sponsor, or its Study Partner(s), determine whether they want a particular patient's EHR (where consent to share the EHR has been captured) to be reviewed and shared by You.

The relevant Study Terms and Conditions will confirm how the EHR has been enabled.

Where a Potential Study Participant consents to share their EHR, depending how the EHR feature is enabled, this consent will be confirmed to You within Recruit and a copy of the EHR will be presented for Your review and approval automatically, or following the request of the research study team.

You can then either:

- approve to send EHR to the Relevant Study Party; or

- decline to send the EHR at this time, in which case the EHR for the Potential Study Participant will not be shared and the Relevant Study Party (for the avoidance of doubt, unless additional functionality has been implemented by Optum (as notified by Optum to You, including making the functionality available within Recruit), You will not be able to reverse this decision within Recruit). The Potential Study Participant's contact details will still be shared in accordance with Stage 1 notwithstanding this dissent and the Potential Study Participant may choose to contact You for further information / to request that You send their EHR manually; or

- choose to redact the EHR manually before sharing with the Relevant Study Party. In these circumstances, You will need to download the EHR, redact or remove relevant information and then send the same via email to the Relevant Study Partner using the email address provided in the relevant Research Study within Recruit. Optum may later make additional functionality available in Recruit to allow You to redact the EHR electronically. When, and if, this functionality is made, You will be able to electronically redact the EHR and thereafter approve to send the redacted EHR within Recruit to the Relevant Study Partner.

Optum shall use its reasonable endeavours to communicate to Potential Study Participants and the Relevant Study Partners of Your decision regarding the sharing of the Potential Study Participant's EHR.

You should periodically review the list of Potential Study Participants to identify new requests from the research study team, or consents from Potential Study Participants.

c) Post Authentication - Relevant Study Party Referral

The Potential Study Participant's response will be recorded by the Relevant Study Party. Any information (including Personal Data) shared by the Potential Study Participant with the Relevant Study Party will be subject to the contract and the privacy policy of the Relevant Study Party.

The Potential Study Participant will be able to choose not to proceed at any time during the process by informing the Relevant Study Party.

6. Sharing of data with and from Relevant Study Parties

a) Optum Referral

Stage 1 – Contact Details

In respect of Potential Study Participants who have provided their consents pursuant to paragraph 5 b) – Stage 1, Optum shall share the relevant Customer Data with the Relevant Study Party. Once this data is shared, the Relevant Study Party will contact the Potential Study Participant(s) directly and will take over in terms of liaising with the individuals going forward in respect of their participation in the Research Study.

Stage 2 – EHR Feature

In respect of Potential Study Participants who provide their consent to share their EHR and who You approve to send their EHR pursuant to paragraph 5 (b) – Stage 2, Optum shall share the EHR and a copy of the Potential Study Participant's consent with the Relevant Study Party. The Relevant Study Party will have 4 months from the date of the EHR being shared to download a copy of the EHR after which it shall be deleted from their instance of Recruit. The EHR will be held and processed by the Relevant Study Party in accordance with the Relevant Study Party's privacy policy as presented to the Consented Patient through the Optum Referral services.

If a Potential Study Participant subsequently wishes to withdraw from further participation in a Research Study, they will need to inform the Relevant Study Party, who should record this in Recruit and You will be informed of the removal of the patient's consent through Recruit.

b) Relevant Study Party Referral

Unless explicitly agreed with You, and subject to relevant consent being provided by the relevant Potential Study Participant(s), Optum will not share any Customer Data with the Relevant Study Party for a Relevant Study Party Referral.

c) Tracking consented and/or randomised Potential Study Participants

Optum will obtain necessary information (which may include Personal Data) from the Relevant Study Party in order to be able to validate Potential Study Participants who have fully consented and/or been randomised and/or who have had their EHR shared (as appropriate). This is to allow Optum to:

- ensure that You are paid the correct amount of Fees; and
- where possible, to be able to file back a Potential Study Participant's consent and/or randomisation for a Research Study to You and/or their medical record within EMIS Web.

In order to be able to safely and securely track Potential Study Participants' consent and/or randomisation, Optum may need to use tracking technology (such as unique URLs). Optum will use such technology to create either fully anonymised or pseudonymised identifiers that:

- do not allow the Relevant Study Party to identify the Potential Study Participant (and therefore, for the purposes of the Relevant Study Party is anonymised data); but
- once confirmed back to Optum by the Relevant Study Party, will allow Optum to re-identify the Potential Study Participants for the above purposes.

You acknowledge that this tracking may not be 'real time' and as such, there may be a delay between the Potential Study Participant being consented and/or randomised and Optum receiving the information to be able to confirm this is the case from the Relevant Study Party. In addition, Optum may not always be able to file back information to You and/or the patient's record.

d) For the duration of Your participation in a relevant Research Study, You instruct Optum to share any updates You make to the relevant Customer Data (in EMIS Web, EMIS-X and/or Recruit), for the relevant Potential Study Participants that You have already shared in accordance with the Agreement, with the Relevant Study Party (i.e. if contact information is updated, this will be shared with the Care Provider etc.).

7. Use of data by Relevant Study Parties

You agree and acknowledge that, notwithstanding whether a Potential Study Participant provides consent via an Optum Referral or a Relevant Study Party Referral, once the Potential Study Participant is in direct contact with the Relevant Study Party:

a) use of any Customer Data sent to the Relevant Study Party in accordance with the terms of this Agreement and any other data (whether Personal Data or not) provided direct by the Potential Study Participant to the Relevant Study Party will be subject to the contract and the privacy policy in place between the Potential Study Participant and the Relevant Study Party;

b) once Customer Data is shared, the Relevant Study Party is a Data Controller (or Data Processor or sub-processor, as the case may be) of its copy of such data in its own right;

c) as such, the Potential Study Participant could agree, for example, to their data being held by the Relevant Study Party so that the Potential Study Participant can participate in other Research Studies not listed in Recruit and/or for purposes not related to Research Studies whatsoever; and

d) Optum has no control over (or responsibility for) such agreements and/or arrangements.

8. Patient Access Referral

a) Where You have chosen to participate in a relevant Study Terms and Conditions, in the event that one or more of the Potential Study Participants identified at Your practice have been the subject of a Patient Access Referral, Optum shall use its reasonable endeavours to notify You of this referral within Recruit.

b) You may or may not be entitled to a payment of a Fee in respect of Potential Study Participant(s) that have been the subject of a Patient Access Referral, this will be set out in the relevant Study Terms and Conditions.

Schedule 3

Data Processing

1 CUSTOMER DATA

1.1 The parties acknowledge that in the context of processing of any:

1.1.1 Customer Data under this Agreement, You are a Data Controller and Optum is a Data Processor, acting under Your instructions (or in respect of a specific Research Study where you have entered into the Sponsor Processor Terms with a Named Party, You are acting as the Data Processor (or sub-processor) of the Named Party and Optum is acting as Your sub-processor); and

1.1.2 Customer Data that has been shared by You with a Relevant Study Party in accordance with the terms of this Agreement, in respect of the copy of such data shared, the Relevant Study Party is a Data Controller (or Data Processor, or sub-processor (as the case may be) for the Sponsor) and Optum is a Data Processor (or sub-processor, as the case may be), acting under the Relevant Study Party's instructions.

1.2 The table in the Appendix to this Schedule sets out the particulars of Processing by Optum.

1.3 You will ensure that You:

1.3.1 collect all of the Customer Data fairly and transparently;

1.3.2 Your Privacy Notice is presented to patients, is fully compliant with Data Protection Laws and has been updated to reflect the use of Personal Data as contemplated under this Agreement; and

1.3.3 have all necessary rights, permissions, consents and notices in place with Data Subjects to enable the lawful transfer of Customer Data to Optum for the duration of this Agreement and to enable Optum to fully comply with its obligations under this Agreement, including performance of the Service, such that the performance of the Service is compliant with the Data Protection Laws.

1.4 Optum shall, in relation to any Customer Data processed in connection with the performance by Optum of its obligations under this Agreement:

1.4.1 process that Customer Data only in accordance with Your written instructions (unless otherwise required by law) and only for the purpose of performing Optum's obligations and exercising its rights under this Agreement;

1.4.2 ensure that it has in place appropriate technical and organisational measures, designed to protect against unauthorised or unlawful processing of Customer Data and against accidental loss or destruction of, or damage to, Customer Data, appropriate to the harm that might result from the unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures;

1.4.3 take all reasonable steps to ensure the reliability and integrity of Staff who have access to and/or process Customer Data;

1.4.4 inform You promptly upon becoming aware of any instruction issued by You under this Agreement that breaches the Data Protection Laws;

1.4.5 not transfer any Customer Data outside of the United Kingdom (although You acknowledge that Customer Data may however be transferred outside of the United Kingdom by a Relevant Study Party as agreed between the Potential Study Participant(s) and the Relevant Study Party, which Optum cannot control);

1.4.6 assist You, at Your cost, in responding to any request from a Data Subject and in ensuring compliance with Your obligations under the Data Protection Laws with respect to security,

breach notifications, impact assessments and consultations with the Data Protection Regulator;

1.4.7 notify You without undue delay on becoming aware of a Personal Data Breach;

1.4.8 at Your written direction, delete or return Customer Data and copies thereof to You on termination or expiry of this Agreement unless required by law to retain Customer Data, in which case Optum shall inform You of such legal requirement; and

1.4.9 allow for audits by You or Your designated auditor in respect of Optum's data processing activities under this Schedule 3.

1.5 You hereby expressly authorise Optum to appoint third parties as its sub-processors in relation to processing Customer Data from time to time. A list of Optum's material sub-processors (as updated by Optum from time to time) as at the date of this Agreement is set out here: https://www.emishealth.com/legal (in respect of which for the avoidance of doubt, You hereby give Your written authorisation) and You should review this list regularly to see if there are any changes to the sub-processors. Any objection to an amendment to the list of sub-processors may be escalated for discussion within 10 days after receipt of a notification of, or otherwise upon You becoming aware of, any change (such notification to include the list of material sub-processors being updated on the webpage provided above). If the parties are (acting reasonably) unable to resolve the objection and Optum informs You that it nevertheless intends to appoint the relevant sub-processor then You may either: (i) accept the change; or (ii) terminate this Agreement upon written notice within one month of raising the objection (and as Your sole and exclusive remedy, Optum will refund any unused prepaid Fees).

1.6 In the event of any loss of, or damage to, any Customer Data, Optum shall use its reasonable endeavours to restore the lost or damaged Customer Data from the latest backup version of Customer Data available to it. If the loss or damage was caused by Optum then it shall undertake such restoration at its own cost and expense and in any other circumstances, it shall be entitled to charge You in respect of any time spent at its then standard rates.

Appendix

Particulars of Data Processing

Purpose of processing:	Performing the Service, as further described in Schedule 2.
Duration of the processing:	For the term of this Agreement.

Nature of processing:	• Generating fully anonymised datasets and/or statistical data in accordance with the permissions set out in this Agreement.
	• Determining feasibility of potential research studies or opportunities including:
	  ○ Validating the cohort definition and ensuring feasibility of Research Studies.
	  ○ Optimising trial design to increase the chances of inception, success and completion of a study.
	• Determining the number of individuals who might be eligible to participate in a Research Study, and the actual names of those individuals, sharing data of consenting individuals with Relevant Study Parties.
	• Tracking consented and/or randomised Potential Study Participants for validating Your Fees and confirming their involvement for the purposes of updating their medical record.

Types of Personal Data (including any Special Category Data):	Full medical record including: Name, email address, contact no, NHS no, practice name, title, first name, last name, age, DOB, gender, home address, prescribed medicines and conditions, observations, vaccinations (and such other personal data which You instruct Optum to process from time to time) and the EHR.
Categories of Data Subject:	Your Patients
Source of Personal Data:	Via data held in EMIS Web

Schedule 4
Authorising an Agent

1. DEFINITIONS

The following definitions shall apply to this Schedule 4:

"**Agent Agreement**" means an agreement between You and an Agent in relation to its rights and obligations in undertaking the Agent Activities (whether in writing or otherwise).

"**Agent Network**" means a network of practices using Recruit that have appointed an Agent to undertake Agent Activities.

"**Agent Request**" means a request from an Agent to join its Agent Network.

"**Assigned**" means where Your Agent has decided to recruit Potential Study Participants for a relevant Research Study from Your practice.

"**Assignment in Progress**" means where Your Agent is considering whether to recruit Potential Study Participants for a relevant Research Study from Your practice.

"**Assignment Status**" means the status of Your practice as Assigned, Assignment in Progress or Not Assigned as determined by Your Agent.

"**Not Assigned**" means where Your Agent has not yet decided to recruit Potential Study Participants for a relevant Research Study from Your practice.

2. AGENT AUTHORISATION

2.1 From time to time an Agent may provide us with the name of Your practice and ask Optum to send You an Agent Request.

2.2 Where requested, Optum will make the Agent Request available to You within Recruit and You can choose (in Your absolute discretion) whether to a) accept the Agent Request, b) reject the Agent Request or c) take no action.

2.3 If you accept an Agent Request:

2.3.1 You confirm to Optum that You have appointed the relevant Agent as Your agent to undertake the Agent Activities on Your behalf;

2.3.2 the terms of this Schedule 4 shall apply to such appointment as between You and Optum;

2.3.3 Optum shall be entitled/instructed to:

2.3.3.1 rely upon any actions, instruction or decisions (whether within Recruit or not) made by the Agent on Your behalf in relation to the Agent Activities; and

2.3.3.2 share such relevant Customer Data (including Personal Data) with the Agent in respect of relevant Potential Study Participants; and

2.3.4 You shall be responsible for the actions and omissions of the Agent under the Agreement as if they were Your own actions or omissions.

2.4 If You reject the Agent Request or take no action, You will be able to continue to use the Service as normal in accordance with the terms of the Agreement.

2.5 You may only appoint one Agent / be part of one Agent Network at any one time.

2.6 Optum cannot control which practice names an Agent provides to / asks Agent Requests to

be sent to and we rely on the assumption that such Agent has previously discussed the Agent Request with You and has a relevant relationship with You. If You have any concerns regarding an Agent Request or are unsure why such a request has been sent, please contact the Agent. Optum does not share any information about You with an Agent prior to Your acceptance of an Agent Request, save to confirm Your Agent Request status being visible to the Agent as 'Not accepted' until such time that You do accept the Agent Request (if at all).

2.7 The terms of the Agreement, and in particular Schedule 4, are for the purposes of confirming Your authorisation to Optum in respect of an Agent and do not create a direct relationship between You and the Agent, which should be governed by an appropriate Agent Agreement.

3. AGENT ACTIVITIES

3.1 Where You have authorised an Agent in accordance with paragraph 2 of this Schedule, Your Agent will be able to see all Study Terms and Conditions available to You from time to time and, where it deems appropriate, accept the terms of such Study Terms and Conditions on Your behalf. On acceptance, You shall be bound by the terms of each Study Terms and Conditions and Optum shall deliver the Services in relation to such term(s) in accordance with the Agreement.

3.2 When Study Terms and Conditions have been accepted by Your Agent, the Agent shall be entitled, on Your behalf, to:

3.2.1 view all relevant Customer Data in relation to Potential Study Participants at Your practice (although note that the Potential Study Participants for Your practice will only be viewable by Your Agent upon the relevant Research Study being Assigned to Your practice);

3.2.2 use the Services and take such action(s) as would otherwise be available to You in accordance with paragraphs 3 to 6 (inclusive) of Schedule 2; and

3.2.3 determine, as it sees fit, Your Assignment Status from time to time. This means that, notwithstanding Your practice being eligible to recruit patients for a Research Study, Your Agent will ultimately determine whether to actually seek to recruit Potential Study Participants or not on Your behalf. You will be able to see Your Assignment Status within Recruit. Any queries in relation to the same should be raised directly with the Agent.

3.3 Where You have authorised an Agent, clause 8 of the Agreement shall not apply and You agree that Optum shall pay all relevant Fees to Your Agent. The arrangement between You and Your Agent regarding such Fees including any amounts that may be payable to You are subject to the relevant Agent Agreement.

3.4 Where you have authorised and Agent to undertake the Agent Activities:

3.4.1 You will not be able to accept / reject Study Terms and Conditions which will be within the control of Your Agent only;

3.4.2 You will be able to view your list of Potential Study Participants for each Research Study in Your list where You will be able to review recruitment invitation status and exclude Potential Study Participants; and

3.4.3 no further actions, Services or functionality will be available to You.

4. TERMINATING AGENT AUTHORITY

4.1 You may terminate Your authority for an Agent to undertake the Agent Activities under this Agreement at any time by giving Optum not less than 7 days' written notice (the "Notice Period").

4.2 Upon termination of Your authority in accordance with paragraph 4.1:

4.2.1 the Agent shall have the authority to undertake the Agent Activities until the end of the Notice Period. Should You wish the Agent to immediately cease all Agent Activities, You should

deal directly with the Agent (and, as relevant, in accordance with Your Agent Agreement with such Agent);

4.2.2 paragraph 3.3 shall continue to apply in relation to all Fees associated with Potential Study Participants invited by the Agent on Your, behalf before the end of the Notice Period. This shall apply notwithstanding whether You choose to send any reminder messages / invitations to such Potential Study Participants (whether manually or automatically); and

4.2.3 at the end of the Notice Period:

4.2.3.1 the Agent will no longer be able to see any Customer Data (however, Optum will still report to the Agent on the number of Potential Study Participants invited by the Agent on Your behalf, that successfully consent to their information being shared with a Relevant Study Party, for the purposes of the payment of Fees to the Agent);

4.2.3.2 You will have full control over the Services reinstated. Any Study Terms and Conditions accepted on Your behalf by Agent shall remain accepted and You will be able to see which Potential Study Participants were invited / have consented; and

4.2.3.3 may appoint a different Agent (should You wish to do so).

4.3 Optum shall use its reasonable endeavours to notify the Agent when it receives a notice under paragraph 4.1 from You however, You should also notify the Agent directly (and where relevant, in accordance with the Agent Agreement).

4.4 The Agent may also confirm to Optum that it wishes to terminate its authority to act on Your behalf. In such circumstances:

4.4.1 Optum shall use its reasonable endeavours to notify You of the termination; and

4.4.2 paragraph 4.2 shall apply to such termination (where the Notice Period shall mean the notice period agreed between Optum and the Agent).

4.5 For the avoidance of doubt, any termination of authority under this Agreement or under Optum's agreement with an Agent shall not terminate or have any other effect under a relevant Agent Agreement (unless so agreed between You and the Agent therein).

5. OPTUM'S LIABILITY

You shall hold Optum harmless and agree that Optum shall have no liability to You in relation to any actions taken by Optum in accordance with instructions of Your authorised Agent in accordance with this Schedule 4.

Schedule 5
Sponsor Processor Terms

1. These terms apply as between You and the relevant Named Party and are effective from the date You agree to the relevant Study Terms and Conditions. Optum will confirm the role of the Named Party within the Study Terms and Conditions i.e. Sponsor, CRO or otherwise. Definitions used in the Agreement shall apply to this Schedule (as relevant).

2. You and the relevant Named Party agree:
    a. to comply with all Data Protection Laws in processing the Personal Data of patients/clinical trial subjects. This Schedule is in addition to and does not replace, relieve or remove a party's obligations or rights under the Data Protection Laws; and
    b. when one Party is processing Personal Data, as Data Controller, for which the other party is at that time a separate and independent Data Controller, to promptly and without undue delay, notify and inform that other party in the event of any Personal Data Breach that relates to that Personal Data.

3. For the purpose of the Data Protection Laws, the Sponsor (set out in the Study Terms and Conditions) is the Data Controller and You are either (i) a Data Processor (if the Named Party is the Sponsor) or (ii) a Sub-Processor (if the Named Party is a Data Processor or Sub-Processor of the Sponsor) in relation to the Processing of Personal Data for the purpose of the relevant Research Study.

4. Your Processing of Personal Data, in accordance with paragraph 3 shall be governed by this Schedule, which sets out the obligations and rights of the Sponsor as Controller and (where relevant) the Named Party as Processor (or Sub-Processor) of the Sponsor. The subject matter, duration, nature, and purpose of the processing, type of Personal Data and categories of data subjects is set out in the Appendix of this Schedule.

5. You are the Controller of Personal Data that You process for purposes other than the Research Study, e.g. the provision of medical care (whether direct or indirect).

6. You, in Your role as Data Processor of the Personal Data under paragraph 3, agree to only process Personal Data for and on behalf of the Sponsor in accordance with the documented instructions of the Named Party as more particularly set out within, and defined by, the relevant Study Terms and Conditions. You agree and acknowledge that the terms of this Schedule apply to any processing You undertake in relation to the relevant Research Study regardless of whether it occurs through use of the Services or otherwise. If You are required by law to otherwise process the Personal Data (excluding processing undertaken by You in accordance with paragraph 5), You shall notify the Named Party before undertaking the processing, unless such notification is prohibited on important grounds of public interest in accordance with GDPR Article 28(3)(a). In the case of such prohibition, You shall notify the Named Party as soon as possible once the prohibition is lifted, if it is lifted.

7. You agree to comply with the obligations applicable to processors described by Article 28 of the GDPR, as well as those additional obligations required by the Named Party pursuant to this Schedule, including but not limited to the following:
    c. implementing and maintaining appropriate technical and organisational security measures for Personal Data processed in Your systems, in keeping with Your obligations as an NHS organisation, thereby providing guarantee to the Sponsor pursuant to GDPR Article 28(1);
    d. ensuring that personnel authorised to process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality (Article 28(3)(b));
    e. taking all measures required by GDPR Article 32 in relation to the security of processing (GDPR Article 28(3c));
    f. complying with the conditions described in GDPR Article 28(2) and (4) for engaging another Data Processor (GDPR Article 28(3d));

g. taking into account the nature of the processing, assist the Sponsor and/or the Named Party (if different), by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects' rights (GDPR Article 28(3e));
h. assisting the Sponsor (and/or the Named Party, if different), to ensure compliance with the obligations pursuant to GDPR Articles 32 to 36, taking into account the nature of the processing and the information available to You (GDPR Article 28(3f));
i. maintaining a record to demonstrate compliance with this paragraph and Data Protection Laws, including the records required pursuant to GDPR Article 30(2); and
j. in the event of any Personal Data Breach by You as a Data Processor or Sub-Processor (as relevant) the You shall: (i) promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to the email address identified in the relevant Study Terms and Conditions (ii) not make any statements or notifications about the Personal Data Breach, as it relates to the processing for the purpose of the Research Study, to any individual affected by the incident, the public or any third party without Sponsor or Named Party (if different) prior written approval; and (iii) immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with Sponsor and the Named Party (if different).

8. In furtherance of its obligations under Article 28 GDPR, with the exception of Optum acting as Your processor in accordance with the Services and Agreement, You agree that You will not engage another processor for the purpose of the Research Study without the prior written authorisation of the Sponsor or Named Party (if different) (GDPR Article 28(2)).

9. Upon termination or expiry of the Study Terms and Conditions for the relevant Research Study, You shall, at the choice of the Named Party, destroy or return all Personal Data to the Sponsor or Named Party (if different) unless there is a legal requirement for retention and storage (GDPR Article 28(3g)) and/or where that Personal Data is held by You as Controller for Your own purpose(s) (including as set out in paragraph 5).

10. You will:
    a. ensure that Your personnel do not process Personal Data except in accordance with the Study Terms and Conditions; and
    b. take all reasonable steps to ensure the reliability and integrity of any of Your personnel who have access to the Personal Data and ensure that the personnel:
        (i) are aware and comply with Your duties under this Schedule;
        (ii) are subject to mandatory training in their information governance responsibilities and have appropriate contracts, including sanctions, including for breach of confidence or misuse of Personal Data; and
        (iii) are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.
11. You agree to:
    a. provide the Sponsor and/or Named Party (if different) with evidence of Your compliance with the obligations set out in this Schedule, or, at the Sponsor and/or Named Party's (if different) discretion and on reasonable notice, to allow the Sponsor, Named Party (if different) or a third party appointed by the Sponsor or Named Party (if different), to audit Your compliance with the obligations described in this Schedule, Data Protection Laws (including but not limited to Article 28 GDPR), subject to the Sponsor, Named Party (if different) or appointed third party, complying with all Your relevant health and safety and security policies; and
    b. obtain prior written agreement of the Sponsor or Named Party (if different) to process Personal Data outside of the UK and the EEA.

12. In addition to Your obligations under paragraph 11b, where You, acting as the Named Party's Data Processor or Sub-Processor, processes Personal Data outside of the UK and the EEA, You warrant that You do so in compliance with the Data Protection Laws.

Appendix

Particulars of Data Processing

Purpose of processing:	Recruitment of Potential Study Participants for the relevant Research Study.
Duration of the processing:	For the term of the relevant Study Terms and Conditions.
Nature of processing:	Utilising the Services or other means decided by You to determine the number of individuals who might be eligible to participate in the relevant Research Study, and the actual names of those individuals, sharing data of consenting individuals with Relevant Study Parties.
Types of Personal Data (including any Special Category Data):	Full medical record including: Name, email address, contact no, NHS no, practice name, title, first name, last name, age, DOB, gender, home address, prescribed medicines and conditions, observations, vaccinations (and such other personal data which You determine to process from time to time for the Purpose of processing).
Categories of Data Subject:	Your Patients
Source of Personal Data:	Via data held in EMIS Web