

MODEL AGREEMENT FOR NON-COMMERCIAL RESEARCH

University College London (UCL) of Gower Street, London, WC1E 6BT hereby internally represented by the Cancer Research UK and University College London Cancer Trials Centre, of 90 Tottenham Court Road, London, W1T 4TJ
(referred to as the “Sponsor”)

AND

[Insert NAME AND ADDRESS OF PARTICIPATING SITE],

(referred to as “the Participating Site”)

Which are collectively referred to as the “Parties” or individually referred to as a “Party”

Study Title: ANIMATE

Reference: EudraCT: 2017-002544-32 / IRAS No. 216147

NOW

WHEREAS the Sponsor is a University;

WHEREAS the Study is coordinated on behalf of the Sponsor by the Cancer Research UK and University College London Cancer Trials Centre (CTC) which is a Clinical Trials Unit;

WHEREAS the Funder is Bristol-Myers Squibb which is a Pharmaceutical Company, which is also supplying the Study Drug to participating sites for use in the Study;

WHEREAS the Study is multi-centred, having more than one participating site;

WHEREAS the Study is a Clinical trial of an Investigational Medicinal Product.

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In respect of the clinical research Study entitled ANIMATE – “A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for autologous stem cell transplant, who fail to reach complete metabolic remission after first or second line salvage therapy” the above Parties HEREBY AGREE AS FOLLOWS:

1. DEFINITIONS

1.1. The following words and phrases have the following meanings:

Agent(s)	Includes, but shall not be limited to, any person undertaking a function in connection with this Agreement (including the Principal Investigator, any nurse or other health professional), any such person's principal employer in the event it is not the Participating Site and where such person is providing services to a Party under a contract for services or otherwise (including clinical academics), and/or any contracted third party providing services to a Party under a contract for services or otherwise.
Agreement	This agreement, together with the schedules annexed hereto.
Background	Intellectual Property Rights and Know How that are provided by one Party to the other Party for use in the Study (whether before or after the date of this Agreement) that do not themselves arise from the Study.
Chief Investigator or CI	The person who takes overall responsibility for the design, conduct and reporting of the Study or if a multi-site Study, the person who takes primary responsibility for the design, conduct and reporting of the entire multi-site Study, whether or not the person is a Principal Investigator at any particular Site.
Clinical Data	Any data which relate to a specific Participant which may include, without limitation, medical records, medical imaging data, scans, questionnaires, readouts of individual biomedical or genetic analysis.
Confidential Information	All information disclosed, (whether in writing, orally or by another means and whether directly or indirectly) by a Party ("Disclosing Party") to another Party ("Receiving Party") directly relating to the Study including, but not limited to information, the release of which is likely to prejudice the commercial business interests of the Disclosing Party, or which is a trade secret, including Know How and shall also include any data disclosed which is Personal Data and/or special category Personal Data, all as defined in the Data Protection Legislation, and/or information that is otherwise confidential patient information.
Controller	Shall have the meaning set out in the Data Protection Legislation.
Data Protection Legislation	All applicable data protection and privacy legislation, regulations and guidance including but not limited to Regulation (EU) 2016/679 (the "General Data Protection Regulation" or "GDPR"), the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003 and any guidance or codes of practice issued by the

	European Data Protection Board or Information Commissioner from time to time (all as amended, updated or re-enacted from time to time).
Data Subject	As defined in the Data Protection Legislation.
Funder	The organisation(s) detailed in Schedule 1 that is/are providing support to the Study.
Intellectual Property Rights	Patents, trade marks, trade names, service marks, domain names copyrights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them.
Know How	All technical and other information which is not in the public domain, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, manufacturing data and information contained in submissions to regulatory authorities.
Material	Any clinical biological sample or portion thereof, derived from Participants, including any information related to such material, supplied by the Participating Site to the Sponsor or its nominee under Schedule 4.
NHS Indemnity Scheme	One of the NHS Litigation Authority Clinical Negligence Scheme for Trusts ("CNST") in England; the Clinical Negligence Fund in Northern Ireland; the Clinical Negligence and other Risks Indemnity Scheme (CNORIS) in Scotland; or the Welsh Risk Pool Service (WRPS) in Wales.
Participant	Any person who consents (where consent is necessary) and is enrolled to take part in the Study. All references to Participants in this Agreement refer to those recruited by or through the Participating Site.
Participating Site	The contracting body for the Site/s.
Personal Data	Any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in Data Protection Legislation and which relates to any Participant or his or her treatment or medical history.
Principal Investigator or PI	The leader responsible for a team of individuals conducting the Study at the Site and who has signed the declaration at Schedule 5
Process	As defined in the Data Protection Legislation (and "Process" and "Processed" shall be construed accordingly);
Processor	Shall have the meaning as set out in the Data Protection Legislation;
Protocol	The full description of the Study with the reference number set out on the front page of this Agreement, together with any amendments thereof, and incorporated into this Agreement by reference.

Results	The research findings produced in the Study as published by the Sponsor and the Chief Investigator.
Site	Any premises occupied by the Participating Site in which or through which the Study will be conducted.
Sponsor	The individual, company, institution or organisation that is (or the institutions or organisations, where there is more than one sponsor under a co-sponsorship or joint-sponsorship arrangement, that are) signatory to this Agreement, that takes responsibility for the initiation, management and financing (or arranging the financing) of the Study.
Study	The clinical research study that is the subject of this Agreement.
Study Data	All discoveries, data, information, theories, methods, computer programmes, format of presentations and applications of the same and all manifestations or expressions of the same in physical, chemical, biological, molecular, electronic or written form arising from the performance of the Study.
Study Drug	The investigational medicinal product (IMP) specified in the Protocol (including, where applicable, placebo).

- 1.2. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

2. OBLIGATIONS OF THE PARTIES

- 2.1. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the Study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects" and the UK Policy Framework for Health and Social Care Research. The Parties shall conduct the Study in accordance with:
 - 2.1.1. the Protocol.
 - 2.1.2. the terms of all relevant regulatory permissions and approvals. These may include, but are not limited to:
 - 2.1.2.1. the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee;
 - 2.1.2.2. the Clinical Trials Authorisation (CTA) granted by the Medicines and Healthcare products Regulatory Agency (the "MHRA");
 - 2.1.2.3. the letter of no objection from the MHRA for the clinical investigation of a non-CE marked medical device or a CE marked medical device being used for a new purpose.
- 2.2. The Parties shall carry out their respective responsibilities in accordance with this Agreement.

- 2.3. The Sponsor shall, on the giving of reasonable prior written notice to the Participating Site, have the right to audit the Participating Site's compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Participating Site's premises and to all relevant documents and other information relating to the Study.
- 2.4. The Participating Site shall;
 - 2.4.1. promptly notify the Sponsor should any responsible body, such as, but not limited to, the MHRA, conduct or give notice of intent to conduct any inspection at the Participating Site in relation to the Study;
 - 2.4.2. allow the Sponsor to support the preparations for such inspection; and
 - 2.4.3. following the inspection, provide the Sponsor with the results of the inspection relevant to the Study. The Sponsor will be responsible for sharing such results with the Funder if required.
- 2.5. In accordance with Participant consent, the Participating Site shall permit the Sponsor's appointed representatives and any appropriately appointed monitor access to all relevant Clinical Data for monitoring, source data verification and adverse event reporting or investigation as appropriate. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the Study, reasonable access to relevant members of staff at the Participating Site and the right to examine any procedures or records relating to the Study, subject at all times to clause 4 of this Agreement. The Sponsor will alert the Participating Site promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Study.

3. LIABILITIES AND INDEMNITY

- 3.1. Nothing in this clause 3 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the Data Protection Legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its Agent(s), fraud or fraudulent misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.
- 3.2. Where a Party is a non-NHS organisation, or an NHS organisation that is not a member of an NHS Indemnity Scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the Study, in respect of any claims brought by or on behalf of a Participant. Where the Party is an NHS organisation and is a member of an NHS Indemnity Scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by the Party and/or its Agents brought by or on behalf of the Participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to clause 3.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS organisation is a member of one of the NHS Indemnity Schemes.
- 3.3. Subject to clauses 3.4, 3.5, 3.6, 3.7 and 3.8, the Sponsor shall indemnify the Participating Site and its Agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands ("Claims") to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and/or contracted third party, in its performance of this Agreement or in connection with the Study.
- 3.4. Subject to clauses 3.3, 3.5, 3.6 and 3.8, the Participating Site shall indemnify the Sponsor and its Agents, against any reasonable claims, proceedings and related costs, expenses,

losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Participating Site, or its Agents, in its performance of this Agreement or in connection with the Study.

- 3.5. An indemnity under clauses 3.3 or 3.4 shall only apply if the indemnified Party:
 - 3.5.1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings;
 - 3.5.2. upon the indemnifying Party's request and at the indemnifying Party's cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and
 - 3.5.3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.
- 3.6. Any indemnity under clauses 3.3 or 3.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party.
- 3.7. The indemnity under clause 3.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:
 - 3.7.1. Participating Site carrying out a treatment or procedure that would be routinely undertaken at or for that Participating Site as part of National Health Service treatment; or
 - 3.7.2. Participating Site preparing, manufacturing or assembling any medicinal product, medical device or other equipment which is not done in accordance
 - 3.7.2.1. with the Protocol; or
 - 3.7.2.2. with written instructions of the manufacturer; or
 - 3.7.2.3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.
- 3.8. No Party shall be liable to another in contract, tort/delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.
- 3.9. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:
 - 3.9.1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Section 7 (4) of the NHS (Wales) Act 2006 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991: which established Trusts in Northern Ireland as appropriate; or
 - 3.9.2. One or more Party is a NHS body and the other Party (ies) is a NHS Foundation Trust; or
 - 3.9.3. All Parties are NHS Foundation Trusts;Then clauses 3.10, 3.11 and 3.12 shall apply.
- 3.10. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland and are indemnified by the same Indemnity Scheme (being one of the NHS

Litigation Authority clinical negligence or the Welsh Risk Pool or the Clinical Negligence Fund in Northern Ireland) and the Party incurring any loss can recover such loss under one of the Indemnity Schemes, then such Party shall rely on the cover provided by the Indemnity Scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant Indemnity Scheme(s) to take this into account in determining the future levies of all Parties in respect of the indemnity schemes.

3.11. If:

3.11.1. The Parties are members of the same Indemnity Scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its Indemnity Schemes; or

3.11.2. All Parties are NHS bodies in Scotland; or

3.11.3. The Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom;

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss. Should the Parties be unable to agree the apportionment the matter shall be resolved in accordance with clause 15.5 of this Agreement.

3.12. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the Indemnity Schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

3.13. Subject to clause 3.1 and 3.7 the liability of the Participating Site to the Sponsor and the liability of the Sponsor to the Participating Site arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the Study should be the greater of the amount of fees payable by the Sponsor to the Participating Site under this Agreement or one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 3.3 and 3.4.

3.14. Notwithstanding clause 3.13, in the case of equipment loaned by or on behalf of the Sponsor to the Participating Site for the purposes of the Study, the Participating Site's liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.

3.15. The Sponsor agrees that in respect of any personal injury or death of any Participant as a result of participation in the Study, it will provide no-fault compensation and will be insured to pay out on any such claims.

4. CONFIDENTIALITY, DATA PROTECTION AND FREEDOM OF INFORMATION

DATA PROTECTION

4.1. Participant Confidentiality

4.1.1. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to Participants.

Data Processing Terms

4.1.2. For the purposes of the Data Protection Legislation, the Sponsor is the Controller and the Participating Site is the Sponsor's Processor in relation to all Processing

of Personal Data that is Processed for the purpose of this Study and for any future research use under the Controllorship of the Sponsor, that would not have taken place but for this Agreement regardless where that Processing takes place.

- 4.1.3. The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 4.1.2, the Participating Site is the Controller of the Personal Data collected for the purpose of providing clinical care to the Participants. This Personal Data may be the same Personal Data, collected transparently and processed for research and for care purposes under the separate Controllorships of the Sponsor and Participating Site.
- 4.1.4. Where the Participating Site is the Sponsor's Processor and thus where the Processing is undertaken by the Participating Site for the purposes of the Study, Clauses 4.1.5 to 4.1.9 below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating Site is Processing the Participant Personal Data as a Controller.
- 4.1.5. The Participating Site agrees only to Process Personal Data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the Study and to ensure the Sponsor's compliance with the Data Protection Legislation;
- 4.1.6. The Participating Site agrees to comply with the obligations applicable to Processors described by Article 28 GDPR including, but not limited to, the following:
 - 4.1.6.1. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the Controller by Article 28(1);
 - 4.1.6.2. to not engage another Processor without the prior written authorisation of the Sponsor (Article 28(2));
 - 4.1.6.3. to Process the Personal Data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating Site shall notify the Sponsor before Processing, or as soon as possible after Processing if legislation requires that the Processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a)).;
 - 4.1.6.4. to ensure that personnel authorised to Process Personal Data are under confidentiality obligations (Article 28(3b));
 - 4.1.6.5. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));
 - 4.1.6.6. to respect the conditions described in Article 28(2) and (4) for engaging another Processor (Article 28(3d));
 - 4.1.6.7. to, taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects' rights (Article 28(3e));
 - 4.1.6.8. to assist the Controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the Processing and the information available to the Participating Site (Article 28(3f));
 - 4.1.6.9. to, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor at the expiry or early termination of the Agreement, unless

storage is legally required (Article 28(3g)) or where that Personal Data is held by the Participating Site as Controller for the purpose of clinical care or other legal purposes; and

- 4.1.6.10. to maintain a record of Processing activities as required by Article 30(2) GDPR.
- 4.1.7. The Participating Site shall ensure that:
 - 4.1.7.1. its Agents do not Process Personal Data except in accordance with this Agreement (and in particular the Protocol);
 - 4.1.7.2. it takes all reasonable steps to ensure the reliability and integrity of any of its Agents who have access to the Personal Data and ensure they:
 - 4.1.7.2.1. are aware and comply with the Participating Site's duties under this clause;
 - 4.1.7.2.2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and
 - 4.1.7.2.3. are informed of the confidential nature of the Personal Data and understand the responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose for lawful and appropriate purposes.
- 4.1.8. The Participating Site agrees to:
 - 4.1.8.1. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating Site's compliance with the obligations described by this Agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the Participating Site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and
 - 4.1.8.2. obtain prior agreement of the Sponsor to store or Process Personal Data outside the European Economic Area.
- 4.1.9. Where the Participating Site stores or otherwise Processes Personal Data outside of the European Economic Area as the Sponsor's Processor, it warrants that it does so in compliance with the Data Protection Legislation.

Data Sharing Terms

- 4.1.10. Personal Data shall not be disclosed to the Sponsor by the Participating Site, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a Participant in connection with the Study.
- 4.1.11. The Sponsor agrees to use Personal Data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
 - 4.1.11.1. Not to disclose Personal Data to any person except in accordance with applicable legal requirements and codes of practice.

- 4.1.12. The Sponsor agrees to comply with the obligations placed on a Controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (Article 5 GDPR)
- 4.1.13. The Sponsor agrees to ensure persons processing Personal Data under this Agreement are equipped to do so respectfully and safely. In particular:
 - 4.1.13.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Site) Processing Personal Data understand the responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose for lawful and appropriate purposes.
 - 4.1.13.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Site) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
- 4.1.14. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
 - 4.1.14.1. To ensure that Personal Data are only accessible to persons who need it for the purposes of the Study and to remove access as soon as reasonably possible once it is no longer needed.
 - 4.1.14.2. To ensure all access to Personal Data on IT systems processed for Study purposes can be attributed to individuals.
 - 4.1.14.3. To review processes to identify and improve processes which have caused breaches or near misses, or which force persons Processing Personal Data to use workarounds which compromise data security.
 - 4.1.14.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
 - 4.1.14.5. To take action immediately following a data breach or near miss.
- 4.1.15. The Sponsor agrees to ensure data are Processed using secure and up to date technology. In particular,
 - 4.1.15.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of Personal Data for the purposes of the Study.
 - 4.1.15.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials.
 - 4.1.15.3. To ensure IT suppliers are held accountable via contracts for protecting Personal Data they Process and for meetings all relevant information governance requirements.

FREEDOM OF INFORMATION

- 4.2.1. Parties to this Agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party in accordance with clause 13, as

soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.

- 4.2.2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the Party responding to the request.
- 4.2.3. Where the Party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days' notice of its intended disclosure.

CONFIDENTIALITY

- 4.3.1. Subject to clause 6 below, the Participating Site agrees to treat the Results, excluding any Clinical Data of the Study, as Confidential Information of the Sponsor and the Sponsor agrees to treat Personal Data and confidential patient information as Confidential Information.
- 4.3.2. The Receiving Party agrees:
 - 4.3.2.1. To take all reasonable steps to protect the confidentiality of the Confidential Information and to prevent it from being disclosed otherwise than in accordance with this Agreement
 - 4.3.2.2. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this clause 4.3.2.
 - 4.3.2.3. To use Confidential Information solely in connection with the operation of the Agreement and not otherwise, except in the case where the Confidential Information is Personal Data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
 - 4.3.2.4. Not to disclose Confidential Information in whole or in part to any person without the Disclosing Party's prior written consent or, where the Confidential Information is Personal Data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
- 4.3.3. The provision of clause 4.3 shall not apply to the whole or any part of the Confidential Information that is:
 - 4.3.3.1. lawfully obtained by the Receiving Party free of any duty of confidentiality;
 - 4.3.3.2. already in the possession of the Receiving Party and which the Receiving Party can show from written records was already in its possession (other than as a result of a breach of clause 4.3.1 or 4.3.2);

- 4.3.3.3. in the public domain (other than as a result of a breach of clause 4.3.1 or 4.3.2);
 - 4.3.3.4. independently discovered by employees of the Receiving Party without access to or use of Confidential Information;
 - 4.3.3.5. necessarily disclosed by the Receiving Party pursuant to a statutory obligation;
 - 4.3.3.6. disclosed with prior written consent of the Disclosing Party;
 - 4.3.3.7. necessarily disclosed by the Receiving Party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;
 - 4.3.3.8. published in accordance with the provisions of clause 6.
- 4.4. The restrictions contained in clauses 4.3 shall remain in force without limit in time in respect of Personal Data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

5. PUBLICITY

- 5.1. Neither Party shall use the name, logo or registered image of the other Party or the employees of such other Party in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.
- 5.2. The content and timing of any publicity, advertising or press release shall be agreed by both Parties, such agreement not to be unreasonably withheld.

6. PUBLICATION

- 6.1. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the Results of the full Study and that the Participating Site shall not publish any Study Data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).

7. INTELLECTUAL PROPERTY RIGHTS

- 7.1. All Background Intellectual Property Rights (including licences) and Know How and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party's rights.
- 7.2. All Intellectual Property Rights and Know How in the Protocol, and in the Study Data, excluding clinical procedures developed or used by the Participating Site independently of the Study, shall belong to the Sponsor. The Participating Site hereby assigns all such Intellectual Property Rights, and undertakes to disclose all such Know How, to the Sponsor.
- 7.3. Subject to clause 7.1 and 7.2, all Intellectual Property Rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Participating Site shall belong to the Sponsor.
- 7.4. At any time within the duration of the Study, the Participating Site shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest

the Intellectual Property Rights in the Sponsor. To give effect to this clause 7.4, the Participating Site shall ensure that its Agents involved in the Study assign such Intellectual Property Rights falling within clauses 7.2 and 7.3 and disclose such Know How to the Participating Site.

- 7.5. Subject to this Clause 7.5 and Clause 7.6, nothing in this clause 7 shall be construed so as to prevent or hinder the Participating Site from using its own Know How or Study Data that is Clinical Data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of an Intellectual Property Right of the Sponsor, or their Funder, or the holder of the Intellectual Property Rights of the Study Drug. This clause 7.5 does not permit the disclosure of any of the Study Data, all of which remain confidential until publication of the Results in accordance with clause 6.1. Any Study Data not so published remains the Confidential Information of the Sponsor, or their Funder, or the holder of the Study Drug and/or Intervention Intellectual Property Rights.
- 7.6. The Participating Site may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use Study Data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of an Intellectual Property Right of the Sponsor or their Funder or the holder of the Intellectual Property Rights of the Study Drug. This clause 7.6 does not permit the disclosure of any of the Study Data, all of which remain confidential until publication of the Results of the Study in accordance with clause 6.1.

8. FINANCIAL AND SUPPLIES ARRANGEMENTS

- 8.1. The Parties agree to financing of the Study as set out in Schedule 3.
- 8.2. Where payments are agreed:
- 8.2.1. The Parties agree that prior to receiving payment the Participating Site shall submit an invoice in accordance with Part A of Schedule 3 setting out the costs incurred and payment claimed.
- 8.2.2. Payment by the Sponsor shall be without prejudice to any claims or rights which the Sponsor may have against the Participating Site and shall not constitute any admission by the Sponsor as to the performance by the Participating Site of its obligations under this Agreement.
- 8.3. The Parties agree to the procurement and provision of any medicine, equipment, materials, consumables software or other items necessary for the Study as set out in Schedule 3. Any such items provided by the Sponsor or on behalf of the Sponsor to the Participating Site shall be used by the Participating Site only for the Study and in accordance with the Protocol, or otherwise as agreed in Schedule 3.
- 8.4. The Sponsor shall use any Study Data, Material or other information provided by or derived from a Participant and provided by or on behalf of the Participating Site to the Sponsor in accordance with the consent provided by the Participant and the Protocol, and in respect of Materials also in accordance with Schedule 4.

9. TERM

- 9.1. This Agreement will commence on the date the final signatory signed the Agreement and shall remain in effect until completion of the Study (which means the conclusion of all Protocol required activities for all enrolled Participants) and close-out of the Participating Site or earlier termination in accordance with clause 10 of this Agreement.

10. TERMINATION

- 10.1. This Agreement may be terminated immediately by notice in writing by either Party if the other Party is:
- 10.1.1. In material or continuing breach of any of its obligations under this Agreement and fails to remedy the breach (if capable of remedy) for a period of 30 calendar days after written notice by the non-breaching Party; or
 - 10.1.2. Declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
- 10.2. Subject to Clause 10.4, the Sponsor may terminate this Agreement by notice in writing:
- 10.2.1. If the regulatory permissions and approvals previously granted to perform the Study are withdrawn;
 - 10.2.2. If funding is withdrawn or terminated for any reason or if it has been agreed that there are insufficient funds available to continue the Study;
 - 10.2.3. If advised to do so by the study management committee/group, trial oversight committee, study oversight group or other similar arrangements as defined in the Protocol;
 - 10.2.4. In the event of cessation of supply of Study Drug, medical device, equipment or similar necessary for the Study, or information or resources critical to the Study.
- 10.3. Subject to Clause 10.4, any Party may terminate this Agreement by notice in writing:
- 10.3.1. If the Principal Investigator becomes unavailable to continue his/her supervision of the Study for any reason and a replacement acceptable to both Parties is not found;
- 10.4. In the event of termination or expiry of this Agreement, or if the Participating Site chooses to cease Participant recruitment at its Site/s in accordance with clause 10.6, the following provisions shall apply:
- 10.4.1. The Parties shall work together to facilitate an orderly cessation of the Study at the Participating Site (or cessation of recruitment of Participants at its Site/s where the Participating Site has chosen to cease recruiting in accordance with clause 10.6), taking into account the rights, safety, well-being and continuity of treatment (if appropriate) of the Participants and applicable law.
 - 10.4.2. The Sponsor shall, subject to the prior compliance of the Participating Site with its obligations on termination, upon receipt of a valid invoice submitted in accordance with Schedule 3, pay the Participating Site any outstanding monies due to the Participating Site as at the date of termination.
 - 10.4.3. The Participating Site shall ensure that there is prompt refund to the Sponsor of the amount, if any, by which the cumulative cost paid by the Sponsor to the Participating Site under this Agreement exceeds the actual commitments incurred by the Participating Site up to the date of termination, or cessation of Participant recruitment, and any other costs in accordance with Schedule 3 and,

in the event of cessation of recruitment of Participants at its Site/s where the Participating Site has chosen to cease recruiting in accordance with clause 10.6, an amendment in writing signed by the Sponsor and the Participating Site shall be made to any payments due under Schedule 3 to reflect the reduction in recruitment numbers..

- 10.4.4. The Participating Site shall provide to the Sponsor all Study Data and other relevant information and/or data relating to work undertaken by the Participating Site prior to and including the date of termination and co-operate with all reasonable requests from the Sponsor including any continued monitoring of Participants in accordance with Protocol.
 - 10.4.5. The Participating Site shall ensure that all reasonable instructions by the Sponsor as regards the return or disposal of all unused supplies, or medical devices or other equipment or items previously provided to the Participating Site for the purposes of the Study are complied with.
 - 10.4.6. The Participating Site shall ensure that the instructions of the Sponsor regarding the transfer and/or storage of all information, material or data relating to the Study collected by the Participating Site in the course of carrying out the Study are complied with.
 - 10.4.7. Unless otherwise agreed in writing with the Sponsor, the costs and expenses of returning, dispatching, transferring or storing items shall be in accordance with Schedule 3.
- 10.5. Termination under this clause 10 will be without prejudice to any other rights or remedies of either Party under this Agreement or at law, and will not affect any accrued rights or liabilities of either Party at the date of termination.
- 10.6. The Participating Site will notify the Sponsor in accordance with clause 13 if, for any reason, it elects to cease Participant recruitment at its Site/s

11 AGREEMENT AND MODIFICATION

- 11.1 Any amendments to this Agreement shall be valid only if made in writing and signed by authorised signatories of the Parties.
- 11.2 This Agreement including its Schedules contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Study.

12 FORCE MAJEURE

- 12.1 No Party shall be liable for any delay in performance or failure to perform its obligations under this Agreement if such delay or failure is due to an occurrence beyond its reasonable control. The Party affected by such occurrence shall promptly notify the other Party. If the circumstances causing the delay or failure to perform continue for longer than thirty (30) calendar days the other Party shall be entitled to terminate this Agreement by notice in writing with immediate effect.

13 NOTICES

- 13.1 Any notice under this Agreement shall be in writing, signed by the relevant Party to the Agreement and delivered personally, by courier, by recorded delivery post, or by facsimile, or by email, providing evidence of receipt.
- 13.2 Notices to the Sponsor and to the Participating Site shall be delivered to the addressee and at the address specified in Schedule 1 or as may be amended by the Parties during the Study.
- 13.3 Notices:
 - 13.3.1 by post will be effective upon the earlier of actual receipt, or 7 calendar days after mailing;
 - 13.3.2 by hand will be effective upon delivery; and
 - 13.3.3 by e-mail will be effective when sent in legible form, but only if, following transmission, the sender does not receive a non-delivery message.

14 ASSIGNMENT AND SUBCONTRACTING

- 14.1 No Party shall novate or assign all or any part of their rights or obligations under this Agreement without the prior written consent of the other Party, notwithstanding the right of the Sponsor to assign its own Intellectual Property Rights.
- 14.2 Except as agreed between the Parties at the commencement of this Agreement and as set out in Schedule 1, the Participating Site shall not subcontract the performance of all or any of its obligations under this Agreement without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed.
- 14.3 The Sponsor(s) may subcontract performance of all or any of its obligations under this Agreement at any time during the term. If in so doing it changes any of the arrangements described in Schedule 2 of this Agreement, it will notify the Participating Site of these changes and, where appropriate, agree to vary this Agreement.
- 14.4 In the event that either Party subcontracts its responsibilities under this Agreement it shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

15 DISPUTE RESOLUTION

- 15.1 In the event of any dispute or difference between the Parties arising in connection with this Agreement, the authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within 7 calendar days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to the senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further 14 calendar days.
- 15.2 If the Parties are unable to resolve a dispute using the procedure outlined in clause 15.1, the Parties will attempt to resolve the dispute by the appropriate method of (in line with clause 18 (Governing Law)):
 - 15.2.1 In England or Wales Parties will refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure; or
 - 15.2.2 In Scotland Parties will refer the dispute to an independent third party. If the Parties are unable to agree on the identity of the third party, the Parties will ask the President of the Law Society of Scotland to appoint a suitable individual to

consider the matter. The person so appointed will act as an expert and not as an arbiter; or

- 15.2.3 In Northern Ireland Parties will refer the dispute to a mediator agreed by the Parties. Where the Parties are unable to agree on the identity of a mediator, the Parties will ask the President of the Law Society of Northern Ireland to appoint a suitable mediator.
- 15.3 Each Party shall each bear its own costs in relation to the settlement of any disputes and the parties shall share equally the costs of any independent third party involved to assist in the resolution of the dispute unless the independent third party directs that costs be apportioned differently.
- 15.4 Any decision reached in accordance with this clause 15 shall be final and binding upon the Parties.
- 15.5 Notwithstanding the provisions of clauses 15.2 to 15.4, where the Agreement is an NHS Contract as defined in Section 9(1) National Health Service Act 2006 or Section 17 National Health (Scotland) Act 1978 or Section 7 (1) of the NHS (Wales) Act 2006 or a HSS contract (now HSC contract) as defined in Article 8 of the Health and Personal Social Service (Northern Ireland) Order 1991 as applicable, any dispute between the Parties shall be referred for determination by:
- 15.5.1 The Secretary of State for Health if both Parties are NHS Organisations in England;
- 15.5.2 The Secretary of State and the Department of Health, Social Services and Public Safety acting jointly if both Parties are NHS Organisations in Northern Ireland;
- 15.5.3 The Scottish Ministers if both Parties are NHS Organisations in Scotland;
- 15.5.4 The Welsh Ministers if both parties are NHS Organisations in Wales; or
- 15.5.5 Where one Party is an NHS Organisation in one jurisdiction and one Party is an NHS Organisation in another jurisdiction, by the appropriate representative bodies in both jurisdictions specified in clauses 15.5.1, 15.5.2, 15.5.3 or 15.5.4 acting jointly.

16 GENERAL

- 16.1 Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any document incorporated therein, the terms of the Protocol shall prevail to the extent of such inconsistency except insofar as the inconsistency relates to clauses 3, 4, 6 and/or 7 of this Agreement where these terms of the Agreement shall prevail.
- 16.2 No failure or delay by any Party to exercise any right under this Agreement will operate as a waiver of it, nor will any partial exercise preclude any future exercise of the same.
- 16.3 If any clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be effective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.
- 16.4 Except as expressly stated nothing in this Agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this Agreement.
- 16.5 This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together shall constitute one and the same instrument.

17 SURVIVAL OF CLAUSES

17.1 The following clauses shall survive the termination or expiry of this Agreement: clauses 1 (Definitions), 3 (Liabilities and Indemnities), 4 (Confidentiality, Data Protection and Freedom of Information), 5 (Publicity), 6 (Publication), 7 (Intellectual Property Rights), 10.4 and 10.5 (Termination), 17 (Survival of Clauses), 18 (Governing Law) and Schedule 4 (Material Transfer Provisions).

18 GOVERNING LAW

18.1 By the signing of this Agreement the Parties agree that the conduct of the Study at the Participating Site is governed by and subject to the national laws and regulations of the Participating Site as provided for and as more particularly set out at Clause 2, Clause 3 and Clause 4. However any other issue, including any issue as to the construction of this Agreement, shall be governed and construed in accordance with the laws governing the country of the United Kingdom in which the Sponsor is established, namely, the laws of England and Wales and shall be subject to the exclusive jurisdiction of the Courts of the Sponsor. Save, that where both Parties agree, having taken into consideration that it would be more reasonable and expeditious both as to time and costs, in such instance to do so, for the agreed issue pertaining to this Agreement, to be subject to the jurisdiction of the defendant.

SIGN OFF

Each Party represents that it has 'redlined' or otherwise called attention to all changes that it made and sent to the other Party in previously-sent drafts of this Agreement, including but not limited to drafts of the schedules.

Signed by the duly authorised representatives of the Parties.

SIGNED ON BEHALF OF THE SPONSOR

.....
Name	Position	Signature	Date

SIGNED ON BEHALF OF THE PARTICIPATING SITE

.....
Name	Position	Signature	Date

Study Title: ANIMATE
Reference: EudraCT: 2017-002544-32 / IRAS No. 216147

SCHEDULE 1

SUMMARY OF STUDY ARRANGEMENTS

Study Drug supplier and Funder(s): Bristol-Myers Squibb, Unit 2, Sanderson Road, Uxbridge, Middlesex UB8 1DH.

Sponsor: University College London of Gower Street, London, WC1E 6BT,

Chief Investigator for the Study: Dr Graham Collins, Department of Clinical Haematology, Oxford Cancer and Haematology Centre, Churchill Hospital, Oxford OX3 7LE.

Substantive Employer: Oxford University Hospitals NHS Foundation Trust, John Radcliffe Hospital, Headley Way, Headington, Oxford, Oxfordshire OX3 9DU.

Principal Investigator: **[Insert NAME and ADDRESS].**

Substantive Employer: **[Insert NAME and ADDRESS].**

NHS Other

If not substantively employed by Participating Site, PI holds honorary/clinical academic contract. Yes

Study coordinating organisation: The Cancer Research UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London W1T 4TJ

Sponsor service providers (for use when outsourcing directly impacts on Participating Site – e.g. use of a CRO, CTU etc.): Central laboratories and central PET laboratory involved in the Study are detailed in the Study Protocol, Study Laboratory Manual and Study Imaging Manual.

Participating Site SubContractors of Protocol-related activities which are not part of standard NHS care: **[Insert NAME and ADDRESS].**

Estimated number of Participants to be recruited at the Site: **[Insert NUMBER, AS APPROPRIATE].**

NOTICES

Notices to the Sponsor shall be addressed to:

Professor Jonathan Ledermann
Director, Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ

ctc.sponsor@ucl.ac.uk

Notices to the Participating Site shall be addressed to:

Study Title: ANIMATE

Reference: EudraCT: 2017-002544-32 / IRAS No. 216147

[Insert JOB TITLE OR POSITION]

[Insert NAME OF NHS BODY]

[Insert ADDRESS]

[Insert E-MAIL ADDRESS]

SCHEDULE 2

Study Conduct at the Participating Site

DIVISION OF RESPONSIBILITIES AND DELEGATION OF ACTIVITIES

(Although some RESPONSIBILITIES cannot be delegated this schedule does allow for a description of delegated ACTIVITIES – e.g. to Chief Investigator, CTU (if legally separate from the Sponsor) or CRO – to be detailed)

The Parties collaborating in the Study will undertake responsibilities as attributed in the table below.

Note 1: Parties should set out any agreed delegation of ACTIVITIES in the table below.

Note 2: Where there are Co-Sponsors, **the name of the Sponsor responsible for each activity should be entered for the activity.**

Note 3: Some responsibilities are only applicable to particular types of study. Where a particular activity is not applicable to the Study “N/A” (Not Applicable) should be entered for the activity.

Note 4: Any additional responsibilities to those set out in this table should be added at the end of the table to preserve the numbering of the standard list and navigation of the contents.

Note 5: All references to Participants refer to those under the care of the Participating Site.

Note 6: All capitalised terms used in the Schedule but not otherwise defined in the Agreement shall have the meaning ascribed to them in relevant legislation.

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
1. Study preparation (All studies)	a) Ensure that the Study and its Protocol have received robust and favourable scientific and, where applicable, statistical peer review	✓		
	b) Ensure appropriate insurance is in place for the design and management of the Study	✓		

<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
c) Ensure that indemnity arrangements are in place to cover Participating Site liabilities		✓	
d) Ensure that insurance or indemnity arrangements are in place to cover Sponsor liabilities	✓		
e) Secure and administer funding for the research costs of the Study	✓		
f) Secure and contract for the supply of resources, where applicable, including medicinal products / devices / Contract Research Organisation services	✓		
g) Ensure that the appropriate contracts and agreements are in place for the Study	✓		
h) Ensure adequate facilities, resources and support (capacity and capability) are available to conduct the Study at the Participating Site		✓	

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
2. Applications, authorisations and registration (All studies)	a) Ensure that the Protocol is compliant with the relevant regulations/ guidelines	✓		
	b) Prepare Participant information sheet and consent form (and assent form where applicable), including, where appropriate, consent for: provision of Material(s) and Personal Data, Clinical Data or other data, as required, to the Sponsor	✓		
	c) Register the Study on an appropriate clinical trial register	✓		
	d) Obtain approvals from relevant Ethics Committee(s)	✓		
	e) Obtain HRA Approval (for NHS sites in England) and/or NHS management permissions as applicable	✓		

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	f) ensure that all relevant departments at the Participating Site are aware of and, where necessary, have agreed to their role in the Study		✓	
	g) Obtain a Clinical Trials Authorisation for a CTIMP from the regulatory authority (MHRA in the UK)	✓		
	h) Obtain a Letter of no objection for the clinical investigation of a non-CE marked medical device from the regulatory authority (MHRA in the UK)	N/A	N/A	N/A
3. Protocol Amendments (All studies)	a) Prepare and submit proposed substantial (and, for any Study of investigational medical devices, non-substantial) amendments to all relevant ethics committee(s) and, if appropriate, regulatory authority(ies)	✓		

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	b) Ensure the Principal Investigator is informed of all amendments requiring implementation at the Participating Site, including the date on which the amendment should be implemented	✓		
	c) Ensure all amendments of which the Participating Site is notified and that require local implementation are implemented at Participating Site, or that the sponsor is promptly notified that the amendment cannot be implemented and given the reason for this		✓	
4. Study Conduct (All studies)	a) Ensure that the Study is managed according to GCP (as defined in the Protocol), all relevant legislation, and the Protocol	✓		
	b) Ensure that the Study is conducted locally according to GCP, all relevant legislation, and the Protocol		✓	

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	c) Submit all Study Data and Materials required for the Study, in accordance with the Protocol and any Study specific manuals provided by the Sponsor		✓	
	d) Ensure that the Participating Site team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive and/or honorary employment contracts in place, where required		✓	
	e) Ensure that no Participant is recruited at Site until the Participating Site has been activated by the Sponsor		✓	
	f) Ensure that the Study is managed, monitored and reported as agreed in the Protocol and/or agreed monitoring plan.	✓		

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	g) Maintain Investigator Site File (and Pharmacy Site File, where relevant) at Participating Site, ensuring compliance with Sponsor requirements and applicable guidance/legislation		✓	
	h) Maintain Trial Master File/Sponsor File, ensuring compliance with applicable guidance/legislation	✓		
	i) Assess capability of Participants to give informed consent		✓	
	j) Ensure no Study procedure is carried out on a Participant until consent (where required) is obtained in accordance with the Protocol		✓	
	k) Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study.		✓	

<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
l) Ensure that all Clinical Data and documentation are available for the purposes of monitoring, inspection or audit		✓	
m) Inform appropriate health or social care professionals if their patient is a Participant in the Study, if required		✓	
n) Ensure relevant Protocol deviations, and all serious breaches of Study conduct and/or GCP are reported to the Sponsor		✓	
o) Report serious breaches of Study conduct and/or GCP to relevant ethics committees and regulatory authority(ies) (as applicable)	✓		
p) Report suspected research misconduct, identified by the Sponsor, to the Participating Site	✓		
q) Report suspected research misconduct, identified by the Participating Site, to the Sponsor		✓	

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	r) Notify the Participating Site, relevant ethics committee(s) and, if applicable, regulatory authority(ies) of the end of the Study	✓		
	s) Notify the Participating Site, relevant ethics committee(s) and, if applicable, regulatory authority(ies) if the Study is terminated early	✓		
5. Adverse events (All studies)	a) Maintain detailed records of all adverse events as specified in the Protocol		✓	
	b) Report adverse events as defined in the Protocol and to legal requirements and in accordance with Participating Site policy		✓	
	c) Ensure that procedures are in place for emergency unblinding of the randomisation code. (If applicable)	N/A	N/A	N/A

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	d) Promptly notify the Sponsor of any urgent safety measure taken to protect Participants at Site		✓	
	e) Promptly inform relevant ethics committee(s), regulatory authority(ies) (if applicable), and all Principal Investigators of any urgent safety measures taken to protect Participants in the Study	✓		
	f) Ensure that all Serious Adverse Events (SAE) are reported to the Sponsor, as specified in the Protocol		✓	
	g) Ensure all SAEs are promptly assessed, and expedited reporting to the relevant ethics committee(s) and regulatory authority (if applicable) is undertaken where necessary	✓		
	h) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of Study safety	✓		

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	i) Ensure that annual safety/progress reports and final Study report are generated and submitted to relevant ethics committee(s) and regulatory authority(ies) (e.g. Development Safety Update Reports, if applicable), within the required timeframes	✓		
	j) Ensure that the Principal Investigator is, at all times, in possession of the current relevant safety information for the Study	✓		
	k) Ensure that all pregnancies are reported to the Sponsor, as specified in the Protocol		✓	
6. Data Management (All studies)	a) Design of case report forms (eCRFs/CRFs) and database	✓		

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	b) Complete eCRFs/CRFs fully, accurately in a contemporaneous manner, and submit in a timely manner and in accordance with the Protocol		✓	
	c) Respond to the Sponsor's requests for data clarification		✓	
	d) Process and code Study Data	✓		
	e) Ensure appropriate analysis of Study Data	✓		
7. Publication (All studies)	a) Prepare and submit abstracts, posters and publications of the Study endpoints	✓		
8. Archiving (All studies)	a) Ensure that the Trial Master File is archived appropriately on conclusion of the Study and retained as required by the Protocol	✓		
	b) Ensure that all Study records held at Site are archived appropriately when notified by the Sponsor and retained as required by the Protocol		✓	

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
9. Clinical Trials involving Investigational Medicinal Products	a) Ensure appropriate arrangements are defined for the supply, labelling, storage and destruction of Study Drug(s)	✓		
	b) Ensure ability to comply with the arrangements for the Study Drug(s)		✓	
	c) Ensure that Study Drug(s) supplied for specific use in the Study is/are used in strict accordance with the Protocol and is/are not used for any other purpose		✓	
	d) Ensure that Study Drug(s) is/are stored in appropriate and secure conditions		✓	
	e) Ensure approvals are in place and issue regulatory 'green light' for release of Study Drug(s)	✓		

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	f) Ensure that appropriate accountability and destruction records are maintained, as required by the Sponsor		✓	
	g) Ensure that the Site is provided with a sufficient number of investigational medicinal devices/disposables required for proper functioning of the device for the planned number of Participants	N/A	N/A	N/A
10. Studies involving CE marked medical devices for new purpose or non-CE marked Medical Device	a) Ensure that investigational medical devices are not used for any purposes other than the conduct of the Study, unless Sponsor permits continued intended use for CE marked device after conclusion of the Study	N/A	N/A	N/A

	<u>RESPONSIBILITY</u> to:	Sponsor	Participating Site	If <u>ACTIVITY</u> is delegated, name the body / individual delegated to:
	b) Ensure that investigational medical devices are stored in appropriate, secure conditions and returned as instructed by Sponsor. Further to ensure that detailed records are maintained regarding its movement from delivery to return/destruction	N/A	N/A	N/A
11. Sample Management	a) Ensure appropriate and timely collection of Material and transfer to the Sponsor's nominated laboratory(ies), all in accordance with the Protocol and in compliance with Schedule 4.		✓	
12. Imaging	a) Ensure timely transfer of PET-CT and contrast-enhanced CT images to the Sponsor's nominated laboratory, in accordance with the Protocol and Trial-Specific Imaging Manual.		✓	

SCHEDULE 3

STUDY SUPPORT ARRANGEMENTS

A. FINANCIAL ARRANGEMENTS

Where no payments are to be made to the Participating Site under this Agreement tick this box and delete the rest of this section A.

The overall, study-wide recruitment for this Study is competitive with a maximum figure of 30 Participants treated, with an expected 120 Participants registered to achieve this. Once the 30 Participants treated target has been reached, the Sponsor will notify the Participating Site. No additional per Participant payments will be made by the Sponsor to the Participating Site for patients consented after such notification becomes effective, in accordance with clause 13.3.

Schedule of payments and details of payment arrangements

	Area of Cost	Payment (£ Sterling)
1	Per Participant payment: For all Participants upon completion of the “eligibility for treatment” visit and receipt of appropriate scans and Materials, as set out in the Protocol	£126.00
2	Per participant payments For Participants who are eligible to receive Study Drug, upon the Participant’s completion of 4 cycles of Study Drug and receipt of appropriate scans and Materials, as set out in the Protocol	£858.00
3	Per participant payment: For Participants who are PET-positive and do not have disease progression after cycle 4, upon the Participant’s completion of Study Drug and 1 month post treatment assessment, and receipt of appropriate scans and Materials, as set out in the Protocol	£1,103.00
4	Per participant payment: For Participants who are eligible to receive Study Drug, upon resolution of all Study data queries	£200.00
5	‘One off’ Study payment: at the end of the Study, upon authorisation from Sponsor to commence Study archiving in consideration of administration time for the preparation of Study documentation held at the Participating Site for archiving	£21.06

- Payments by the Sponsor during the course of the Study are dependent on continued availability of funds from the Funder.
- The Sponsor reserves the right to amend/withhold final payments in cases where the Participating Site has not performed their duties according to the terms of the Protocol and/or this Agreement.
- The Participating Site is expected to keep accurate accounts of all costs incurred in the performance of the Agreement. All costs incurred under the Agreement will be subject to audit by Sponsor. The Site shall allow the appropriate Sponsor representatives (including the Funder) access to records where necessary to support costs relating to this Agreement.
- Payment shall be made in Pounds Sterling according to the schedule above on presentation of VAT (if applicable) invoices from the Site.
- Details of requested payments, including Participant number and amounts requested, must be submitted with each invoice.

Invoices, **quoting UCL purchase order number** (obtainable from the Study contact below), to be submitted six monthly in arrears to:

ANIMATE Trial Coordinator
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London W1T 4TJ
Ctc.animate@ucl.ac.uk

Payments to be made by BACS Transfer to: **[Insert BANK NAME]**.

Sort code: **[Insert SORT CODE]**

Account: **[Insert ACCOUNT NUMBER]**

And send the relevant paper work to **[Insert ADDRESSEE FOR PAPERWORK]** at the above address

Invoices must be paid promptly. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the Funder as a result of such delay or inadequacy.

B. SUPPLIES ARRANGEMENTS

Where no items are to be provided to, or procured for/by, the Participating Site under this Agreement tick this box and delete the rest of this section B.

Any medicine, equipment, materials, consumables, software or other items being provided by the Sponsor or procured by the Participating Site for use in the Study shall be specified below.

Note 1: Parties should complete the table below. If the Participating Site is to procure any Items and is to be reimbursed by the Sponsor this should be specified in this Schedule. Similarly if the Participating Site is to pay the Sponsor for any Items provided to the Participating Site by or on behalf of the Sponsor this should be specified in this Schedule.

Note 2: Parties should specify in this Schedule, as appropriate, arrangements for:

- Ownership of items
- Insurance
- Storage instructions
- Instructions for use, return and/or destruction
- Any training to be provided
- Maintenance of equipment

Item	Quantity	Frequency of supply	Responsibility to supply/procure (either Sponsor or Participating Site only)
Nivolumab (Study Drug)	Up to 25 x 100mg vials per Participant	Initial supply upon registration of first Study Participant, resupply as required for Participant eligible to receive Study Drug as per Protocol	Sponsor

1. The Study Drug is provided to the Participating Site only for use in Participants within the Study.
2. All instructions and arrangements relating to the Study Drug are detailed in the 'Summary of Drug Arrangements' (SoDA) document for the Study.

Study Title: ANIMATE

Reference: EudraCT: 2017-002544-32 / IRAS No. 216147

3. Collection and shipment instructions for Materials obtained by the Participating Site in the Study are detailed in the 'ANIMATE Laboratory Manual'.

SCHEDULE 4

MATERIAL TRANSFER PROVISIONS*

1. Where the Protocol requires the Participating Site to supply Material to the Sponsor or to a third party nominated by the Sponsor, this Schedule 4 shall apply.
2. In accordance with the Protocol, the Participating Site shall send Material to the Sponsor or, in accordance with provision 8 below, to a third party nominated by the Sponsor.
3. The Participating Site warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the Protocol.
4. Subject to provision 3 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or that the Materials are free of extraneous or biologically active contaminants which may be present in the Materials.
5. The Sponsor shall ensure, or procure through an agreement with the Sponsor's nominee as stated in provision 2 above that:
 - 5.1 the Material is used in accordance with the Protocol, the consent of the Participant, and the ethics approval for the Study;
 - 5.2 the Material is handled and stored in accordance with applicable law;
 - 5.3 the Material shall not be redistributed or released to any person other than in accordance with the Protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the Participant's consent; and
 - 5.4 no alteration shall be made to the title, coding or acronym of the Material.
6. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.
7. The Participating Site and the Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this Schedule 4.
8. To the extent permitted by law the Participating Site and its staff shall not be liable for any consequences of the supply to or the use by the Sponsor of the Material or of the supply to or the use by any third party to whom the Sponsor subsequently provides the Material or the Sponsor's nominee as stated in provision 2 above, save to the extent that any liability which arises is a result of the negligence of the Participating Site.
9. The Sponsor undertakes that, in the event that Material is provided to a third party in accordance with provision 2 above, it shall require that such third party shall undertake to handle any Material related to the Study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this Schedule 4.
10. Any surplus Material that is not returned to the Participating Site or retained for future research (in line with Participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

*These provisions do not remove the need for the Sponsor to clearly lay out in their Protocol (and to potential Participants in the patient information sheet/s) at a minimum the following information for all Material taken: 1) The nature of the Materials, 2) The reason that the Material is being taken, 3) where the Material is to be sent and, 4) what will happen to any remaining Material once it has been processed//analysed, etc. for the purposes of this Study (e.g. return, retention or destruction). Detailed guidance on what information should be included in a protocol may be found on the HRA website: www.hra.nhs.uk

SCHEDULE 5

PRINCIPAL INVESTIGATOR DECLARATION

As a Principal Investigator for the Study I declare that:

1. I acknowledge the Agreement, and the roles and responsibilities to be undertaken as Principal Investigator at the Participating Site.
2. I am free to participate in the Study, and am not restricted by any third party obligations which might prevent or restrict my performance of the obligations as Principal Investigator.
3. I have considered the facilities required for the Study, and am satisfied that the Participating Site can, and will continue to, make appropriate facilities available for the proper performance of the Study.
4. I shall conduct the Study at the Participating Site in accordance with the Protocol.
5. I consent to the Sponsor(s), and to any relevant third party providing support, products and/or services to the Study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the Study.
6. I confirm that where I wish to delegate responsibilities to another member of the Study team, that individual will be appropriately qualified for the delegated role, will receive sufficient support and training to fulfil that role and all delegated duties will be detailed in a delegation log, or as required by the Sponsor.
7. I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
8. During the Study, I will not serve as an investigator or other significant participant in any study for another sponsor if such activity might adversely affect my ability to perform my obligations as Principal Investigator to the Study.
9. Neither I, nor any dependents, have entered into and will not enter into arrangements, financial or otherwise, with any third party providing support, products and/or services to the Study that would present a conflict of interests.

Signed:

Date:

Name:

Title: