

Study Title: COLCOT – Colchicine Cardiovascular Outcomes Trial
Reference: EudraCT no.: 2014-005172-28

MODEL AGREEMENT FOR NON-COMMERCIAL RESEARCH IN THE HEALTH SERVICE

This Agreement dated the date of last signature is between

Hampshire Hospitals NHS Foundation Trust, Aldermaston Road, Basingstoke, RG24 9NA,
(referred to as "the NHS Organisation")

AND

GREATER GLASGOW HEALTH BOARD constituted in terms of the National Health Service (Scotland) Act 1978 (as amended) and having its principal office at JB Russell House, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12 0XH (the '**Health Board**')
(referred to as "the Sponsor")

Montreal Heart Institute – 5000 Belanger east, Montreal, Quebec, H1T1C8
(referred to as "the Sponsor")

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

The above Parties agree to the following obligations, terms and conditions when carrying out the clinical research study entitled *Colchicine Cardiovascular Outcomes Trial (COLCOT)* sponsored by the *Montreal Heart Institute*.

1. DEFINITIONS

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

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|---------------------------------|---|
| 1.1.1. Chief Investigator | 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 an investigator at any particular site. |
| 1.1.2. Confidential Information | All information, communication or proprietary information, whether oral, written or digital, provided, disclosed, furnished or prepared before, on or after the Effective Date, about Sponsor or about the Study, that reveals scientific, technical, commercial, financial or similar information, and all copies and tangible or intangible embodiments thereof, including without being limited to all information pertaining to the drug, the materials, the IPR the Study, the budget, the Study brochure, the Study Documentation and other documentation and the Intellectual Property (and any Study IP) and research data, information or documentation derived from or relating to the foregoing or to this Agreement. |
| 1.1.3. Health Board | The Clinical Research Organisation which shall be responsible for some duties related to the Study. |
| 1.1.4. Intellectual Property | All intellectual property rights or moral rights of any kind or nature throughout the world including, without limitation all materials, concepts, know-how, formulae, inventions, improvements, processes, patterns, machines, manufactures, compositions of matter, compilations of information, algorithms, technical developments or information (such as software, firmware and hardware), recipes, data, works, drawings, templates, methods, devices, models, prototypes, specifications, apparatus, improvements, Study data, results and other forms of IPR, whether or not patentable or copyrightable, and all: (i) patents, patent applications, continuations, continuations-in-part, divisionals, reissues, re-examinations; (ii) copyrights, copyright applications and copyrightable subject matters, registrations substitutions and extensions; (iii) industrial designs, applications and registrations; (iv) business names, patents, trademarks, trade names, certification marks, service marks, domain names and their respective applications and registrations; (v), trade secrets, know-how, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights, and all other (vi) type proprietary information 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, such as the right to apply for protections under statutory proceedings available for those purposes. |
| 1.1.5. Multi-Site Study | Where the Study is part of a study being carried out by or on behalf of the Sponsor at different sites. |

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1.1.6. NHS Organisation	The NHS contracting body carrying out the research, including Health and Social Care (HSC) Organisations established in Northern Ireland.
1.1.7. Principal Investigator	The leader responsible for a team of individuals conducting the Study.
1.1.8. Participant	Patient, service user, carer, relative of the deceased, professional carer, employee, or member of the public, who consents to take part in the Study. All references to Participants refer to those recruited at or through the Site.
1.1.9. Protocol	The description of the Study as contained in Schedule 1 and all amendments thereto. Such amendments will form part of this Agreement.
1.1.10. Results	All discoveries, data, information, theories, methods, computer programs, 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.
1.1.11. Site	Any premises occupied by the NHS Organisation in which or through which the Study will be conducted.
1.1.12. Study	The clinical research study being carried out by the NHS Organisation at the Site.

2. STUDY GOVERNANCE

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 following relevant guidance:

- 2.1.1. The World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects".
- 2.1.2. The Research Governance Framework for Health and Social Care, Second Edition, April 2005, or the Research Governance Framework for Health and Social Care in Wales, November 2001 or the Scottish Executive Health Department Research Governance Framework for Health and Community Care, Second Edition, February 2006 or the Research Governance Framework for Health and Social Care in Northern Ireland, December 2006 or the latest version of the relevant Research Governance Framework should it be revised and reissued.

2.2. 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 does not relate to matters of medicine and science, such as clauses 4, 5, 7 and/or 8 of this Agreement where these terms of the Agreement shall prevail.

3. OBLIGATIONS OF THE PARTIES

3.1. The Parties shall conduct the Study in accordance with:

- 3.1.1. The current version of the Protocol. Substantial amendments to the Protocol shall form part of this Agreement following confirmation in writing by the Parties.

- 3.1.2. The terms of all relevant regulatory permissions and approvals. These may include, but are not limited to:
- 3.1.2.1. The Study's Authorisation (CTA) granted by the Medicines and Healthcare products Regulatory Agency (MHRA).
 - 3.1.2.2. The terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee.
 - 3.1.2.3. 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.
 - 3.1.2.4. The permission given by or on behalf of the Site R&D management (NHS permission).
 - 3.1.2.5. informed consent form from each Study Subject prior to the Study Subject's participation in the Study and the other authorizations such as the ones that may be required pursuant to applicable laws to communicate or disclose personal health information.
- 3.2. The Health Board and UK Chief Investigator shall be responsible for obtaining and maintaining the approvals listed in paragraphs 3.1.2.1, 3.1.2.2, 3.1.2.3, 3.1.2.4 and 3.1.2.5, and for keeping Sponsor fully apprised of the progress of these submissions and directions, and provide the Sponsor and the NHS Organization with all approvals as well as all correspondence relating to such submissions.
- 3.3. The Parties shall carry out their respective responsibilities in accordance with this Agreement including those set out in the Schedules, the Study documentation and the written instructions of the Sponsor. The NHS Organization and the Principal Investigator shall also ensure that the Study team members and agents will comply with the terms of this Agreement. The role of the Principal Investigator may not be modified or substantially reduced and the Principal Investigator shall not be replaced without Sponsor's prior written consent, and if the replacement proposed is not satisfactory, the Sponsor shall be entitled to terminate the Agreement pursuant to Paragraph 11.3.6 hereunder. On the giving of reasonable written notice, the Sponsor shall have the right to audit the other Parties compliance with this Agreement. Such right shall include access to all relevant documents and other information relating to the Study, inspection of the trial site(s), examination of procedures, records or data relating to the Study or any other form reasonably deemed appropriate by the Sponsor. The Principal Investigator and Study team members shall make themselves available, shall ensure that the Study documentation is ready for review prior to any visit, and shall cooperate with the Health Board or Sponsor.
- To the extent permitted by Applicable Law, the NHS Organization and the Principal Investigator shall without delay: (i) inform the Sponsor of any intended or actual inspection, written inquiry or visit to the trial site by any regulatory authority in connection with the Study; (ii) forward to the Sponsor copies of any correspondence from any such regulatory authority; (iii) use its best efforts to obtain the consent of the regulatory authority to have a representative of the Sponsor present during any visit in an advisory capacity, (iv) give the Sponsor the opportunity to review and comment on any regulatory authority documents prior to responding to any regulatory authority; and (v) provide Sponsor with a detailed written report of the visit.
- 3.4. The Principal Investigator represents and warrants: (i) that he (or she) – and that all Study team members – hold the necessary education qualifications, licenses, authorizations and other certifications and have the necessary expertise, time and resources to perform the Study; and (ii) that he (or she) will remain a member in good standing of the applicable health profession regulatory

body.

- 3.5. The NHS Organization and the Principal Investigator represent and warrant: (i) that they are not and have never been debarred, proposed for debarment, subject to potential sanctions (via a warning letter, notice of initiation of disqualification proceeding, opportunity of explaining or by any other means) or otherwise disqualified or suspended from performing a clinical study or subject to any restrictions or sanctions by any regulatory authority or REB with respect to the performance of a clinical study or scientific or clinical investigations; and (ii) that they are not currently using, and shall not use the services of any person proposed for or subject to any event listed in point (i); and (iii) that they will immediately notify Sponsor if either of them becomes aware of any actual or threatened debarment, proposal for such debarment, disqualification or suspension.

4. LIABILITIES AND INDEMNITY

- 4.1. Nothing in this clause 4 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence of that Party or its employees, students, consultants and subcontractors, including researchers, or to restrict or exclude any other liability of any Party which cannot be so restricted in law.
- 4.2. Subject to clauses 4.3, 4.4, 4.5, 4.6, 4.7 and 4.8 the Sponsor shall, in accordance with the Letter of Indemnification, indemnify and keep the NHS Organisation and its employees, students, consultants and subcontractors, including researchers, indemnified against any claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the NHS Organisation:
- 4.2.1. Undertaking the Study in accordance with the Protocol written instructions from the Sponsor and all applicable laws, governmental requirements medical standards; and/or
- 4.3. The indemnity shall only apply if the NHS Organisation:
- 4.3.1 Informs the Sponsor in writing as soon as reasonably practicable following receipt of notice of such claim or proceeding;
- 4.3.2 Upon the Sponsor's request and at the Sponsor's cost gives the Sponsor full control of the claim or proceedings and provides all reasonable assistance; and
- 4.3.3 Makes no admission in respect or such claim or proceedings other than with the prior written consent of the Sponsor.
- 4.4. The indemnity shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages and demands arise or result from:
- 4.4.1 The wrongful acts or omissions or negligence or breach of statutory duty of the NHS Organisation or its students, consultants and subcontractors, including researchers; or
- 4.4.2 A treatment or procedure routinely undertaken as part of NHS treatment.
- 4.5. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:
- 4.5.1. 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 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
- 4.5.2. One or more Party is a NHS body and the other Party (ies) is a NHS Foundation Trust; or

4.5.3. All Parties are NHS Foundation Trusts;

Then clauses 4.6, 4.7 and 4.8 shall apply.

4.6. 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.

4.7. If:

4.7.1. 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

4.7.2. All Parties are NHS bodies in Scotland; or

4.7.3. 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 16.5.

4.8. 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.

4.9. The liability of the NHS Organisation to the Sponsor in respect of any contractual liability the Sponsor may or does incur to a third party arising or resulting from this Agreement shall be limited to all fees payable by the Sponsor to the NHS Organisation in accordance with clause 9.

4.10. No Party shall be liable to another in contract, tort, 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.

4.11. The NHS Organization and the Principal Investigator shall be responsible and liable for the acts and omissions of their respective employees acting as Study team members and agents in connection with the Study, as if such acts and omissions were those of the NHS Organization or the Principal Investigator.

4.12. The NHS Organization and the Principal Investigator shall maintain appropriate and sufficient liability coverage in respect of the type of activities undertaken in connection with the Study and their respective obligations to third parties under this Agreement. For the Principal Investigator, this may include membership in its medical association providing for professional liability protection. Evidence of such insurances shall be provided upon request. Such insurance policies or membership shall not be cancelled without the prior written consent of Sponsor. The terms of any insurance or the amount of cover shall not relieve any Party of its liabilities under this Agreement.

5. CONFIDENTIALITY, DATA PROTECTION AND FREEDOM OF INFORMATION

5.1. Medical confidentiality

- 5.1.1. The Parties agree to adhere to the principles of medical confidentiality in relation to Participants. The Parties shall comply with the requirements of the common law of confidentiality, the Data Protection Act 1998 and, as appropriate, the NHS Confidentiality Code of Practice or the Scottish Executive Health Department NHS Code of Practice on Protecting Patient Confidentiality or the Confidentiality: Code of Practice for Health and Social Care in Wales or the Code of Practice on Protecting the Confidentiality of Service Users in Northern Ireland, (when implemented).
- 5.1.2. Personal data shall not be disclosed to the Sponsor or Health Board by the NHS Organisation, 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.
- 5.1.3. Neither the Sponsor, the Health Board, nor the NHS Organisation shall disclose the identity of Participants to third parties without the prior written consent of the Participant except in accordance with the Data Protection Act 1998 or, as appropriate, the NHS Confidentiality Code of Practice or the Scottish Executive Health Department NHS Code of Practice on Protecting Patient Confidentiality or the Confidentiality: Code of Practice for Health and Social Care in Wales or the Code of Practice on Protecting the Confidentiality of Service Users in Northern Ireland, (when implemented).

5.2. Freedom of Information

- 5.2.1. Parties to this Agreement which are subject to the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party in accordance with clause 14, as soon as reasonably practicable, and in any event, not later than five working days after receiving the request.
- 5.2.2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under FOIA or FOI(S)A is a decision solely for the Party responding to the request.
- 5.2.3. Where the Party responding to an FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least two working days notice of its intended disclosure.

5.3. Confidential Information

- 5.3.1. Each Party agrees to ensure that information supplied to them under this Agreement and belonging to or licensed to the other Party and marked as confidential is treated as confidential. Despite the foregoing, the parties agree that all Confidential Information disclosed by the Sponsor shall be deemed confidential unless otherwise is expressly provided for in writing by Sponsor or the person disclosing it on Sponsor's behalf.
- 5.3.2. The NHS Organisation agrees to treat the Results of the Study as confidential.
- 5.3.3. Each Party agrees:
 - 5.3.3.1. To ensure that any of their employees, students, consultants or sub-contractors who participate in the operation of the Study, and who are granted access to Confidential Information on a "need-to-know" basis, are made aware of, and abide by, the requirement of clause 5.3.

- 5.3.3.2. To use the Confidential Information solely in connection with the operation of the Agreement and not otherwise and in any event not to use such information to its benefit or to the benefit of any third party.
- 5.3.3.3. To preserve the confidential nature of the information and to treat Confidential Information with at least the same degree of care that it uses to protect the confidentiality of its own most sensitive information, and in any event with no less than any reasonable standard of care. Not to copy, modify, alter, erase, transfer, distribute, publicize or otherwise render accessible or disclose the Confidential Information in whole or in part to any person without the other Party's prior written consent.
- 5.3.3.4. To notify the Sponsor and the Health Board and to comply with their written instructions should the regulatory authority or competent tribunal request the disclosure of Confidential Information, or should a loss, theft or accidental or unauthorized access, disclosure, copying, use, incorporation, publication, modification or deletion of Confidential Information occur.
- 5.3.3.5. Upon Sponsor's request to: (i) safely return and cease to use all Confidential Information disclosed by the Sponsor; or (ii) irrevocably destroy or erase all such Confidential Information or documents, as attested by a certificate confirming that all such information and document have irrevocably been destroyed or erased, as the Sponsor shall direct.

5.3.4. The provision of clause 5.3 shall not apply to the whole or any part of the Confidential Information that is:

- 5.3.4.1. Lawfully obtained free of any duty of confidentiality.
- 5.3.4.2. Already in the possession of the Party receiving such information (other than as a result of a breach of clause 5.3.1 or 5.3.2) provided that such information was not disclosed in connection with this Agreement.
- 5.3.4.3. In the public domain (other than as a result of a breach of clause 5.3.1 or 5.3.2 or 5.3.3).
- 5.3.4.4. Necessarily disclosed pursuant to a statutory obligation, provided that prior written notice was given to the Sponsor in a timely manner and that the Party complied with Sponsor's instructions to the fullest extent permitted by law, it being understood that Paragraph 5.3.3.2 shall remain applicable.
- 5.3.4.5. Disclosed with prior written consent of the other Party.
- 5.3.4.6. Necessarily disclosed by a Party by virtue of its status as a public authority in terms of the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002.

the whole as attested by proper contemporaneous written evidence.

5.4. The restrictions contained in clause 5.3 shall continue to apply after the termination of this Agreement for 10 years, and with respect to information that constitutes trade secrets until such information no longer constitutes trade secrets.

6. PUBLICITY

6.1. No Party shall use the name, logo or registered image of the other Party(ies) or their employees in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

- 6.2. The content and timing of any publicity, advertising or press release made by the NHS Organization or the Principal Investigator shall be agreed by all Parties involved; such agreement not to be unreasonably withheld.
- 6.3. Despite the foregoing, the Sponsor shall be entitled to identify the NHS Organization and the Site(s) as the place where the Study was performed and the Principal Investigator and clinical team members in connection with the Study activities.

7. PUBLICATION

- 7.1. The Parties recognise that the Research Governance Framework referenced in clause 2 of this Agreement places an obligation on NHS Organisations carrying out health and social care research to publish their work. The Parties agree that this clause 7 should be interpreted in light of such obligation, provided that such Framework shall not alter Sponsor's right: (i) to publish the first publication, (ii) to ensure that no Confidential Information belonging to it and no information pertaining to its Intellectual Property is included in the publication (or that such publication is delayed), (iii) to provide NHS Organization with comments (it being understood that the Sponsor is not granted the right to edit such publications, (iv) to have a statement included in any publication to the effect that the creation of the data was supported by the Sponsor, (v) to be granted the right to reproduce and distribute copies of any publication in accordance with NHS Organization property rights.
- 7.2. Following completion of the Study, the Sponsor shall use all reasonable endeavours to ensure the appropriate publication or other dissemination of the conclusions of the Study. Should the Study form part of a study being undertaken at a number of separate sites this obligation shall arise following completion of the entire Multi-Site Study.
- 7.3. The NHS Organisation shall not publish or otherwise disseminate the conclusions of the Study, including all or any part of the Results of the Study without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed. Any publication or other dissemination of the conclusions of the Study by the NHS Organisation shall not occur until the Sponsor has published the conclusions of the Study in accordance with clause 7.2 and shall refer to publication by the Sponsor in such form as the Sponsor may reasonably direct.

8. INTELLECTUAL PROPERTY RIGHTS

- 8.1. All background Intellectual Property rights (including licences) and know-how 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 infringe any third party's rights.
- 8.2. All invention, development, discovery or other Intellectual Property and know-how arising exclusively or resulting from the Study, but excluding all clinical procedures exclusively developed or used by the NHS Organisation, shall belong to the Sponsor and shall be disclosed in writing and without delay to the Sponsor. The NHS Organisation hereby assigns all such Intellectual Property rights ("IPR"), and undertakes to disclose all such know-how, to the Sponsor.
- 8.3. Subject to clause 8.1 and 8.2, all property rights in any material (whether tissue, cellular, genetic, biochemical or otherwise) deriving or arising from biological material or any derivations provided to the Sponsor by the NHS Organisation shall belong to the Sponsor.
- 8.4. The NHS Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the IPR in the Sponsor. To give effect to this clause 8.4, the NHS Organisation shall ensure that persons involved in the Study assign such IPR, and disclose such know-how to the NHS Organisation.

- 8.5. Nothing in this clause 8 shall be construed so as to prevent or hinder the NHS Organisation from using memory know-how gained during the performance of the Study in the furtherance of its normal activities of providing or commissioning clinical services without the use of IPR or Sponsor's Confidential Information, 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 and that this right only refers to their honestly gained memory of such know-how and shall in no event extend to the Sponsor's trade secrets or Confidential Information. Furthermore, this clause 8.5 does not permit the disclosure of any of the Results of the Study, all of which remain confidential.

9. FINANCIAL AND SUPPLIES ARRANGEMENTS

- 9.1. The Parties agree to financing of the Study as set out in Schedule 3. In the event that amendments to the Protocol require changes to the financial arrangements, an amended financial schedule will be signed by the Parties and attached at Schedule 3 of this Agreement.
- 9.2. Where payments are agreed:
- 9.2.1. The Parties agree that prior to payment the NHS Organisation shall submit an invoice setting out the costs incurred and payment claimed.
- 9.2.2. Payment by the Sponsor shall be without prejudice to any claims or rights which the Sponsor may have against the NHS Organisation and shall not constitute any admission by the Sponsor as to the performance by the NHS Organisation of its obligations under this Agreement.
- 9.3. 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 to the NHS Organisation shall be used by the NHS Organisation only for the Study and in accordance with the Protocol.
- 9.4. The Sponsor shall use any tissue, sample, data, material or other information provided by or derived from a Participant and provided by or on behalf of the NHS Organisation to the Sponsor in accordance with the consent provided by the Participant.

10. TERM

- 10.1. This Agreement shall commence on the date the final signatory signed the Agreement and shall remain in effect until completion of the Study as specified in the Protocol, or until earlier termination in accordance with this Agreement. If the Protocol does not specify when the Study is complete, then it shall be deemed to be when all Parties have completed their respective obligations as described in the Protocol and in Schedule 2, and all services to be performed by the NHS Organization were performed to the satisfaction of the Sponsor acting reasonably.

11. SUSPENSION OR EARLY TERMINATION

- 11.1. Any Party may suspend their involvement in the Study pending the outcome of an investigation of a serious adverse event or otherwise on grounds of Participant safety.
- 11.2. This Agreement may be terminated immediately by notice in writing by any Party if another Party is:
- 11.2.1. 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 days after written notice by the non-breaching Party; or

- 11.2.2. 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 or, in the case of the NHS Organisation, if it is a NHS Foundation Trust listed in the register of NHS Foundation Trusts maintained pursuant to Section 39 of the National Health Service Act 2006, any step or proceedings is taken against the NHS Organisation by the Independent Regulator under Sections 52-55 of that Act; or if not and the Secretary of State makes an order under either the National Health Service Act 2006 Section 70 or the National Health Service (Residual Liabilities) Act 1996 Section 2 in respect of the NHS Organisation transferring its property rights and liabilities to one of the bodies referred to in Section 70(2) National Health Service Act 2006 or Section 2(2) National Health Service (Residual Liabilities) Act 1996 as applicable.
- 11.3. The Sponsor may terminate this Agreement by notice in writing and without liability for such termination:
- 11.3.1. If the regulatory permissions and approvals previously granted to perform the Study are withdrawn.
- 11.3.2. 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.
- 11.3.3. If the Principal Investigator becomes unavailable to continue his/her supervision of the Study for any reason and a replacement acceptable to all Parties is not found.
- 11.3.4. If (including but not limited to): insufficient numbers of Participants are being recruited by the NHS Organisation to the Study; insufficient numbers of Participants are being recruited to the Study across all the study centres; interim analysis of the data from this Study or the results of another study supersede the necessity for completion of this Study; following 30 days prior written notice of termination to the NHS Organisation.
- 11.3.5. In the event of cessation of supply of medicinal product, medical device or information or materials critical to the Study.
- 11.3.6. For any other reason upon 30 days prior written notice.
- 11.4. The NHS Organisation may terminate this Agreement on one month's notice in writing to the Sponsor and Health Board. Prior to so terminating this Agreement, the NHS Organisation shall discuss with the Sponsor and Health Board the reasons for wishing to terminate and explore alternative arrangements to termination.
- 11.5. In the event of termination of this Agreement under clause 11 the following provisions shall apply:
- 11.5.1 The Sponsor shall, subject to the prior compliance of the NHS Organisation with its obligations on termination, upon receipt of a valid invoice, pay the NHS Organisation any outstanding monies due to the NHS Organisation as at the date of termination.
- 11.5.2 The NHS Organisation 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 NHS Organisation under this Agreement exceeds the actual commitments incurred by the NHS Organisation up to the date of termination and any other costs in accordance with Schedule 3.
- 11.5.3 The NHS Organisation shall provide to the Sponsor all Results of the Study and other relevant information or data relating to work undertaken by the NHS Organisation prior to the date of termination and co-operate with all reasonable requests from the Sponsor at the cost and expense of the Sponsor including any continued monitoring of Participants.
- 11.5.4 The NHS Organisation shall ensure that all instructions by the Sponsor and/or Health Board as regards the return or disposal of all unused supplies, or medical devices or other

equipment or items previously furnished to the NHS Organisation for the purposes of the Study are complied with.

11.5.5 The NHS Organisation shall ensure that the instruction of the Sponsor regarding the transfer or storage of all information, material or data relating to the Study collected by the NHS Organisation in the course of carrying out the Study are complied with.

11.5.6 Unless otherwise agreed in writing with the Sponsor, the Sponsor shall pay the costs and expenses of returning, dispatching, transferring or storing items in accordance with clauses 11.5.4 and 11.5.5.

The parties agree that Paragraphs 11.5.3, 11.5.4 and 11.5.5 shall also apply in case of expiration of the term of this Agreement or of any renewal as may be agreed by the parties.

11.6 Any termination of this Agreement under this clause 11 will be without prejudice to any other rights or remedies of any Party under this Agreement or at law, and will not affect any accrued rights or liabilities of any Party at the date of termination shall survive the expiry or termination of this Agreement.

12 AGREEMENT, MODIFICATION AND AUTHORITY OF CO-SPONSORS

12.1 Any amendments to this Agreement shall be valid only if made in writing, agreed and signed by the Parties.

12.2 Where there is more than one Sponsor, each Sponsor has the authority to act on behalf of all co-Sponsors. Any amendments to this Agreement signed by one Sponsor shall be valid and binding on all co-Sponsors and any instructions or consent given by one Sponsor is deemed to be given on behalf of all co-Sponsors.

12.3 The Health Board has the authority to act on behalf of the Sponsor in relation to the activities allocated to it by the Sponsor (as indicated in Shedule 2)

12.4 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, which is the subject of this Agreement. Nothing in this Agreement will, however, operate to limit or exclude any liability for fraud.

13 FORCE MAJEURE

13.1 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 30 working days the other Party(ies) shall be entitled to terminate this Agreement by notice in writing with immediate effect.

14 NOTICES

14.1 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, providing evidence of receipt, but not by e-mail.

14.2 Notices to the Sponsor, the Health Board and to the NHS Organisation shall be delivered to the person and at the address specified in Schedule 3.

15 ASSIGNMENT AND SUBLETTING

- 15.1 No Party shall novate, assign, or subcontract all or any part of their rights or obligations under this Agreement without the prior written consent of the other Parties.

16 DISPUTE RESOLUTION

- 16.1 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 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 days.
- 16.2 If the Parties are unable to resolve a dispute using the procedure outlined in clause 16.1, the Parties will attempt to resolve the dispute by the appropriate method of:
- 16.2.1 In England or Wales Parties will refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure; or
- 16.2.2 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
- 16.2.3 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.
- 16.3 The Parties shall each bear their own costs in relation to the settlement of any disputes and 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.
- 16.4 Any decision reached in accordance with this clause 16 shall be final and binding upon the Parties.
- 16.5 Notwithstanding the provisions of clauses 16.2 to 16.4, where the Agreement is an NHS Contract as defined in Section 9(4) National Health Service Act 2006 or Section 17 National Health (Scotland) Act 1978 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:
- 16.5.1 The Secretary of State for Health if both Parties are NHS Organisations in England or Wales;
- 16.5.2 The Scottish Ministers if both Parties are NHS Organisations in Scotland;
- 16.5.3 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; or
- 16.5.4 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 16.5.1, 16.5.2 or 16.5.3 acting jointly.

17 GENERAL

- 17.1 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.
- 17.2 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.

- 17.3 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.

18 SURVIVAL OF CLAUSES

- 18.1 The following clauses shall survive the termination or expiry of this Agreement: clauses 1, 4, 5, 6, 7, 8 and 19.

19 GOVERNING LAW

- 19.1 Subject to clause 19.2:

19.1.1 If the Site is located in England or Wales, this Agreement is deemed made and shall be interpreted in accordance with the laws of England and Wales and the Parties submit to the exclusive jurisdiction of the English and Welsh Courts.

19.1.2 If the Site is located in Scotland this Agreement is deemed made and shall be interpreted in accordance with the laws of Scotland and the Parties submit to the exclusive jurisdiction of the Scottish Courts.

19.1.3 If the Site is located in Northern Ireland this Agreement is deemed made and shall be interpreted in accordance with the laws of Northern Ireland and the Parties submit to the exclusive jurisdiction of the Northern Irish Courts.

- 19.2 The Parties may agree to override clause 19.1.1, 19.1.2 and 19.1.3 and nominate the English and Welsh or Scottish or Northern Irish laws and court jurisdiction to apply to this Agreement irrespective of the location of the Site or Sites. Any such nomination must be in writing and signed by all Parties.

SIGN OFF

Signed by the duly authorised representatives of the Parties on the date stated at the beginning of this Agreement

SIGNED ON BEHALF OF THE SPONSOR

ANDREAS OEFANOS	DIRECTOR, Medical Affairs		02 MAR 2017
Name	Position	Signature	Date

SIGNED ON BEHAL OF THE HEALTH BOARD

ROMA ARMSTRONG	SUR RTO MANAGER		13/2/17
Name	Position	Signature	Date

Study Title: COLCOT – Colchicine Cardiovascular Outcomes Trial
Reference: EudraCT no.: 2014-005172-28

SIGNED ON BEHALF OF NHS ORGANISATION

<i>S. Lewis</i>	<i>ROD Drury</i>	<i>[Signature]</i>	<i>9.2.17</i>
.....			
Name	Position	Signature	Date

Study Title: COLCOT – Colchicine Cardiovascular Outcomes Trial
Reference: EudraCT no.: 2014-005172-28

SCHEDULE 1

STUDY PROTOCOL

- Note 1: The Protocol must set out the objectives, design, methodology, statistical and organisational arrangements.
- Note 2: The Parties should check that there are no conflicts between Agreement clauses and Protocol. Any conflicts that are identified must be resolved prior to signing this Agreement.
- Note 3: Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any document incorporated therein, clause 2.2 of this Agreement shall apply.

Summary of Management Arrangements

Funder: Montreal Heart Institute Sponsor: Montreal Heart Institute – Montreal Health Innovations Coordinating Centre, 4100 Molson Street, Suite 400, Montreal, Quebec, Canada H1Y 3N1

Chief Investigator for the Study in UK: Professor Colin Berry.....

Employer: University of Glasgow, NHF Glasgow Cardiovascular Research Centre, 126 University Place, Glasgow G12 8TA.....

Principal Investigator....Dr Jason Glover, Basingstoke and North Hampshire Hospital, Aldermaston Road, Basingstoke, RG24 9NA

Employer: Hampshire Hospitals NHS Foundation Trust, Aldermaston Road, Basingstoke, RG24 9NA

Study UK coordinating organisation: NHS Greater Glasgow & Clyde, R&D Management Office, West Glasgow ACH, Dalnair St., Glasgow G3 8SW

Others organisations (specify)

Number of Participants to be recruited at the Site target of 20.....

Number of samples/ records to be provided by the Site.....N/A.....

Timelines:

Milestone	Target date
Provision of materials for Ethics Committee submission	Completed
Ethics Committee submission	20/06/16
First Participant recruited	[Insert DATE]
Last Participant recruited	[Insert DATE]
[Insert other milestones as applicable]	[Insert DATE]

Study Title: COLCOT – Colchicine Cardiovascular Outcomes Trial
Reference: EudraCT no.: 2014-005172-28

COLCOT Protocol #MHIPS-003 (Amendment 1 FINAL Version 01/06/2015 plus COLCOT UK specific appendix Version 1.0, 02/06/2016)

SCHEDULE 2

DIVISION OF RESPONSIBILITIES

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

- Note 1:** Parties should set out the agreed division and/or delegation of responsibilities in the table below. Where there is more than one Sponsor, the name of the Sponsor responsible for each activity should be given. Some responsibilities are only applicable to particular types of study. Where a particular responsibility is not applicable to the Study, "not applicable" should be entered in the column designating "Responsible Party". Any additional responsibilities to those set out in this table should be added at the end to preserve the numbering of the standard list and navigation of the contents.
- Note 2:** Where both the Sponsor and NHS Organisation are named in respect of a particular responsibility, liability for such responsibility is not joint and several. Their respective responsibility shall be as laid down in applicable legislation, guidance and the governance arrangements for the Study or as is otherwise applicable to their respective roles in the Study.
- Note 3:** All references to Participants refer to those recruited at or through the Site.
- Note 4:** All capitalised terms used in the Schedule but not otherwise defined in the Agreement shall have the meaning ascribed to them in the Medicines for Human Use (Clinical Trials) Regulations 2004

Responsibility to:		Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
1. Study preparation (All studies)	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor	
	b) Secure and administer funding for the Study.	Sponsor	
	c) Secure and contract for the supply of resources including medicinal products / devices / Contract Research Organisation services.	Sponsor	
	d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor/ Health Board	
	e) Notify the substantive employers of investigators in writing, in advance of the Study commencing, of their participation in the Study.	NHS Organisation	
2. Applications and Registration (All studies)	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	Sponsor/Health Board	

Responsibility to:		Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	b) Prepare Participant information sheet and consent form, including where appropriate consent to providing Participant tissue, sample, medical data or other material to the Sponsor and other relevant documents prior to ethics submission. c) Prepare and submit ethics application. d) Register the Study with an appropriate protocol registration scheme. e) Obtain NHS permission.	Sponsor/Health Board Sponsor/ Health Board Sponsor Sponsor/Health Board	
3. Protocol Amendments (All studies)	a) Prepare and submit proposed substantial amendments of the Protocol to the regulatory authority(ies), relevant ethics committee and NHS Site. b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor/Health Board Sponsor/Health Board and NHS Organisation	
4. Study Conduct (All studies)	a) Ensure that legislation in relation to research is followed within the Site b) Ensure that the Study Site team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive or honorary employment contracts in place, where required. c) Ensure that no Participant is recruited until a favourable ethical opinion has been provided d) Ensure that no Participant is recruited to the Study until satisfied that all relevant regulatory permissions and approvals have been obtained. e) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and clause 2 of this Agreement f) Ensure that the Study is managed,	NHS Organisation NHS Organisation Sponsor/Health Board and NHS Organisation Sponsor/Health Board and NHS Organisation Sponsor/Health Board and NHS Organisation Sponsor and	

	Responsibility to:	Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	monitored and reported as agreed in the Protocol. g) Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study. h) Maintain and archive Study documentation at the Site. i) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit and that the appropriate consent has been provided by the Participant. j) Inform appropriate health or social care professionals if their patient is a Participant in the Study in accordance with the Research Governance Framework. k) Ensure adequate facilities, resources and support are available to conduct the Study at the Site. l) Report suspected research misconduct. m) Notify the regulatory authority(ies) of the end of the Study. n) Notify the regulatory authority(ies) and relevant ethics committee if the Study is terminated early.	NHS Organisation NHS Organisation NHS Organisation NHS Organisation NHS Organisation NHS Organisation Sponsor/Health Board and NHS Organisation Sponsor/Health Board Sponsor/Health Board	
5. Adverse events (All studies)	a) Maintain detailed records of all adverse events as specified in the Protocol. b) Report adverse events as agreed in the Protocol and to legal requirements and in accordance with NHS Organisation policy. c) Ensure that procedures are in place for emergency unblinding of the randomisation code.	Sponsor/Health Board and NHS Organisation Sponsor/Health Board and NHS Organisation Sponsor	

Responsibility to:		Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	d) Promptly inform regulatory authorities, ethics committees and investigators of any urgent safety measures taken to protect Participants in the Study. e) Ensure that annual safety reports and end of Study reports are generated and submitted to the regulatory authority and relevant ethics committee within the required timeframes. f) Ensure that all investigators are, at all times, in possession of the current relevant safety information for the Study.	Sponsor/Health Board Sponsor/Health Board Sponsor	
6. Data Management (All studies)	a) Design of case report forms and database. b) Ensure appropriate analysis of data.	Sponsor Sponsor	
7. Publication (All studies)	a) Initiate and coordinate review and submission of abstracts, posters and publications.	Sponsor	
8. Archiving (All studies)	a) Ensure that all Study records are archived appropriately on conclusion of the Study and retained for 25 years	Sponsor	
9. Clinical Trials involving Medicinal Products	a) Ensure that the Study is conducted in accordance with the principles of Good Clinical Practice (GCP). b) Request Clinical Trials Authorisation from the regulatory authority (MHRA in the UK). c) Ensure that Investigational Medicinal Product (IMP) is not used for any purposes other than the conduct of the Study and is used in strict accordance with the Protocol. d) Ensure that all Serious Adverse Events (SAE), other than those specified in the Protocol as not requiring immediate reporting, are promptly assessed as regards the requirement for expedited reporting to the regulatory authority and relevant ethics committee. e) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of trial safety.	Sponsor Sponsor/Health Board NHS Organisation Sponsor/Health Board Sponsor	

Responsibility to:		Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	f) Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are identified and fully reported to the regulatory authority and relevant ethics committee within the required timelines. g) Ensure that investigators are aware of any SUSARs occurring in relation to the Investigational Medicinal Product (IMP). h) Ensure IMP is provided and labelled in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004. i) Ensure that IMP is stored in appropriate and secure conditions and that detailed records are maintained regarding its movement from delivery to return/destruction.	Sponsor/Health Board Sponsor Sponsor NHS Organisation	
10. Studies involving CE marked medical devices for new purpose or non-CE marked Medical Device NA	a) Ensure that sufficient product is available for the planned number of Participants. b) Ensure that investigational medical devices are not used for any purposes other than the conduct of the Study. c) Obtain a letter of no objection from the Medicines and Healthcare products Regulatory Agency for the clinical investigation of a non-CE marked medical device or a CE marked medical device being used for a new purpose d) Ensure that adverse events are reported to the Medicines and Healthcare products Regulatory Agency. e) 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.	Sponsor NHS Organisation Sponsor Sponsor NHS Organisation	

Responsibility to:		Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
11. [Insert other responsibilities, if necessary]	a) [Insert additional responsibilities if necessary e.g. regarding storage and use of tissue samples.]		

SCHEDULE 3

FINANCIAL ARRANGEMENTS

INVESTIGATOR FEES COLCHICINE-OUTCOMES												
	Screening	Rando										
Visit	1	2	3	4	5	6	7	8	9	10	11	EOS
Month		0	1	3	6	9	12	15	18	21	24	
Informed Consent	\$80											
Medical/Surgical history	\$50											
Phone contact				X		X		X		X		
Review Inclusion/exclusion	\$20	\$20										
Urine Pregnancy test (only women of childbearing potential)		\$15										
Review of Chemistry and Hematology (once per year)		\$30					\$25				\$25	\$25
Chemistry and Hematology blood draw			\$90									
Blood draw for biomarkers (optional)		\$30										\$30
Blood draw for pharmacogenomic evaluation (optional)		\$30										
Record AEs/MACE		\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20
Review con meds	\$25	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$20
Study medication dispense/return/pill counts		\$15	\$15		\$20		\$20		\$20		\$20	\$20
CRF completion	\$20	\$20	\$15	\$15	\$15	\$15	\$15	\$15	\$15	\$15	\$15	\$20
TOTAL	\$195	\$200	\$160	\$55	\$75	\$55	\$100	\$55	\$75	\$55	\$100	\$135

Schedule of payments and details of payment arrangements

Invoices to be submitted Caroline Bannon:

4100 Molson street, Montreal, Quebec H1Y 3N1, Canada

Payment will be in CAD. Payments will be processed on a quarterly basis will be issued and sent out within 30 days from the processing/run date. Payments will be made for all CRF's received and validated to be clean prior to this date, according to the attached payment schedule.

Payment to be made by cheque payable to:

Hampshire Hospitals NHS Foundation Trust

and remitted to:

R&D Manager

Hampshire Hospitals NHS Foundation Trust

Research Department

Room 32 , F Floor

Basingstoke and North Hampshire Hospital

Study Title: COLCOT – Colchicine Cardiovascular Outcomes Trial
Reference: EudraCT no.: 2014-005172-28

Aldermaston Road

Basingstoke

RG24 9NA

Or arrange BACS Transfer to: **NatWest**

Sort code: **60-70-80**

Account: **10011668**

And send the relevant paper work to **R&D Manager** at the above address

Where no payments are to be made tick this box

☐

SUPPLIES ARRANGEMENTS

Any medicine, equipment, materials, consumables, software or other items ("Items") being provided by the Sponsor or procured by the NHS Organisation for use in the Study shall be specified below.

Note 1: Parties should complete the table below. If the NHS Organisation is to procure any Items and is to be reimbursed by the Sponsor this should be specified in this Schedule. Similarly if the NHS Organisation is to pay the Sponsor for any Items provided to the NHS Organisation 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 NHS Organisation)

Where no Items are to be provided or procured tick this box

☐

Study Title: COLCOT – Colchicine Cardiovascular Outcomes Trial
Reference: EudraCT no.: 2014-005172-28

NOTICES

Notices to the Sponsor shall be addressed to:

Director Administration
Montreal Heart Institute Coordinating Center
4100 Molson suite 400
Montreal, Quebec H1Y3N1
Fax: 1+ 514-461-1301

Notices to the Health Board shall be addressed to:

Dr Maureen Travers,
Research Coordinator,
R&D Management Office,
Clinical Research & Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow G3 8SW

Notices to the NHS Organisation shall be addressed to:

R&D Manager
Hampshire Hospitals NHS Foundation Trust
Research Department
Room 32 , F Floor
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
RG24 9NA

Email: research.team@hhft.nhs.uk

