**Outcomes of liver intervention versus observation for disappeared colorectal liver metastasis (LORDS-M)**

**Please complete the document, sign, send an electronic copy for us ([digitalresearch@abdn.ac.uk](mailto:digitalresearch@abdn.ac.uk) and** [**mohamed.bekheit@nhs.scot**](mailto:mohamed.bekheit@nhs.scot)**), keep a copy for your records and approval process.**

This Agreement is made as of -------------- (“Effective Date”) BETWEEN NHS Grampian / Medical School, in University of Aberdeen And Department of ------------- in Hospital (“------------ Partner Institution”)

**BACKGROUND**

1. Coordinating Centre is lead coordinator for a multi-centre trial called “**Outcomes of liver intervention versus observation for disappeared colorectal liver metastasis (LORDS-M)**”

2. Coordinating Centre wishes to appoint ---------- partner and the ----------- partner has agreed to assist. Coordinating Centre in coordinating the Study in -------- (country) in accordance with the terms and conditions of this Agreement.

3. Coordinating Centre wishes to appoint ---------- Partner and ---------- Partner has agreed to act as Coordinating Centre’s representative within the borders of ---------------- to be responsible for matters related to any personal information handled by Coordinating Centre, in accordance with the GDPR and other applicable laws to personal information and data governance.

**THEREFORE, the Parties agree as follows:**

**1. DEFININITIONS AND GLOSSARY**

1.1. For the purposes of this Agreement:

a. “Agreement” means this agreement and all Schedules, Appendices and other documents as may be incorporated by reference;

b. “Background Intellectual Property” means Intellectual Property owned by each of the Parties at the commencement of the Agreement;

c. “CRF” means Case Report Form;

d. “------- Participating Centres” means Participating Centres in ------ (country).

e. “GCP” means good clinical practice as laid down by the ICH topic E6 (Note for Guidance on GCP): A standard for the design, conduct, performance, monitoring, recording, analyse and reporting of clinical trials that provides assurance that the data and recorded results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected;

f. “Institutional Review Board or “(Research) Ethics Board” means an independent body constituted of medical, scientific and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in the Trial, among other things, reviewing, approving and providing continuing review of the Trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial participants;

g. “Intellectual Property” includes all copyright and neighbouring rights, all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trademarks (including service marks), registered designs, confidential information (including trade secrets and know-how) and circuit layouts, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields;

h. “Investigator” means clinician entering patients in the Trial at a Participating Centre;

i. “Parties” means the Parties to this Agreement, specifically: NHS Grampian / Medical School in University of Aberdeen, PI, ------------ Partner Institution and ---------- Partner Investigator and “Party” means any of them as the context requires;

j. “Participating Centres” means any Trial centres participating in the Trial including investigators and institutions;

k. “Principal Investigator” means the lead clinician at each Participating Centre who is responsible for the conduct of the trial at that site;

l. “Personal Data” means data in oral or recorded form which relate to a person who can be identified

i. from those data, or

ii. from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual;

m. “Protocol” means the protocol entitled “**Outcomes of liver intervention versus observation for disappeared colorectal liver metastasis (LORDS-M)**”;

n. “Research Results” means all data, information and results arising from the Trial;

o. “Trial” means the clinical trial described in the Protocol; which in this phase observational and is regarded as Audit;

p. “Trial Data” means the formatted data sets containing the patient data reported by Investigators on case report forms and data queries".

**2. CONDUCT OF THE TRIAL**

2.1. The Trial is an intergroup trial in which Coordinating Centre is the lead coordinating group of the Trial. Coordinating Centre has delegated certain activities and functions to ------------- Partner. Each shall undertake the Trial in their respective countries as set down in the Protocol and the Roles and Responsibilities Table;

2.2. The Trial shall be conducted by Coordinating Centre. ------------- Partner will not make decisions independent of the Coordinating Centre. Coordinating Centre will retain the authority to make decisions independent of the ------------- Partner:

a. In accordance with the Protocol and any amendments to the Protocol as approved by the

Executive Committee, the Coordinating Centre and by the main Research Ethics Boards at

the ------------- Partner Site;

b. ------------- Participating Centres to be selected by ------------- Partner;

c. With Trial participants selected in accordance with the eligibility criteria specified in the Protocol and only after all necessary legal, regulatory or other approvals (if needed) have been granted including those of the Institutional Review Board or of any ethics committee,at the Participating Centres and strictly in accordance with the terms of any such approval;

d. In accordance with the Declaration of Helsinki 1996, and with the principles of GCP;

e. In accordance with the requirements laid down by applicable law in the countries where the Trial is conducted, including but not limited to PIPL and the Data Security Law (“DSL”) of the ----------- (Country).

2.3. In accordance with applicable data protection legislation, the party processing data on behalf of the other agrees the signature of this Agreement serves as prior agreement of the party acting as the data processor of the other party to store or process Personal Data at sites outside of ----------. The Parties shall comply with the requirements of the common law of confidentiality, the Data Protection Act 1998 and, as appropriate.

2.4. Personal data shall not be disclosed to the Coordinating Centre by the ------------- Partner, 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.

2.5. The Parties shall use their best efforts to complete the Trial and to perform their obligations under this Agreement. The Parties offer no guarantee that a particular result will be obtained or that the result of the work may be used for a specific purpose.

2.6. The Parties acknowledge that it is the intent of PIPL that the Parties shall enter into standard contractual terms governing the transfer of data out of ------. ------------- Partner shall inform Coordinating Centre as soon as possible if such standard contractual terms are created by the ------. Once standard contractual terms are available, the Parties shall either amend this Agreement to incorporate the terms or terminate the Agreement.

2.7. The Parties agree to comply with the Draft Outbound Data Transfer Security Assessment

Measures from the ------. In particular, the Parties acknowledge that the outbound transfer of data from ------ may require a security assessment or certification from a specialized body in accordance with Article 38 of PIPL.

2.8. ------------- Partner shall, and shall ensure that all ------------- Participating Centres shall, receive a separate consent to enable the disclosure of data to Coordinating Centre in accordance with Article 25 of PIPL.

2.9. ------------- Partner shall ensure that all ------------- Participating Centres shall comply with all applicable laws during the conduct of the Study, including but not limited to PIPL and DSL, and shall only provide data to NHS Grampian / University of Aberdeen in accordance with applicable laws and all required consents.

2.10. If ------------- Partner discovers that data has been sent to Coordinating Centre which violates applicable laws, including PIPL or DSL, ------------- Partner shall inform Coordinating Centre within one (1) business day. If Coordinating Centre discovers, or is informed by ------------- Partner, that Coordinating Centre has received data in violation of applicable laws, Coordinating Centre shall return or delete such data immediately.

2.11. The ------------- Partner, Participating Centres and/or Site Investigators will be responsible for providing all required equipment, personnel and any other support necessary to commence and complete the Trial.

2.12. Coordinating Centre reserves the right to audit the ------------- Partner, the Participating Centres, the Trial or have the Trial audited by a designee to document the authenticity of recorded data and adherence with the Protocol and this Agreement. Any such audits shall occur at mutually agreeable times during normal business hours. During the audit the ------------- Partner shall provide a team member to assist the auditor for the duration of the visit. Patients/subjects participating in the Trial shall be informed by Principal Investigator or ------------- Partner, that their records may be reviewed for this purpose, including by government health authorities. The confidentiality of such patient records will be respected fully as required by law. The ------------- Partner and Principal Investigator shall provide such monitor(s) free and uninhibited access to laboratory test results, reports and other patient/subject records needed to verify the entries on the case report forms.

**3. CONFIDENTIALITY**

3.1. The Parties may wish to disclose information to each other in connection with the Trial that is either non-public, confidential or proprietary in nature and is identified by the disclosing party to the recipient as confidential ("Confidential Information"). In consideration of the Parties’ disclosure of Confidential Information to each other, each recipient agrees that, during the Trial and for a period of five years from the expiration or termination of the Trial, it shall retain in confidence the Confidential Information belonging to the other, and will prevent disclosure of such Confidential Information to third parties. The Parties agree that for the purposes of the Trial, the Results of the Trial constitute the Confidential Information of the Coordinating Centre and/or PI.

3.2. These restrictions shall not apply to Confidential Information which:

a. Was known to, or was otherwise in the possession of the receiving party or its affiliate prior to receipt from the other party;

b. At the time of disclosure is or thereafter becomes part of the public domain without breach of this Agreement;

c. Is developed by or on behalf of the receiving party or its affiliates independently of any disclosure hereunder;

d. Is at any time after disclosure of the Confidential Information acquired by the receiving party from a third party having the right to disclose the same to the receiving party without breach of obligation owed by that third party to the disclosing party;

e. Must be disclosed to potential patients during the recruitment process or to patients who are or were enrolled in the Trial, or their lawful representatives, in order to obtain and maintain written informed consent or as the information relates to their health, safety or diagnosis.

3.3. For the purposes of this section 6, Participating Centres and their respective personnel, the Investigators, Research Ethics Committee members reviewing the Trial for the Participating Centres, and the Data Monitoring Committee are not considered third parties and Confidential Information may be disclosed to Participating Centres if reasonably necessary for the purposes of the Trial.

3.4. Notwithstanding anything else in this Agreement, no Party will be bound by any obligations of confidentiality where maintaining confidentiality could prejudice patient safety or welfare, or where they are obliged by law or regulation to disclose such information. In the event that Confidential Information is required to be disclosed by law or regulation, the party required to make the disclosure shall notify the party which disclosed the Confidential Information to allow that Party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

3.5. The Parties shall ensure that their respective employees, subcontractors, and agents, the Participating Centres and any other persons assisting in the conduct of the Trial, including the Investigator, to whom Confidential Information is disclosed, are informed of the obligations of confidentiality under this Agreement and are made subject to the same obligations of confidentiality as set out herein.

**4. LIABILITY & INSURANCE**

4.1. The Sponsor agrees that the appointment of ------------- Partner Institution as the lead ------------- site for the Study will in no way, in and of itself, pass any of the Sponsor’s responsibilities or liabilities as Sponsor of the Study to ------------- Partner, except as explicitly set out within this Agreement. Each Party shall be solely liable for any loss, damage or injury to third parties to the extent resulting from the performance of the said Party’s obligations by it or on its behalf under this Agreement or from its use of Research Results.

4.2. No Party shall be responsible for any lost profits, lost opportunities, or other indirect or consequential damages suffered by another Party.

4.3. The Parties shall cooperate with each other in the defence of any third-party action, including providing each other with prompt notice of any such action and provision of all material documentations. The Parties have a right to retain their own counsel to conduct a full defence of any such action.

4.4. NHS Grampian / Medical School in University of Aberdeen, PI, ------------- Partner Institution, ------------- Partner Investigator and their respective Participating Centres will not indemnify participants in the Trial for non-negligent harm.

4.5. NHS Grampian / Medical School in University of Aberdeen and ------------- Partner Institution shall each maintain appropriate insurance or selfinsurance sufficient to cover its liabilities under this Agreement. PI shall maintain membership in the Canadian Medical Protective Association (CMPA) during the term of this Agreement, and ------------- Partner Investigator shall maintain equivalent professional liability protection if applicable. Upon request, each Party shall provide to the others a certificate of insurance or of CMPA membership as appropriate.

4.6. The contract Parties agree to remain silent about the applicable law for this agreement.

**5. ACCESS TO TRIAL DATA AND INTELLECTUAL PROPERTY**

5.1. No Party transfers to the other Party by operation of this agreement any right in or license to any Background Intellectual Property owned as of the Effective Date or to Intellectual Property arising outside of the research conducted under this Agreement.

5.2. Coordinating Centre and/or PI shall own the Trial Data and Results of the Study, in accordance with its institutional policies. Coordinating Centre grants ------------- Partner a non-exclusive, nonsublicensable, royalty-free license to use the Trial Data and Results of the Study for internal, non-commercial academic and research purposes, and for publication (subject to the publication requirements in section 9 of this Agreement).

5.3. Any inventions, discoveries, new uses, processes, or compounds (the “Inventions”) arising directly out of the Study or performance of this Agreement (the “Inventions”) shall be owned by the Coordinating Centre and/or PI, in accordance with the institutional policies of the inventing Party. Coordinating Centre and/or PI, agrees to grant to ------------- Partner a royaltyfree, non-exclusive license to use Inventions for internal and academic research purposes.

**6. PUBLICATION**

6.1. Lead by Coordinating Centre and/or PI, the Parties shall make the first presentation or publication of the Research Results jointly in conjunction with the publication of the results from all Investigators and Participating Centres. Authorship of the initial publications of Research Results shall be decided by the Executive Committee, in accordance with the criteria for authorship as formulated by the International Committee of Medical Editors and published in its Uniform Requirements for Manuscripts submitted to Biomedical Journals (NEJM 336(4):309-316, January 23, 1997). The Parties intend that functioning as the ------------- Partner Investigator and providing critical input on the manuscript development and finalization would meet criteria for authorship. The Executive Committee’s objective is to disseminate the results of the Trial within a reasonable period of time.

**7. TERM AND TERMINATION OF THE AGREEMENT**

7.1. The Agreement shall take effect on the Effective Date, and shall remain in force for the duration of the Trial at all Participating Centres, unless terminated early in accordance with this section

7.2. Either party may terminate this Agreement if the other party breaches any provision of this Agreement and does not cure said breach within 30 days of written notice.

7.3. The Agreement can be terminated early, only after discussion between the Parties, for the following reasons:

a. Any safety and/or efficacy concerns as determined by Data Safety Monitoring Committee, by giving written notice to the other party with immediate effect; or

b. A decision of a regulatory body.

7.4. Coordinating Centre may terminate this agreement for any reason upon 90 days advance notice to ------------- Partner.

7.5. The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrued prior to the date of termination.

**8. NOTICES**

8.1. Notices shall be in writing and shall be delivered by postage-prepaid mail, courier, electronic mail or personal delivery and shall be addressed to each Party respectively as set out in below, unless changed by written notice. In the case of personal delivery or courier, notice shall be deemed to have been given when received by the intended recipient; in the case of electronic mail, notice shall be deemed to be given on the first business day following receipt of transmission by sender; and, in the case of mailing, notice shall be deemed to be given seven days after having been mailed. The parties shall deliver all notices of termination by courier or personal delivery.

For Mohamed Bekheit, NHS Grampian / Medical School, University of Aberdeen, Aberdeen, Scotland

Department of Surgery, Ward 208, Pink Zone, Level 4, Aberdeen Royal Infirmary, NHS Grampian, Aberdeen, AB25 2ZN, UK.

Tel: +44 (0) 13435 - 67577

Mail: [mohamed.bekheit@nhs.scot](mailto:mohamed.bekheit@nhs.scot)

For ------------- Partner Institution:

(“------------- Partner Institution”)

Physical address: ---------------------

Email: ---------------------

For ------------- Partner Investigator:

9. GENERAL

9.1. Publicity - No Party may use the name of another Party, nor of any of another Party’s employees, in any publicity without the prior written approval of an authorized representative of the Party. Each Party may provide a brief listing of the Trial, including the title, and the name of the Parties, as part of any public or internal compendium of that Party’s or the investigator’s research.

9.2. Order of Precedence - In the event and to the extent of an inconsistency or conflict between any terms of this Agreement, including its schedules and appendices and any other documents incorporated here by reference, the conflict or inconsistency will be resolved by giving those provisions and documents the following order of descending precedence:

a. This Agreement;

b. The schedules to this Agreement; however, in the event of any inconsistency between this agreement and the Protocol, this Agreement shall govern and control as to any legal issue,and the Protocol shall govern and control as to any issue regarding treatment of Study subjects.

9.3. Entire Agreement and Amendment - This Agreement including all attached appendices constitute the entire agreement between the parties with respect to this subject matter. This Agreement supersedes and takes the place of all prior agreements, negotiations, and discussions between the Parties with respect to this subject matter. Any amendment or modification to this Agreement or its appendices shall not be effective unless it is in writing, identified as an amendment or modification to this Agreement and signed by authorized representative(s) of each Party to this Agreement.

9.4. Assignment – A Party shall not assign any of its rights or delegate any of its obligations under this Agreement without the prior written permission of the other Party(ies), such permission not to be unreasonably withheld or delayed, provided that, upon written notice to the other Party(ies), a Party may assign this Agreement to a wholly-owned subsidiary or to a successor of all or substantially all of a Party’s business without such permission.

9.5. Force Majeure - No Party shall be liable to any other Party(ies), or be in default under this Agreement for its failure to perform any obligation under this Agreement, if such failure arises for any reason beyond its control, including but not limited to strikes, lock-outs, third party labour disputes, acts of God, acts of nature, fire, flood, storm, power shortage/power failure, sabotage, epidemic or pandemic, or any other acts of any authorities or any applicable regulation. After any such event, the Party relying on this section shall (i) notify the other Party(ies) as soon as reasonably practicable and (ii) make reasonable efforts to mitigate the effects of such event. In the event of an extended delay, the Parties may terminate this Agreement, in accordance with its termination provisions.

9.6. No Party is an agent, joint venturer, partner, or employee of the other as a result of this

Agreement and no Party will represent itself in any way or to take any actions or create any obligation or liability that could establish or imply any such relationship as a result of this Agreement.

9.7. Waiver - Any Party may seek to waive an obligation under the Agreement. Any such waiver will be valid only if the Party granting the waiver provides it in writing and will apply only to the specific obligation referred to and for the period agreed and will not be deemed a continuing waiver.

9.8. Rights and Remedies Cumulative - The rights and remedies of the Parties under this Agreement are cumulative and are in addition to, and not in substitution for, any of its rights and remedies provided by law or in equity.

9.9. Counterparts, Electronic Signatures and Electronic Delivery - This Agreement may be executed by electronic signatures using digital signature software or if signed manually may be delivered electronically in optically scanned form, executed in one or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one Agreement.

9.10. English Language. This Agreement shall be drafted in English and translated into ------------- to allow ------------- Partner to comply with applicable laws. In the case of any inconsistency or discrepancy between original English texts and their translation into -------------, original versions in English shall prevail.



Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Mohamed Bekheit\_\_ , Aberdeen, 28-08-2022

NHS Grampian / Medical School, University of Aberdeen, Aberdeen, Scotland

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department of ------------ in -------- Hospital, ---------(Country)

LORDS-PANC 临床研究合作协议

本协议自\_\_\_\_\_\_\_\_\_\_\_（填写生效日期）起生效

由（Medical School, University of Aberdeen,）Mohamed Bekheit 教授（PI）和东部战区总医院重症医学科 （“中方合作机构”）李维勤教授共同签署。

背景

1. 研究中心是多中心研究的主要协调单位，本试验名为“急性胰腺炎合并内脏静脉血栓的治疗多中心注册研究”和相关子研究。

2. 研究中心希望委托中国合作方作为该研究在中国的组长单位，且中国合作方同意根据本协议的条款和条件协助“研究中心”在中国的研究工作。

3. 研究中心希望委任中国合作方，中国合作方也同意作为研究中心在中华人民共和国境内的代表，根据中国《个人信息保护法》（"PIPL"）第 53 条的规定，负责研究中心处理的任何个人信息的相关事宜。

因此，双方达成如下协议：

1. 术语及其定义

1.1. 为充分解释本协议，以下为用语释义：

a. “协议”，指本协议及所有通过引述纳入的附表、附录和其他文件。

b. “背景知识产权”，指协议开始时各方所拥有的知识产权；

c. “CRF”，指病例报告表；

d. “中国参与中心”，指在中国参与研究的中心；

e. “GCP”，指 ICH 专题 E6（GCP 指南注释）修订的临床实践规范：为保证临床试验方案设计、组织实施、工作情况、监督稽查、记录、分析、和报告的规范，确保数据和结果的科学、真实、可靠，保护受试者的权益和安全；

f. “机构审查委员会” 或 “（研究）伦理委员会”，指由医学、药学及其他背景人员组成的独立机构，其职责是通过独立地审查、同意、跟踪审查试验方案及相关文件、获得和记录受试者知情同意所用的方法和材料等，确保受试者的权益、安全受到保护；

g. “知识产权”，包括所有版权和有关权利，与发明（包括专利权）、植物品种、注册和未注册商标（包括服务商标）、已注册的设计、机密信息（包括商业机密和专有技术）和电路布局有关的所有权利，以及因工业、科学、文学或艺术领域的活动而产生的所有其他权利；

h. “研究者”，指在各参与中心负责纳入受试者的临床医生；

i. “双方”，指签订本协议的双方，具体是阿伯丁大学、医院、PI、中方合作机构和中方主

要研究者，”一方”是指上下文指代的任何一方；

j. “参与中心”，指参与试验的所有研究中心，包括研究人员和机构；

k. “主要研究者”，指负责在该参与中心实施临床研究的主要医生；

l. “个人资料”，指与指定人员有关的口头或记录的资料

i. 从这些资料中，或

ii. 从这些资料或其他数据控制员有或可能有的信息包括对个人的任何意见及数据控制员或与个人有关的其他人意图的说明；

m. “研究方案”，指本协议附件 1 中标题为“高蛋白营养方案对重症患者的影响——多中

心注册随机对照临床研究和相关子研究”（简称“EFFORT 研究”）的研究方案；

n. “研究结果”，指本研究得到的所有数据、信息和结果；

o. “研究”，指研究方案中所述的临床研究；

p. “研究数据”，指研究人员在病例报告表和数据查询中收集到的患者数据并进行格式化的数据集”。

2. 研究实施

2.1. 该研究是一项多中心研究，研究中心是各中心之间的主要协调者。研究中心已委托中国合作方相关任务和和职能。中国合作方应在中国进行本研究，具体参照研究方案（以及分工和职能表；

2.2. 本研究应由研究中心实施安排。中国合作方不可脱离于研究中心独自做决议。研究中心将保留独立于中国合作方做决议的权力：

a. 根据执行委员会、研究中心和中国合作方的研究伦理机构批准的研究方案和研究方案修正内容开展研究；

b. 由中国合作方选择中方参与中心；

c. 参与中心根据方案中规定的资格标准选择受试者，且需获得包括机构审查委员会或

其他任何伦理委员会对所有必要的法律、监管或其他内容进行批准（如需要），并严格遵守此类审查条目；

d. 遵守 1996 年赫尔辛基宣言和 GCP 原则；

e. 遵守开展研究所在国的法律规定的各项要求，包括但不限于 PIPL 和中华人民共和国的《数据安全法》（"DSL"）。

2.3. 根据已施行的数据保护法规，中国合作方作为数据处理代理，同意签署本协议。本协议为事先协议，通过签署本协议，研究中心可代中国合作方在中国境外的网站存储或处理个人数据。双方应遵守《普通保密法》、1998 年《数据保护法》以及（视情况而定）。

2.4. 中国合作方不得向研究中心披露受试者个人资料，除非直接或间接需要为满足研究方案要求或监察需要或报告不良事件。

2.5. 双方应尽力完成研究并履行该协议规定的义务。双方不保证会获得特定结果或将研究结果用于特定目的。

2.6. 双方承认，PIPL 的意图是双方应签订标准的合同条款来管理数据向中国境外的转移。如果中华人民共和国制定了此类标准合同条款，中国合作伙伴应尽快通知研究中心。一旦

有了标准合同条款，双方应修改本协议以纳入这些条款或终止本协议。

2.7. 双方同意遵守《中华人民共和国境外数据传输安全评估办法（草案）》（作为附表 3 附于本文）。特别是，双方承认，根据 PIPL 第 38 条的规定，从中国向外转移数据可能需要专门机构的安全评估或认证。

2.8. 中国合作方应确保所有中国参与中心收到一份单独的同意书，以便按照 PIPL 第 25 条的规定向研究中心披露数据。

2.9. 中国合作方应确保所有中国参与中心在研究过程中遵守所有适用的法律，包括但不限于PIPL 和 DSL，并且只在符合适用法律和所有必要同意的情况下向研究中心提供数据。

2.10. 如果中国合作方发现发送给研究中心的数据违反了适用法律，包括 PIPL 或 DSL，中国合作方应在一个工作日内通知研究中心。如果研究中心发现或被中国合作方告知，研究中心收到了违反适用法律的数据，研究中心应立即退回或删除这些数据。

2.11. 中国合作方、参与中心和/或分中心主要研究者负责提供本研究所需的各项设备、人员和其他支持以保障本项目的完成。

2.12. 研究中心保留对中国合作方、参与中心、本研究或由指定人员对本研究进行审查的权利，以确保数据记录的真实性及遵守研究方案和本合作协议。审查需在双方同意的正常工作时间内进行。审查期间，中国合作方应派遣一名团队成员协助审核员在中国访问期间的工作。主要研究者或中国合作方应告知参与研究的患者/受试者，他们的相关资料可能会因此被审查，包括接受政府卫生部门的审查。根据法律要求，此类患者资料将严格保密。中国合作方和主要研究者应向审查人员自由提供且不限制其调取实验室检测结果、报告和其他患者/受试者记录，以检查病例报告表中的内容。

3. 保密

3.1. 双方可能需要向对方披露与研究有关的非公开、保密或专有信息且披露方向接收方确认此信息为机密（“机密信息”）。考虑到双方向对方披露保密信息，各接收方同意，在研究期间以及研究到期或终止后的五年内，应保密属于对方的机密信息，并防止向第三方披露机密信息。就本研究的目的而言，双方同意研究结果构成研究中心和/或 PI 的机密信息。

3.2. 以上限制不适用于以下机密信息：

a. 接收方在接收前已知晓或已拥有信息的所有权；

b. 在披露时或之后该信息成为公共信息的一部分，而不违反本协议；

c. 由接收方或接收方的附属机构发起的且独立于任何披露的信息；

d. 无论何时，接收信息方从第三方获取保密资料后，且第三方在不违反对披露方应尽义务的情况下，有权向接收方提供同样资料；

e. 必须告知潜在招募患者或已纳入或即将纳入研究的患者或其合法代表，以获得和保留书面知情同意或与其健康、安全或诊断有关的信息。

3.3. 出于第 6 条款的目的，参与中心及其各自的人员，主要研究人员，研究伦理委员会成员以及数据监管委员会不被认为是第三方，如果有合理必要性，可以向参与中心披露机密

信息。

3.4. 尽管本协议中有任何其他规定，任何一方如保密可能损害患者的安全或福利，或因法律法规有义务披露此类信息，均不受任何保密义务的约束。如果法律或法规要求披露机密信息，被要求披露的一方应通知信息披露方，以允许该方主张根据该法律或法规可能获得的任何排除或豁免。

3.5. 双方应确保各自的员工、联系人员、代理人、参与中心和协助进行本研究的其他任何人员，包括披露机密信息的研究者，均被告知本协议项下的保密义务，并遵守本协议规定的保密义务。

4. 责任和保险

4.1. 研究中心委托中国合作机构作为本研究在中国的组长单位，不会将研究中心作为研究发

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代表履行本协议项下的义务或因其使用研究结果而造成的对第三方的任何损失、损害或

伤害承担全部责任。

4.2. 任何一方均不对另一方所遭受的任何利润损失、机会损失或其他间接或后果性损害负

责。

4.3. 双方应相互合作，为任何第三方诉讼行为辩护，包括及时向对方提供任何此类行为的通

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4.4. 阿伯丁大学、PI、中国合作机构、中国主要研究者及其各自的参与中心将不为非过失伤害赔偿研究参与者。

4.5. 合同双方同意对本协议的适用法律保持沉默。

5. 研究数据获取和知识产权

5.1. 任何一方均不得通过本协议的实施向另一方转让自生效日期起拥有的任何背景知识产权或根据本协议进行的研究之外产生的知识产权的任何权利或许可。

5.2. 研究中心和/或 PI 应根据其机构政策拥有研究数据和研究结果。研究中心授予中国合作方非独家、不可再许可和免版税的许可，以将研究数据和研究结果用于内部、非商业学术和研究目的，并用于发表文章（遵守本协议第 9 条的出版要求）。

5.3. 任何直接因本研究或履行本协议（“发明”）而产生的发明、发现、新用途、工艺或化合物（“发明”）应遵循发明方的机构政策归研究中心和/或 PI 所有。研究中心和/或 PI 同意授

予中国合作方免版税、非独家的许可，将发明用于内部和学术研究。

6. 出版

6.1. 在研究中心和/或 PI 的领导下，各方应共同进行研究结果的首次演示或发布。研究成果最初发表的论文的作者身份应由执行委员会决定，根据国际医学编辑委员会（International Committee of Medical Editors）制定并在其《生物医学期刊稿件统一要求》中公布的作者标准（NEJM 336（4）:309-316， 1997 年 1 月 23 日）进行作者排序。双方希望，作为中

Page 6 of 15方合作研究者，为文章的内容和定稿提供关键意见，以达到作者身份的标准。执行委员会的目标是在合理的时间内宣布研究的结果。

7. 协议的期限和终止

7.1. 本协议自生效日期起生效，并在所有参与中心的研究期间保持有效，除非根据本合约第 9条提前终止。

7.2. 如果另一方违反本协议的任何条款，且未在书面通知后 30 天内纠正该违约行为，则任何一方均可终止本协议。

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对于邮寄，通知将被视为在邮寄后七天发出。双方应通过快递或个人送达的方式送达所

有终止通知。

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