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NIHR001/0428

SCHEDULE E

VARIATION TO CONTRACT

Project Title: SPARK: SuPporting African communities to increase the Resilience and mental health of Kids with developmental disorders and their caregivers

Project Application No: **NIHR200842**

Contract between the Secretary of State for Health and Social Care (“the Authority”) and (“the Contractor”) dated 21 April 2020 (“the Contract”).

Date: 31 October 2023

1. The Contract is varied as follows:

- **Section 1, conditions 1-4 shall be deleted and replaced with:**

1. In consideration of the rights and obligations recorded in this Contract:
 - a. The Contractor will undertake a research project entitled SPARK: SuPporting African communities to increase the Resilience and mental health of Kids with developmental disorders and their caregivers in accordance with the work specified in Section 3, being project application NIHR200842 dated 04 September 2019, with amending Correspondence dated 24 January 2020 the “**Research**”.
 - b. In the event of a Public Health Emergency (as defined below), the Authority may direct the Contractor to perform further work in addition to (or in replacement of) the Research in accordance with Section 2, Clause 3.14.
2. On condition that the Contractor complies with the terms of this Contract, the Authority will pay the Contractor the Approved Cost as set out in Section 4 in respect of: (i) undertaking the Research in accordance with this Contract.
3. This Form of Contract (Section 1) together with its Schedules and the attached Sections 2 to 7 inclusive are the documents which collectively form the “**Contract**” (as defined in Section 2).
4. The Contract affected by the signing of this Form of Contract constitutes the entire agreement between Parties relating to the subject matter of the Contract and supersedes all prior negotiations, representations or understandings.

- **Section 2, Condition 1. Definitions and Interpretation**

The following definitions shall be added and/or replace definitions of the same name:

“**Commercial Use**” means any use activity and/or agreement that, supports the generation of revenue including but not limited to:

- (a) any use in support of an application for regulatory approval for a product or service;
- (b) any use in support of the development, promotion or use of a product or service

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- that will be made available on a fee paying basis;
- (c) any use in support of the development, promotion or provision of Health Care direct to an individual on a fee paying basis;
 - (d) the provision of a product or a service to any Health Service Body or to any patient under the care of a Health Service Body; and/or;
 - (e) the granting of an option, a licence, and/or an assignment of Intellectual Property.
- For the avoidance of doubt, this does not include licences granted to the academic or research institutions or any Health Service Body for the purposes of academic research or teaching.

“Completion Date” shall be revised: “means [28/02/2026]”

“Final Report” means the comprehensive report prepared by the Contractor at the conclusion of the Research for the Authority as described in Clause 14. For the avoidance of doubt this definition does not extend to any Arising Know How, Research Data, Foreground IP or other Intellectual Property described therein.

“Final Report Summary” means a summary of the findings of the Research as described in Clause 14.]

“Public Health Emergency” means any situation that the Chief Medical Officer for England deems necessary to activate urgent public health research in response to taking account of the World Health Organisation health emergencies list as amended from time to time.

“Public Health Emergency Services” means any work specified by the Authority that directly relates to responding to a Public Health Emergency.

“Serious Misconduct” means any of the following: Transactional Sex: abuse or harassment of any form (including but not limited to bullying, Sexual Exploitation, Sexual Abuse, Sexual Harassment, psychological abuse and physical violence); non-consensual or unlawful sexual activity; or, any other form of violence, exploitation or abuse.

“Sexual Abuse” means the actual or threatened physical intrusion of a sexual nature, whether by force or under unequal or coercive conditions and includes but is not limited to all sexual activity with someone under the age of 18, regardless of local age of majority or consent.

“Sexual Exploitation” means any actual or attempted abuse of a position of vulnerability, differential power, or trust, for sexual purposes and includes but is not limited to profiting monetarily, socially, or politically from sexual exploitation of another.

“Sexual Harassment” means any unwelcome sexual advances (including but not limited to sexual advances made without touching) and includes but is not limited to requests for sexual favours, or other verbal or physical behaviour of a sexual

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nature, which may create a hostile or offensive environment.

[**“Third Party IP”** shall be added to read: “means any Intellectual Property which is owned or controlled by any party (including any collaborator) other than the Contractor and over which the Contractor has or can reasonably expect to secure a formal agreement or licence to use in the performance of the Research or to perform the provisions of this Contract.]

“Transactional Sex” includes, but is not limited to, the exchange of money, employment, goods, or services for sex and such reference to sex shall include sexual favours or any form of humiliating, degrading or exploitative behaviour.

- **Section 2, Condition 3 shall be amended by adding:**

3.14. In the event of a Public Health Emergency, the Authority may:

3.14.1. direct the Contractor to suspend or cease any part of its current activity insofar as it is reasonably possible having regard to:

- (a) the interests of individual study participants; and
- (b) any binding commitments that cannot be delayed, deferred or cancelled; and

3.14.2. direct the Contractor to perform Public Health Emergency Services in replacement of any part of the Research.

3.15. The Contractor shall comply with relevant policies and related strategies in place or introduced by the Authority and that are notified to the Contractor including but not limited to:

3.15.1. Policies listed at Section 7 as may be updated by the Authority from time to time; and

3.15.2. Policies relating to informatics and open access.

- **Section 2, Condition 6 shall be amended by adding:**

6.5. The Authority may vary the Contract at any time by giving written notice to the Contractor:

6.5.1. in the event of a Public Health Emergency;

6.5.2. to the extent that any policy listed in Section 7 or that has been notified to the Contractor in accordance with Clause 3.15 is revised or updated.

- **Section 2, Conditions 8.2 and 8.3 shall be deleted and replaced with:**

8.2 The Contractor must notify the Authority’s Representative of any intention to issue a press release (whether it will be issued by the Contractor or any other party) at least two (2) business days prior to any press release issued by it or on its behalf, directly related to the Research or Foreground IP, Arising Know How or Research Data or of

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matters arising from such Research. The Contractor shall send one draft copy of the proposed press release to the Authority's Representative at least two (2) business days before the date intended for release. For the avoidance of doubt this obligation shall continue in full force and effect following expiry of the Research.

8.3. In the event that the Contractor fails to comply with Clause 8.1, or 8.2 and subject to Clause 20.3, the Authority may, in addition to any remedy afforded under the NIHR Research Outputs and Publications Guidance:

8.2.1. suspend or reduce its payment of amounts due under the payment schedule in SECTION 4 of the Contract; and/or

8.2.2. require repayment of all or part of the funding provided under this Contract.

The Contractor further acknowledges that a breach of Clause 8.1 or Clause 8.2 by the Contractor may be taken into account by the Authority when considering future applications for NIHR funding from the Contractor.

- **Section 2, Conditions 8.5, 8.6, 8.7 and 8.8 shall be deleted and replaced with:**

8.5. Subject to the provisions of Clause 9 (Confidentiality) and Clause 14.1 (content of Reports) and notwithstanding the provisions of Clause 16 (Intellectual Property Rights) and), 17 (Exploitation of Intellectual Property):

8.5.1. the Contractor hereby grants to the Authority the irrevocable, perpetual, non-exclusive, sub-licensable, royalty-free licence to publish the Reports at any time either: (a) under CC-BY licence terms or equivalent; or, (b) pursuant to the Open Government Licence v3.0 or equivalent as appropriate;

8.5.2. the Authority may publish the Reports in accordance with the licence granted under this Clause 8.5 for any purpose including: in accordance with the Authority's position on Open Access to research (as updated from time to time); and, any entry in a register of research findings or an individual issue of or a review article in a monograph series prepared on the Authority's behalf. Where it is reasonably possible, the timing of any such publication will be subject to consultation with the Contractor and will take account of the Authority's position and policies on publication in force from time to time, publication timetables in other peer-reviewed journals and the need to make research findings publicly available as soon as practicable;

8.5.3. For the avoidance of doubt, the licence granted under this Clause 8.5 relates to the copyright in the Report and does not extend to the Intellectual Property described therein.

8.6. The Contractor undertakes to obtain any and all appropriate third party licences and permissions necessary to grant the licences under Clause 8.5 where such rights are the property of a person or organisation other than the Contractor. The Contractor shall provide the Authority with all appropriate details including proof that the

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Contractor has obtained such licences and/or permissions and/or assignment and details of the acknowledgements required by owners of the rights licensed or assigned.

- 8.7. The Authority is entitled to publish the whole or any part of the Final Report or the Final Report Summary or a summary of any of them. If the Contractor wishes the Authority to delay such publication, it must submit a request in writing to the Authority's Representative giving reasons for the requested delay which shall be considered in accordance with the NIHR's Information for Authors' Dual Publication Guidance and Embargo Policy as amended from time-to-time.

- **Section 2, Conditions 8.9 and 8.10 shall be deleted and replaced with:**

8.9 The Contractor shall ensure that the outcome of the Research is prepared for publication in a suitable peer-reviewed journal and shall ensure that:

- 8.9.1. prior to publication, appropriate measures (including but not limited to applying for registration of Intellectual Property and ensuring that the proposed publication does not contain any commercially sensitive information) are in place to ensure that Foreground IP, Arising Know How and Research Data are each adequately protected;
- 8.9.2. it, and any other publication, including patent applications, of or resulting from research carried out under this Contract shall acknowledge the Authority's financial support and carry a disclaimer relevant to the programme as set out in the Authority's NIHR research outputs and publications guidance as amended from time to time.

- **Section 2, Condition 38 shall be deleted and replaced with:**

- 38.1. The Contractor shall, and shall procure that each Collaborator and Sub-contractor(s) shall, take all reasonable steps to comply with the "NIHR Policy on Preventing Harm in Research" and "NIHR Safeguarding Guidance" as published from time-to-time including but not limited to:
- 38.1.1. taking all reasonable steps to prevent actual, attempted or threatened Serious Misconduct by its employees or any other persons engaged and controlled by it to perform any activities under this Contract; and
 - 38.1.2. adopting robust safeguarding and whistleblowing policies and procedures to promote and support the reporting and investigation of suspected misconduct, illegal acts, Serious Misconduct or failures to investigate any such matter;
 - 38.1.3. developing, implementing and maintaining a safeguarding plan throughout the term (including monitoring);
 - 38.1.4. providing regular training to Key Staff, Collaborators and any other persons engaged and controlled by it to perform any activities under this Contract;
 - 38.1.5. taking all reasonable steps to ensure that the Key Staff and others employed,

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- retained or contracted by the Contractor to perform any activities under this Contract do not engage in sexual activity with any individual under the age of eighteen (18), even if the age of majority or age of consent is lower in the relevant territory. Furthermore, the Contractor shall take all reasonable endeavours to ensure that the Key Staff and others employed, retained or contracted by the Contractor to perform any activities under this Contract do not engage in Transactional Sex; and
- 38.1.6. taking any other Good Industry Practice measures (including any innovative solutions).
- 38.2. The Contractor shall:
- 38.2.1. maintain detailed records of any allegation of Serious Misconduct relating to the performance of any activities under this Contract;
- 38.2.2. report any complaints or concerns promptly regarding possible Serious Misconduct relating to the performance of any activities under this Contract to the relevant authorities (including local law enforcement or other agencies), the Authority's Representative and the Authority at ODAsafeguardingconcerns@dhsc.gov.uk; and
- 38.2.3. take all reasonable steps to ensure that individuals are enabled to report concerns and complaints of any Serious Misconduct through supportive, confidential and accountable mechanisms.
- 38.3. The Contractor shall take all reasonable steps to investigate allegations or suspicions of Serious Misconduct and take appropriate corrective action, including disciplinary action, against individuals, and will keep the Authority and relevant authorities informed of the progress of the investigations as appropriate, such investigations and actions to be reported to the Authority as soon as is reasonably practicable.
- 38.4. The Contractor shall not employ or engage any person or organisation whose previous record or conduct that is known to the Contractor, or reasonably ought to be known by a diligent Contractor having undertaken appropriate checks, indicates that they represent an increased and unacceptable risk of committing Serious Misconduct.
- 38.5. The Contractor shall, and shall use reasonable efforts to ensure that each Collaborator, Sub-Contractor or any other person involved in the performance of any activities under this Contract shall:
- 38.5.1. Comply with all Applicable Laws relating to:
- (a) Safeguarding and the protection of children and vulnerable adults including but not limited to the vetting of personnel working closely with children and vulnerable adults in accordance with the UK Safeguarding Vulnerable Groups Act 2006 (as amended) or comparable provisions in the territory in which the Contractor is based or the activities under this Contract are carried out; and
 - (b) Bullying and harassment.
- 38.6. Where the Authority reasonably believes that there is an increased risk to safeguarding, the

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Contractor shall comply with any reasonable request by the Authority for additional vetting to be undertaken or processes or measures to be put in place.

38.7. Within six (6) months of the date of this Contract, and annually thereafter, certify to the Authority in writing signed by an officer of the Contractor, compliance with this Clause 38 by the Contractor and all Collaborators and other persons performing activities under this Contract. The Contractor shall provide such supporting evidence of compliance as the Authority may reasonably request.

38.8. In the event that the Contractor fails to comply with any of this Clause 38, the Authority reserves the right to:

38.8.1. deem this to be a material breach and terminate this Contract in accordance with Clause 21.3 herein; and/or

38.8.2. suspend or reduce its payment of amounts due under the payment schedule in Section 4 of this Contract; and/or

38.8.3. require repayment of all or part of the funding provided under this Contract; and/or

38.8.4. take a breach of this Clause 38 by the Contractor into account when considering future applications for funding from the Contractor.

38.9. For the avoidance of doubt, the Contractor shall:

38.9.1. obtain written confirmation from any Collaborator, and any subcontractor retained by the Contractor or by any Collaborator, subcontractors that they accept the standards set out in this Clause; and

38.9.2. ensure that all subcontracts reflect the terms and requirements of this Clause in each case, prior to the Collaborator or other subcontractor performing any activity under this Contract.

- Section 3 **shall be replaced** by the revised Section 3 below
- Section 4 **shall be replaced** by the revised Section 4 below
- A new Section 7 **shall be added** as set out below

2. Words and expressions in this Variation shall have the meanings given to them in the Contract.

3. The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

SIGNED:

For: The [Redacted]
By:..... [Redacted]

Full Name:..... [Redacted]

Position:..... Senior Manager: Research Policy

Date:..... 13-Nov-2023 | 3:09 PM GMT

SIGNED:

For: T [Redacted]
By:..... [Redacted]

Full Name:..... [Redacted]

Position:..... Senior Research Funding Associate

Date:..... 13-Nov-2023 | 10:51 AM GMT

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SECTION 3: RESEARCH

Project Synopsis

African children with developmental disorders (including intellectual disability and autism) and their caregivers experience severe challenges. Due to community stigma and parental blame, children with developmental disorders are often locked in their home. Most children with developmental disorders in sub-Saharan Africa do not attend school and receive no formal support. Affected families often live in poverty as care responsibilities mean caregivers are unable to work. Caregivers report severe stress and social isolation; many caregivers report mental health problems, including suicidal thoughts.

This project aims to improve the wellbeing and mental health of children with developmental disorders and their caregivers, by developing and evaluating a model of care with and for local communities. First, we propose to train persons who know the local child community well (e.g. health workers or teachers) to help them identify children with developmental disorders and to raise community awareness. Identified children will be referred to the new Caregivers Skills Training (CST) programme developed by the World Health Organization (WHO). Second, we will test how well the CST works and whether the programme provides value for money. The CST teaches caregivers strategies to support their child's development and reduce challenging behaviours. The programme also addresses caregiver wellbeing, and because the programme is delivered in groups it helps parents escape social isolation. Third, we will involve local leaders, teachers, health workers and parents of children with developmental disorders in the development of the care model so that barriers to accessing health and education services can be overcome, and to promote community-based support and inclusion.

Our team has previously adapted and pilot-tested the CST programme in Ethiopia and Kenya, showing that the training can be delivered by non-specialist facilitators and is liked by caregivers. In this new project we propose to conduct the first large scale evaluation of the impact of the programme across both countries, including rural and urban settings. In addition to comparing families who participated in the programme with families who have not yet taken part, we will collect information from each setting to explore context-specific issues.

Local communities and stakeholders have been involved in all our previous studies in Kenya and Ethiopia. This project will benefit from their ongoing input to make sure the care model proposed meets the local needs and fits in within the existing health and education systems.

Supported by academics from King's College London, University of Oxford and WHO, the research will be conducted by Ethiopian and Kenyan researchers, clinicians and students. The findings will be shared with local stakeholders, including policy makers, local and national governments as well as with WHO and international partners to inform future implementation of care models for children with developmental disorders across the world.

IATI description and objectives

A UK and low- and middle-income country (LMIC) research partnership to improve the wellbeing and mental health of children with developmental disorders and their caregivers, by developing and evaluating a model of care with and for local Kenyan and Ethiopian communities.

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Many African children with developmental disorders (including intellectual disability and autism) and their caregivers experience severe challenges. Due to community stigma and parental blame, children with developmental disorders are often locked in their home. Many of these children do not attend school and receive no formal support. Affected families often live in poverty as care responsibilities mean caregivers are unable to work. Caregivers also report severe stress and social isolation, and associated mental health problems, including suicidal thoughts. This project seeks to improve the mental health of Kenyan and Ethiopian children and their caregivers through developing care-giver training packages, raising awareness and promoting community based support and inclusion. The objectives and intended impacts are as follows:-

- (1) Working directly with communities to understand and break down barriers to accessing health and education services.
- (2) Awareness raising and education activities to promote community based support and inclusion.
- (3) Training local caregivers to identify children with development disorders and facilitate referrals to a new “Caregivers Skills Training” (CST) package developed by the World Health Organization. The package teaches parents / caregivers strategies to support child development, and since it is a group delivered activity it also helps alleviate the social isolation experienced by the caregiver.
- (4) Evaluate how well the CST package works in improving the mental health and wellbeing of children with developmental disorders and their caregivers, and whether the package offers value for money.

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SECTION 4: FINANCIAL ARRANGEMENTS

PAYMENT SCHEDULE

It is intended that the indicated amounts will be paid by the Authority to the Contractor within 30 days of the dates listed.

Date	Amount (£)
1. 30 September 2020	98,014.00
2. 01 December 2020	294,043.00
3. 15 March 2021	294,043.00
Financial Year 2020/2021 sub-total	686,100.00
4. 30 June 2021	0.00
5. 30 September 2021	82,718.00
6. 24 November 2021	306,201.00
7. 31 March 2022	0.00
Financial Year 2021/2022 sub-total	388,919.00
8. 30 June 2022	0.00
9. 30 September 2022	143,070.00
10. 23 November 2022	376,531.00
11. 31 March 2023	155,342.00
Financial Year 2022/2023 sub-total	674,943.00
12. 30 June 2023	70,487.00
13. 30 September 2023	226,987.00
14. 21 November 2023	226,987.00
15. 31 March 2024	476,184.00
Financial Year 2023/2024 sub-total	1,000,645.00
16. 30 June 2024	307,411.00
17. 30 September 2024	307,411.00
18. 21 November 2024	307,411.00
19. 31 March 2025	307,411.00
Financial Year 2024/2025 sub-total	1,229,644.00
20. 30 June 2025	101,322.00
21. 30 September 2025	101,322.00
22. 20 November 2025	101,322.00
23. 31 March 2026	101,322.00
Financial Year 2025/2026 sub-total	405,288.00
TOTAL	4,385,539.00

An appropriate inflation uplift may be added by the Authority to these payments.

Upon conclusion of the Research, the Contractor shall submit a Final Statement of Expenditure to the Authority, accounting for all costs properly incurred under the Contract. Only upon receipt of this document, and with agreement from the Authority's Representative, will the final payment of any outstanding funds be made.

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SECTION 7: POLICIES

NIHR policy on preventing harm in research

<https://www.nihr.ac.uk/documents/nihr-policy-on-preventing-harm-in-research/27567>

NIHR Safeguarding Guidance

<https://www.nihr.ac.uk/documents/nihr-safeguarding-guidance/25744>

NIHR Policy on Bullying and Harassment

<https://www.nihr.ac.uk/documents/nihr-policy-on-bullying-and-harassment/24041>

NIHR Privacy Policy

<https://www.nihr.ac.uk/documents/nihr-privacy-policy/12242>

Research Outputs and Publications Guidance

<https://www.nihr.ac.uk/documents/nihr-research-outputs-and-publications-guidance/12250>

UK Policy Framework for Health and Social Care Research

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

Dual Publication Guidance

<https://www.journalslibrary.nihr.ac.uk/information-for-authors/our-policies/nihr-dual-publication-policy.htm>

Embargo Policy:

<https://www.journalslibrary.nihr.ac.uk/information-for-authors/our-policies/embargo.htm>

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Standard NHS Accounting Policy and Guidance

<https://www.england.nhs.uk/financial-accounting-and-reporting/financial-reporting/>

NIHR Open Access Publication Policy:

<https://www.nihr.ac.uk/documents/nihr-open-access-policy-for-publications-submitted-on-or-after-1-june-2022/28999>

NIHR Open Access Publication Policy Guidance:

<https://www.nihr.ac.uk/documents/nihr-open-access-policy-guidance-articles-submitted-on-or-after-1-june-2022/30212>

NIHR Open Access Publications Funding Guidance:

<https://www.nihr.ac.uk/documents/nihr-open-access-publications-funding-guidance/30210>

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