University of Exeter Clinical Trials Unit
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Memorandum of Understanding between

< Practice Name, Org ID >

and

ERICA trial research team
Clinical Trials Unit, University of Exeter Medical School

The above parties agree to work in full co-operation and undertake to adhere to the following conditions when carrying out the research project entitled:

A pragmatic cluster randomised controlled trial assessing the clinical effectiveness and cost-effectiveness of electronic risk-assessment for cancer for patients in general practice (ERICA)

DEFINITIONS

Chief Investigator – The Chief Investigator is the person with overall responsibility for the conduct of the entire trial and for all personnel involved in the trial. The Chief Investigator for ERICA is **Professor William Hamilton** who is an employee of the College of Medicine and Health, University of Exeter.

Practice Research Champion (aka Research Champion) – The practice Research Champion is the person at the participant general practice who will act as key contact regarding the running of the trial at his/her practice.

The Research Champion named below is employed by **Practice**. The Research Champion is responsible for acting as key contact for and overseeing the above study at **Practice.**

_____Name_____

REC - Research Ethics Committee. The REC for ERICA is **London – City and East: ref 19/LO/0615**.

The Parties – The ERICA trial research team and **Practice.**

OBLIGATIONS OF THE PARTIES

The parties shall conduct the trial in accordance with:

(i) the protocol.

(ii) the terms and conditions of the approval of **London – City and East Research Ethics Committee: REC ref 19/LO/0615**

Activities and responsibilities of the participant general practice

Practice preparation and initiation

The Research Champion will ensure that a meeting has taken place and that all GPs in the participating general practice have been informed of the trial and its aims.

The Research Champion will ensure that at least half of the practice's GPs agree to participate in the research trial. This means that, should the practice be allocated to the intervention arm of the trial, at least half of all practice GPs have in principle agreed to make use of the eRAT software throughout the two year duration of the trial.

If the practice is allocated to the control arm of the trial, the Research Champion will endeavour to ensure that they and other GPs in the practice do not acquire eRATs or use other forms of electronic clinical decision support for cancer during the two year period of the trial.

If electronic clinical decision support are already available in the practice but are inactive, the Research Champion will endeavour to ensure that they remain so throughout the two year duration of the trial.

Allocation to Intervention arm

Training

If the participant general practice is allocated to the intervention arm, the Research Champion will complete the on-line training, which comprises watching short tutorial videos on how to download the eRATs, how to use the eRATS, and Frequently Asked Questions (FAQs).

The Research Champion will complete the short quiz assessing understanding of the videos.

The Research Champion will ensure that all GPs have undertaken the required training in use of the eRAT software: this may include a presentation of the tutorial videos and discussion of the FAQs at a practice meeting. The practice champion may alternatively encourage all GPs to individually watch the tutorial videos and take the brief quiz.

Electronic Risk Assessment Tools (eRATs)

Should the participant general practice be randomly allocated to the intervention arm of the ERICA trial, the Research Champion will ensure that the eRAT software has been installed in the practice system.

If the participant general practice is allocated to the control arm of the trial, the practice will provide usual care. The Research Champion will ensure that the practice does not activate any eRAT software or alternative cancer risk tool during the two year trial period.

Participation in nested studies

During the trial period, the research team will approach a small subset of practices, in both arms of the trial, to seek engagement with one or more optional smaller studies. These nested studies will further explore the use of eRATs and the patients identified through them.

The Research Champion will have responsibility for informing their practice of the requirements for these studies and ascertaining whether colleagues wish their practice to participate. Participation in any nested studies will be entirely voluntary.

If the participant general practice agrees to take part in a nested study, they will have responsibility for running reports to support the identification of patients to approach for participation. Practices in the intervention arm will need to 'switch on' the eRAT reporting mechanism for a period of two weeks. This will provide a list of patients for whom the eRATs produced a prompt for possible cancer.

Practices in the control arm will help identify patients to approach by identifying patients with a 2% risk of cancer or greater (i.e. those for whom an eRAT would have produced a prompt) through a database search (search terms to be provided by the research team).

Pending necessary ethical approval, the results of the reports/database search will be securely sent to the research team who will identify patients to invite to participate.

The practice will send the invitation letter and materials to participants identified by the research team (letter written by and materials provided by research team).

Notification of operational changes

The Research Champion should inform the ERICA trial team as soon as is practicable if:

i) the practice is to merge with another practice, separate or close
ii) the practice is to change its principal clinical software system

Research governance

The Research Champion will ensure that the research activities (which relate primarily to nested studies) are conducted in accordance with International Conference for Harmonisation of Good Clinical Practice (ICH GCP) requirements and that any data transfer or management is compliant with the General Data Protection Regulations 2018 and the Data Protect Act 2018.

Fidelity monitoring

Intervention practices: The Research Champion will complete a short interim questionnaire within the first 12 months of the start of the trial to report on training activities and usage or eRATs.

The Research Champion will complete a brief 'exit' questionnaire at the end of the trial reporting on eRAT usage since the interim report.

Control practices: the Research Champion will complete a short interim questionnaire within the first 12 months of the start of the trial to report on whether there has been any contamination due to use of electronic risk assessment for cancer.

The Research Champion will complete a brief 'exit' questionnaire at the end of the trial reporting on any potential contamination due to use of electronic risk assessment for cancer since the interim report.

Activities and responsibilities of the Chief Investigator (or his delegated research team)

Practice preparation and initiation

The Chief Investigator or his delegate will support the practice in the preparation and initiation of the study. They will provide access to recruitment materials including information sheets and summary videos.

A trial 'help line' will be available during core working hours, 9am – 5pm.

Allocation to Intervention arm

A delegate of the Chief Investigator will, via the Research Champion, inform the practice of their allocation outcome. Practices will be informed within a reasonably time period following initial screening and receipt of the completed practice agreement whether they have been allocated to the intervention arm or the control arm of the trial.

Training

The Chief Investigator or his delegate will make available the suite of tutorial videos.

A trial 'help line' will be available during core working hours, 9am – 5pm to support any training questions. The Trial team will arrange additional training support if required.

Electronic Risk Assessment Tools (eRATs)

The Chief Investigator or his delegate will support the Practice Champion with the acquisition and download of the eRATs.

If any installation problems arise, the research team will arrange on behalf of the practice for the eRAT developer's IT team to support the practice.

Participation in nested studies

The Chief Investigator or his delegate will provide practices with the necessary guidance on how to identify potential participants for the nested studies.

Guidance on how to 'switch on' the eRAT reporting mechanism will be provided.

The database search terms will be provided.

The research team will ensure they have the appropriate security measures in place to process and hold any pseudo-anonymised contained within the reports.

The research team will provide all necessary materials required for invitation of participants in the nested study.

Good Clinical Practice

The Chief Investigator or his delegate will ensure that the research activities (which relate primarily to nested studies) are conducted in accordance with International Conference for Harmonisation of Good Clinical Practice (ICH GCP) requirements and that any data transfer or management is compliant with the General Data Protection Regulations 2018 and the Data Protect Act 2018.

LIABILITY AND INDEMNITY

Each party is responsible for the acts and omissions of its own staff, including its staff on honorary contracts and others engaged by it, including the Chief Investigator and the Practice Research Champion.

Non-NHS employees must hold an honorary contract with the relevant NHS Trust to cover their liabilities and prospective liabilities under this agreement in this trial.

CONFIDENTIALITY

Confidential Information

Each party shall use its best endeavours to ensure that only those persons directly concerned with the carrying out of this trial have access to personal data or confidential information and each party agrees to ensure that they do not knowingly permit the use of, or disclose, such data to any other person other than:

- a person duly authorised by the party to whom the confidential information relates
- to the extent permitted by this agreement
- to the extent require by law

All information related to the ERICA trial shall be considered confidential.

FINANCIAL ARRANGEMENTS

In consideration of the provision of the Services by the participant practice, payments will be made to the participant practice from the ERICA trial research team and also from the **region** Local Clinical Research Network (LCRN) in accordance with the payment schedule set out below. ERICA trial research team will endeavour to make payments to practices in a timely way following completion of the participation in the study.

Intervention Practices
Research costs: £470.55
Service Support Costs – these are as agreed with the general practice's LCRN

Control practices
Research costs: £204.40
Service Support Costs – these are as agreed with the general practice's LCRN

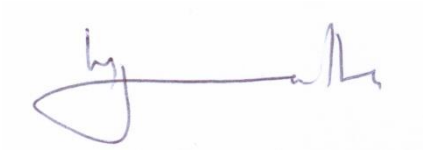
EARLY TERMINATION

A party may terminate this agreement on notice to the other parties with immediate effect if it is reasonably of the opinion that the trial should cease in the interests of the health of the patient participants involved in this trial.

The participant general practice has the right to notify the REC **London – City and East Research Ethics Committee: ref 19/LO/0615** of any concerns regarding the overall conduct of this research, without prior communication with the ERICA trial research team.

SIGNATURES

Signed by Professor William Hamilton (Chief Investigator)



Signed by: NAME (Research Champion) on behalf of Practice

Organisation ID: …… …….. IT System: EMIS/SystmOne

Signature…….. Date……..

Name (block capitals)……..

Position……..

Signed by: NAME (Lead GP) on behalf of Practice

Signature…….. Date……..

Name (block capitals)……..

Position……..