

North East - Newcastle & North Tyneside 2 Research Ethics Committee

NHS BT Blood Donor Centre
Holland Drive
Newcastle upon Tyne
Tyne and Wear
NE2 4NQ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

02 June 2020

Professor Isabel Oliver
Interim Director of National Infection Service, Co-Director of Health Protection Research Unit in Behavioural Science and Evaluation and Director of Research, Translation and Innovation.
Public Health England
National Infection Service
Field Epidemiology South West
Bristol
BS1 6EG

Dear Professor Oliver

Study title: Evaluating Detection of SARS-CoV-2 antibodies using home test kits (EDSAB-HOME)
REC reference: 20/NE/0166
Protocol number: NR0198
IRAS project ID: 284980

Thank you for your letter responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/>

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/>

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/>.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|-------------|
| Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [HTA biobank approval] | V1 | 29 May 2020 |
| Copies of advertisement materials for research participants [Recruitment Poster] | V01.02 | 09 May 2020 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsorship in Principle] | | |
| IRAS Application Form [IRAS_Form_22052020] | | 22 May 2020 |
| Letters of invitation to participant [Advertising Email] | V02.02 | 10 May 2020 |
| Letters of invitation to participant [Advertising Email] | V02.03 | 30 May 2020 |
| Other [HRA Response to Reviewers] | V1 | 30 May 2020 |
| Participant consent form [Consent form] | V01.02 | 30 May 2020 |
| Participant information sheet (PIS) [Participant Information Sheet] | V4.03 | 28 May 2020 |

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|--|--------|-------------|
| Research protocol or project proposal [Project Protocol] | V04.03 | 30 May 2020 |
| Summary CV for Chief Investigator (CI) [PI CV] | | 21 May 2020 |
| Validated questionnaire [Questionnaire] | | |

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

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| IRAS project ID: 284980 Please quote this number on all correspondence |
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With the Committee's best wishes for the success of this project.

Yours sincerely



pp
Professor Andy Hall
Chair

Email: newcastlenorthtyneside2.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Elizabeth Coates