

21 July 2016

Prof Andrew Pollard
Professor of Paediatric Infection and Immunity / Director Oxford Vaccine Group
University of Oxford
Oxford Vaccine Group, CCVTM, Churchill Hospital, Old Road
Oxford
OX3 7LE

Dear Prof Pollard

Study title: Investigating the role of typhoid toxin in the pathogenesis of enteric fever: A double-blinded, randomised, outpatient human challenge study.
REC reference: 16/SC/0358
Protocol number: OVG 2016/03
IRAS project ID: 205635

Thank you for your letter of 15th July. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 14 July 2016

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
IRAS Checklist XML [Checklist_15072016]		15 July 2016
Other [TYGER REC Cover Letter (15-Jul-2016)]		15 July 2016
Participant information sheet (PIS) [TYGER Study Information Booklet ICF (V2.0 14-Jul-2016) tracked]	2.0	14 July 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [TYGER Social Media Advert (V1.0 13-Jun-2016)]	1.0	13 June 2016
Copies of advertisement materials for research participants [TYGER Compliment slip for Oxford Brookes (V1.0 13-Jun-2016)]	1.0	13 June 2016
Copies of advertisement materials for research participants [TYGER Website Recruitment Text Long (V1.0 13-Jun-2016)]	1.0	13 June 2016
Copies of advertisement materials for research participants [TYGER	1.0	13 June 2016

Recruitment closed text (V1.0 13-Jun-2016)]		
Copies of advertisement materials for research participants [TYGER Recruitment compliment slip (V1.0 13-Jun-2016)]	1.0	13 June 2016
Copies of advertisement materials for research participants [TYGER Recruitment ongoing text (V1.0 13-Jun-2016)]	1.0	13 June 2016
Copies of advertisement materials for research participants [TYGER Recruitment text long (V1.0 13-Jun-2016)]	1.0	13 June 2016
Copies of advertisement materials for research participants [TYGER Recruitment text short (V1.0 13-Jun-2016)]	1.0	13 June 2016
Copies of advertisement materials for research participants [TYGER Recruitment text Staff Gateway (V1.0 13-Jun-2016)]	1.0	13 June 2016
Covering letter on headed paper [TYGER REC Cover Letter (14-Jun-2016)]		14 June 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical Trials Confirmation of cover letter (30-Jul-2015)]		30 July 2015
GP/consultant information sheets or letters [TYGER GP Case Treatment Commencement Letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP Case Treatment Completed (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP Challenge Notification Letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP eligibility letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP enrolment notification letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP Non-case treatment commencement letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP Non-case treatment completed (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP Notification of study start (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP Screening Exclusion letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP stool clearance notification letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER GP Withdrawal Letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER Practice manager compliment slip (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER PHE Case treatment commencement letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER PHE information letter - challenged (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER PHE information letter - Update (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER PHE Non-case treatment commencement letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER PHE stool clearance (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER Employer Occ Health letter - clearance (V1.0 13-Jun-2016)]	1.0	13 June 2016
GP/consultant information sheets or letters [TYGER Employer Occ	1.0	13 June 2016

Health letter - vulnerable (V1.0 13-Jun-2016)]		
IRAS Application Form [IRAS_Form_22062016]		22 June 2016
IRAS Checklist XML [Checklist_16062016]		16 June 2016
IRAS Checklist XML [Checklist_15072016]		15 July 2016
Letter from sponsor [160614 A POLLARD PID 12067 signed sponsor letter (14-Jun-2016)]		14 June 2016
Letters of invitation to participant [TYGER Participant Invitation letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
Letters of invitation to participant [TYGER Screening invitation text (V1.0 13-Jun-2016)]	1.0	13 June 2016
Letters of invitation to participant [TYGER Ultrasound letter template (V1.0 13-Jun-2016)]	1.0	13 June 2016
Letters of invitation to participant [TYGER Further Information Text (V1.0 13-Jun-2016)]	1.0	13 June 2016
Non-validated questionnaire [TYGER Website Screening Questions (V1.0 13-Jun-2016)]	1.0	13 June 2016
Non-validated questionnaire [TYGER Questionnaire text (V1.0 13-Jun-2016)]	1.0	13 June 2016
Non-validated questionnaire [TYGER Consent Quiz (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [How To HandWash Poster (01-May-2009)]		01 May 2009
Other [TYGER 24 hour contact letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Contact Details Check (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER D0 Reminder Email (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER D-7 Reminder Email (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Day 0 Visit Reminder (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER End of Study Letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Enteric Precautions (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Map (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Participant Contact Screening Invitation Letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Stool specimen collection procedure (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Reminder messages options (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [TYGER Results letter (V1.0 13-Jun-2016)]	1.0	13 June 2016
Other [University of Oxford insurance policy schedule & certificate 2015 2016 (01-Aug-2015)]		01 August 2015
Other [TYGER REC Cover Letter (15-Jul-2016)]		15 July 2016
Participant consent form [TYGER Study Card (V1.0 13-Jun-2016)]	1.0	13 June 2016
Participant consent form [TYGER Medical photography and film consent form (V1.0 13-Jun-2016)]	1.0	13 June 2016
Participant consent form [TYGER Continued Informed Consent Form (V1.0 13-Jun-2016)]	1.0	13 June 2016
Participant information sheet (PIS) [TYGER Study Information Booklet ICF (V2.0 14-Jul-2016) tracked]	2.0	14 July 2016
Research protocol or project proposal [TYGER Protocol (V1.0 13-Jun-2016)]	1.0	13 June 2016
Sample diary card/patient card [TYGER Study Card (V1.0	1.0	13 June 2016

13-Jun-2016)]		
Sample diary card/patient card [TYGER Medic Alert Card (V1.0 13-Jun-2016)]	1.0	13 June 2016
Sample diary card/patient card [TYGER Visit Schedule Confirmation (V1.0 13-Jun-2016)]	1.0	13 June 2016
Summary CV for Chief Investigator (CI) [Prof Andrew Pollard CV - Chief Investigator (24-Apr-2015)]		24 April 2015
Summary CV for student [M Gibani Research CV (13-Oct-2015)]		13 October 2015
Summary CV for supervisor (student research) [Prof Andrew Pollard CV - Chief Investigator (24-Apr-2015)]		24 April 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/SC/0358	Please quote this number on all correspondence
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Yours sincerely



Natasha Bridgeman
REC Manager

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Copy to: *Ms Heather House, Oxford University Hospitals NHS Trust*