

(..... indicates redacted information)

Page 1 is clear
Page 2 answers to numbered questions retyped for clarity
Page 3 answers to numbered questions retyped for clarity

4. Please see amended COREC application form (A10).
5. Volunteers are always told of the reason if they are rejected after screening for any study at PAREXEL. If during the screening process any evidence is found of disease that may require further investigation or treatment the volunteer is always advised (in private and in confidence) by a member of the medical staff. In the majority of cases the volunteer is happy for a letter to be written to his/her GP and then takes over the management of the case. If the volunteer does not wish this contact, his/her wishes are respected. Any medical event occurring after dosing is followed up and managed where necessary by consultants on a private basis paid for by PAREXEL and ultimately the sponsor.

This full medical screen is valued by volunteers and regarded by many as a major benefit from participation. We have in the past detected several new cases of diabetes, hypercholesterolaemia, hypertension, leukaemia, hepatitis and HIV (among others) and in this way feel that PAREXEL makes a positive contribution to society.

6. Please see amended COREC application form.
7. Researchers would consult..... at the.....
8. provided the explanation at the meeting. This was not standard and did not think this was necessary for this study. The Committee asked if the monoclonal antibody could cause a flare up of TB. responded that there was a slight possibility that it could. added that the majority of volunteers tend to be South African travellers and that PAREXEL could add to the exclusion criteria that if they have been exposed to active TB in close family members then they may not take part. The Committee noted this point.
9. The breakdown of the payment fee of £2,000 is as follows: Screening visit 1: £75, screening visit 2: £50. In house stay 0700 day1 to day 3 10am £150 per day = £450. Out patient visits (13 in total) including post study visit includes ECG blood sampling, physical exam (lymph node palpitation: £75 per visit **NB covers all travel costs = £975**, inconvenience payment for long study follow up period £75 per week for 6 weeks = £450.
10. Please see amended Patient Information Sheet.
11. Please see attached reports and CVs