National Patient Safety Agency

National Research Ethics Service

**ANNUAL PROGRESS REPORT TO MAIN RESEARCH ETHICS COMMITTEE**
**(For all studies except clinical trials of investigational medicinal products)**

*To be completed in typescript and submitted to the main REC by the Chief Investigator. For questions with Yes/No options please indicate answer in bold type.*

## 1. Details of Chief Investigator

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|---|---|
| Name: | Professor Christopher EM Griffiths |
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## 2. Details of study

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|---|---|
| Full title of study: | British Association of Dermatologists Biological Interventions Register |
| Name of main REC: | North West England |
| REC reference number: | 07/MRE08/9 |
| Date of favourable ethical opinion: | 14/11/2007 |
| Sponsor: | University of Manchester |

## 3. Commencement and termination dates

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|---|---|
| Has the study started? | *Yes* |
| If yes, what was the actual start date? | 16/08/2007 |
| If no, what are the reasons for the study not commencing?<br>What is the expected start date? | |
| Has the study finished? | *No*<br>*If yes, complete and submit "Declaration of end of study" form, available at www.corec.org.uk* |

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| If no, what is the expected completion date?<br><br>*If you expect the study to overrun the planned completion date this should be notified to the main REC for information.* | |
| If you do not expect the study to be completed, give reason(s) | |

**4. Site information**

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| Is this a study requiring site-specific assessment (SSA) and ethical approval of each site and local Principal Investigator?<br><br>If yes, how many UK research sites have been recruited<br><br>Has the Site Specific Information Form (SSIF)* been submitted to the local REC for each local Principal Investigator?<br><br>**or Part C or Annex D of the former MREC application form if submitted prior to 1 March 2004* | *Yes*<br><br>*Proposed in original application: 200*<br>*Actual number recruited to date:107*<br><br>*Yes up until change in April 2009 now Trust R & D only* |
| Is this study "SSA-exempt"? *<br><br>If yes, how many UK sites are currently involved in facilitating this research?<br><br>** or was previously designated as a "no local investigator" or "no local researcher" study* | *No*<br><br>*76 currently have local R & D approval* |
| Do you plan to increase the total number of UK sites proposed for the study?<br><br>If yes, how many sites do you plan to recruit?<br><br>*In the case of studies requiring SSA, all sites must be approved by the main REC as part of the favourable opinion.* | *No* |

**5. Recruitment of participants**

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|---|---|
| *Number of participants recruited: | *4,000 per biologic drug and 4,000 controls*<br>*854 biologic cohort and 207 controls* |
| *Number of participants completing trial: | *Proposed in original application: 4,000 per biologic drug and 4,000 controls*<br>*Actual number completed to date: Five year follow-up so none as yet* |
| *Number of withdrawals due to:<br>(a) lack of efficacy<br>(b) adverse events<br>(c) self-withdrawal<br>(d) non-compliance<br>Total number of withdrawals: | <br>N/A<br>N/A<br>3<br>N/A<br>none |

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| Have there been any serious difficulties in recruiting participants? | *Falling behind recruitment targets* |
| If Yes, give details: | Some delays due to the local sites approval process and also insufficient local infrastructure to support recruitment of patients. It is anticipated that the recent acceptance of BADBIR onto the UKCRN Study Portfolio will facilitate recruitment |
| Do you plan to increase the planned recruitment of participants into the study?<br><br>*Any increase in planned recruitment should be notified to the main REC as a substantial amendment for ethical review.* | *No* |

** In the case of international trials, please provide separate figures for UK and non-UK participants.*

## 6. Safety of participants

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|---|---|
| *Have there been any* related *and* unexpected *Serious Adverse Events (SAEs) in this study?* | *No* |
| Have these SAEs been notified to the Committee?<br><br>*If no, please submit details with this report and give reasons for late notification.* | *Not applicable* |
| Have any concerns arisen about the safety of participants in this study?<br>*If yes, give details and say how the concerns have been addressed.* | *No* |

## 7. Amendments

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|---|---|
| Have any substantial amendments been made to the trial during the year? | *Yes* |
| If yes, please give the date and amendment number for each substantial amendment made. | Amendment 4 (revised) 05/11/09 |

## 8. Other issues

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|---|---|
| Are there any other developments in the study that you wish to report to the Committee?<br><br>Are there any ethical issues on which further advice is required? | *No*<br><br>*No*<br><br>*If yes to either, please attach separate statement with details.* |

## 9. Declaration

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| Signature of Chief Investigator: | |
| Print name: | |
| Date: | |