What is the purpose of the study?

The purpose of the research study is to assess whether new biologic or immunomodulator treatments (such as Benepali, Cosentyx, Taltz, Humira, Stelara) used in the treatment of psoriasis have a greater risk of serious side effects or long term health problems than established treatments such as ciclosporin, methotrexate and PUVA. As psoriasis is a long term condition requiring lifelong treatment it is important to establish how these drugs compare to the other treatment options available in terms of safety when used long-term (for a period of many years).

The biologic drugs and immunomodulators have been carefully tested in clinical trials before being approved for use. However, as clinical trials are run for a relatively short period of time (on average up to a year), have limited numbers of participants compared with those which will be ultimately treated with the drug and may exclude patients with additional diseases (co-morbidities), it may mean that the picture might not be complete in terms of long-term use.

In contrast, BADBIR will collect information (data) on patients treated with biologics and immunomodulators attending regular dermatology clinics over a long period. Patients who have co-morbidities will also be included therefore the results are likely to be more representative of the “real world” use of these drugs.

The study is designed such that a large group of patients being treated with biologics and immunomodulators are compared to an equally large group of patients treated with established therapies (conventional). The study team will observe how often side effects occur in all three groups of patients.

Rates of untoward medical events will be compared between the groups and the results will then be used to provide patients with a better picture of any increased risk of the new therapies.

The study is being funded by the British Association of Dermatologists (BAD), a society of dermatologists aiming to give the best patient care to individuals with skin diseases. The BAD receive funds from a number of pharmaceutical companies who manufacture the biologic therapiess to support this study.

Why have I been chosen and what your contribution means?

You have been chosen to participate as you have been started on a biologic, immunomodulator therapy or one of the established treatments for psoriasis. By participating, you will help us build up the amount of data available for analysis.
Do I have to take part?

You do not have to take part. If you do decide to take part, you can keep this sheet and will be asked to sign a consent form. Your participation will not interfere with the standard of care you receive. By signing the consent form, you would be confirming your willingness to take part.

What are the risks of taking part?

The study will run alongside your routine clinical care at the hospital; it will not influence this process at all. Therefore, there are no foreseeable medical risks associated with participating in this study.

What are the benefits of taking part?

Although there is no clinical benefit gained by participation in the study, the information obtained from this study may result in changes in future treatment of patients with psoriasis and will help patients and doctors make more informed treatment decisions.

Will the research influence the treatment I receive?

The research does not alter the treatment you receive. Your specialist will start and stop treatments as determined by your clinical condition.

What will happen if I take part?

Your participation will involve the following:

(i) Agreement to complete the questionnaires and other survey forms about your health. You should note that some of the questions may be of a sensitive or personal nature. You are not compelled to answer all of the questions.

(ii) Agreement with your specialist to provide information of relevance to this study from your hospital medical records to the BADBIR study team at the University of Manchester. This will be information regarding the treatments you are receiving, assessments of your skin, details of any illnesses you have and body measurements including height and weight. Copies of the data collection questionnaires are available on the BADBIR website http://www.badbir.org/.

(iii) Agreement for your date of birth and NHS number (and also in Scotland your name) to be shared with national providers of healthcare data (including NHS Digital in England) for the purpose of linking to information held about any hospital admissions you have had, details if you are registered as having cancer or in the event of your death. This will enable these organisations to provide the BADBIR study team with information about these events that may not have been reported via the dermatology team. This will result in a more complete picture of your health experiences and will enable the study to provide more accurate results on the long-term safety of the biologic and immunomodulating drugs. There are different data providers in each area of the UK. A complete and up to date list of the national data providers linked with BADBIR is summarised at the end of this information sheet in appendix 1. This information can also be viewed at www.badbir.org. Please speak to your dermatologist or clinic nurse if you need assistance accessing this website link.
At this stage we do not know how long we will want to collect this information from you and about you. It is likely to be for at least five years. Research data will be stored for 15 years following study end and subsequently securely destroyed.

### How will my data be processed?

Information will be updated at least annually by the dermatology team and collected via a computer system. Data will be sent using a secure network.

### How will your data be kept secure and confidential?

The University of Manchester is responsible for the purpose and manner in which your data are processed. They will ensure that your data are processed fairly and lawfully in accordance with the Data Protection Act 1998. Your personal data will not be shared with other parties beyond the data controllers, providers of healthcare data and approved data processors (any person or organisation that processes your data on behalf of the data controllers) where appropriate contractual agreements are in place with the data controllers.

BADBIR at The University of Manchester has a number of rigorous procedures in place to protect your personal data and keep it secure as follows:

- All BADBIR staff will sign annual confidentiality agreements as part of their employment contracts
- Computer security to block unauthorised access to the computers/systems that hold personal information. Personal identifiable data will be held in an encrypted format at the University of Manchester. Encryption allows information to be stored in an unreadable manner making it accessible to the research team (named by the study's Chief Investigator) only with the use of a University of Manchester username and password. This information is held for the sole purpose of linking to information already stored by national providers of healthcare data e.g. NHS Digital in England. Your identifiable data will not be shared with any other parties beyond this.
- If your data is provided as part of a larger dataset to researchers outside of the BADBIR team, information that could identify you will not be provided

### Involvement of Third Parties

A number of pharmaceutical companies who manufacture these biologic and immunomodulating therapies will have access to some study data (not personally identifiable e.g. name postcode, NHS/CHI number) so that they can update records with the international regulatory government agencies responsible for drug safety e.g. US Food and Drug Administration (FDA). Therefore, there is a small possibility that medical information may be sent outside the European Union for analysis. By signing the consent form you are agreeing to this transfer.

Your hospital medical records will state that you are in this Register. By signing the consent form, you are allowing the dermatology team to permit these records to be viewed by the BADBIR team at the University of Manchester or possibly agencies such as the MHRA or authorised members of the Ethics Committee or Hospital. This is for the purpose of checking that the data is correct or checking that the study is being carried out properly.
How do I withdraw from the study if I want to?

You can withdraw at any time from the study after giving your signed consent by contacting your local dermatology research team. You do not need to give a reason and your medical care or legal rights will not be affected.

BADBIR will be most valuable if few people withdraw from it, so potential participants are asked to discuss any concerns they might have with their dermatology team or the BADBIR team. The desired level of withdrawal can be selected from the following three options:

Option 1: No further questionnaires:
You would not answer any further questionnaires about your health, but BADBIR would continue to receive information from the team at the hospital and via the linkage with the national providers of healthcare data.

Option 2: No further participant or hospital contact:
No further information would be received from the hospital but information would still be collected through the linkage with the national providers of healthcare data.

Option 3: Complete withdrawal:
No further information would be collected from the hospital and BADBIR would contact the national providers of healthcare data to remove the link to your record so no further information was received on your health status from the time you withdrew.

Who has reviewed the study?

Before any research study can go ahead, it has to be checked by a research ethics committee and the Health Research Authority (HRA) to make sure that the research is fair and transparent. The study has been reviewed and approved by the North West 7 REC GM Central Research Ethics Committee (Ref: 07/MRE08/9).

Who is organising the study?

The study is being co-ordinated and sponsored by the University of Manchester and the lead researchers, Professor Christopher Griffiths or Dr Kathy McElhone can be contacted if you have any concerns about any aspect of this study (Tel: 0161 306 1894). If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Research Practice Governance Co-ordinator at The University of Manchester on 0161 275 5436.

Where can you see the study results?

Any study results or published reports using the data will be anonymised and it will not be possible to identify you.

Study results will be published in medical journals and a summary version will be available at http://www.badbir.org/. These will also be available to your consultant (Tel: ####### Fax: ####### Email: ####### Postal Address in Letterhead) whom you should contact for further information.
Appendix 1 - Summary of Linkage Organisations

A summary of the national providers of healthcare data BADBIR links to is outlined below. In England, Wales and Northern Ireland, the BADBIR study will provide your NHS/HCN number alongside your date of birth to link to your record with the data provider. In Scotland, your name and date of birth will be used alongside your CHI number and date of birth. The data returned to the study from every provider will be pseudonymised using your study ID.

This information is accurate at the time this consent form was approved for use. An up-to-date summary will always be available at www.badbir.org. Please speak to your dermatologist or clinic nurse if you need assistance accessing this website link:

### England:

<table>
<thead>
<tr>
<th>Linkage Type</th>
<th>Data Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Registration Data</td>
<td>NHS Digital on behalf of Public Health England (PHE)</td>
</tr>
<tr>
<td>(Malignancy)</td>
<td></td>
</tr>
<tr>
<td>Civil Registration Data</td>
<td>Sourced from civil registration data and provided by NHS Digital on behalf of the Office for National Statistics</td>
</tr>
<tr>
<td>(Mortality)</td>
<td></td>
</tr>
<tr>
<td>Inpatient Admission</td>
<td>NHS Digital (Hospital Episode Statistics)</td>
</tr>
</tbody>
</table>

### Northern Ireland:

<table>
<thead>
<tr>
<th>Linkage Type</th>
<th>Data Provider</th>
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<tbody>
<tr>
<td>Malignancy</td>
<td>Northern Ireland Cancer Registry (NICR)</td>
</tr>
<tr>
<td>Mortality</td>
<td>Health and Social Care Business Services Organisation (BSO)</td>
</tr>
</tbody>
</table>

### Scotland:

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<tr>
<th>Linkage Type</th>
<th>Data Provider</th>
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</thead>
<tbody>
<tr>
<td>Malignancy</td>
<td>National Health Service Central Register (NHSCR)</td>
</tr>
<tr>
<td>Mortality</td>
<td>National Health Service Central Register (NHSCR)</td>
</tr>
<tr>
<td>Inpatient Admission</td>
<td>National Services Scotland (NSS)</td>
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</table>

### Wales:

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<tr>
<th>Linkage Type</th>
<th>Data Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Registration Data</td>
<td>NHS Digital on behalf of Public Health Wales</td>
</tr>
<tr>
<td>Civil Registration Data</td>
<td>Sourced from civil registration data and provided by NHS Digital on behalf of the Office for National Statistics</td>
</tr>
<tr>
<td>Inpatient Admission</td>
<td>NHS Wales Informatics Service (Patient Episode Database for Wales)</td>
</tr>
</tbody>
</table>