UNIVERSITY OF BIRMINGHAM CLINICAL TRIALS QUESTIONNAIRE

Cover is automatic and a Questionnaire is NOT needed if the research is within the UK and limited to the following activities:

i. Questionnaires, interviews, psychological activity including CBT;
ii. Venepuncture (withdrawal of blood);
iii. Muscle biopsy;
iv. Measurements or monitoring of physiological processes including scanning;
v. Collections of body secretions by non invasive methods;
vi. Intake of foods or nutrients or variation of diet (other than administration of drugs).

In addition, for clinical trials where the University is not taking on (co-) Sponsorship and the University staff member(s) only take(s) on peripheral activities as listed in the document 'Clinical Trials Activities and Insurance cover', no further referral is required.

Refer all other Research involving human participants to the **Clinical Trial Research Insurance Administrator with the following information to arrange cover**.

1. **Title of Research:**

2. **Name(s) of sponsoring organisations:**

3. **Does the research involve -**

a. investigating or participating in methods of contraception? Yes/No
b. assisting with or altering the process of conception? Yes/No
c. the use of drugs? Yes/No
d. the use of surgery (other than biopsy)? Yes/No
e. genetic engineering? Yes/No
f. subjects under 5 years of age? (other than activities i-vi above) Yes/No
g. subjects known to be pregnant? (other than activities i-vi above) Yes/No
h. pharmaceutical product/appliance designed or manufactured by the institution? Yes/No
i. work outside of the United Kingdom? Yes/No

If 'Yes' to any of the questions, 3a-i above, and where applicable (i.e. where this questionnaire is completed for follow-on trials), provide details of SUSARs on a separate sheet (fatal or life threatening events).

Please also provide: the **Protocol**, the **Patient Information Sheet** and **Informed Consent Forms**, and completed **page 2 of this Questionnaire**.

Name: **Date:**

*NB: for the purpose of indemnity/cover **Clinical Trial** means: an investigation or series of investigations conducted on any person for a **Medicinal Purpose**.

Medicinal Purpose means:

a) treating or preventing disease or diagnosing disease or
b) ascertaining the existence degree of or extent of a physiological condition or
c) assisting with or altering in any way the process of conception or
d) investigating or participating in methods of contraception or
e) inducing anaesthesia or
f) otherwise preventing or interfering with the normal operation of a physiological function

Employee Activity Form

1. Has NHS Indemnity been provided? YES NO

2. Will Medical Practitioners be covered by the MDU or other body? YES NO

3. This section aims to identify those staff involved, their employment contract and the extent of their involvement in the Research.

Name the employer and if an NHS honorary contract is held :
(In some cases it may be more appropriate to refer to a group of persons rather than individuals.)
Principal Investigator:

Name	Employer	NHS Honorary contract?	Yes/No

Activities undertaken:

Others:

Name	Employer	NHS Honorary contract?	Yes/No

4. Please provide any further relevant information here:

Please copy this form if necessary and continue to list all individuals or groups of staff involved with the Research

