

Research involving Human Participants Questionnaire (Clinical Trial*)

Cover is automatic and a Questionnaire is NOT needed if the research is within the UK & 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 variation of diet (other than administration of drugs &/or nutrients).

Refer all other Research involving human participants to the Insurance Officer with the following information to arrange cover (which may incur a charge). Prompt submission of the Questionnaire is recommended, and for an early indication of terms, please submit the research proposal even in the absence of full information.

1. Institution:

Department:

2. Title of Research:

3. Name(s) of Sponsoring organisation:

4. Does the research involve:

a) investigating or participating in methods of contraception?	<input type="checkbox"/>
b) assisting with or altering the process of conception?	<input type="checkbox"/>
c) the use of drugs &/or nutrients?	<input type="checkbox"/>
d) the use of surgery (other than biopsy)?	<input type="checkbox"/>
e) genetic engineering?	<input type="checkbox"/>
f) subjects under 5 years of age? (other than activities i-vi above)	<input type="checkbox"/>
g) subjects known to be pregnant? (other than activities i-vi above)	<input type="checkbox"/>
h) pharmaceutical product/appliance designed or manufactured by the institution?	<input type="checkbox"/>
i) work outside of the United Kingdom?	<input type="checkbox"/>
j) E-Cigarettes or vapes (electronic cigarettes)	<input type="checkbox"/>

If 'Yes' to any of the questions, 4a)-i) above, and if this is a follow-on Phase, provide details of any SUSARs on a separate sheet (fatal or life-threatening events).

Please also provide: the Protocol, the Patient Information & Patient Consent forms, and completed page 3 of this Questionnaire.

Name:

Date (DD/MM/YYYY):

*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?
2. Will Medical Practitioners be covered by the MDU or other body?
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 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?

Activities undertaken:

Others

Name:

Employer:

NHS Honorary contract?

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.