

**CANCER RESEARCH UK POLICY ON CLINICAL TRIALS IN RESPONSE TO THE
IMPLEMENTATION OF THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS)
REGULATIONS 2004**

Background

- A In response to the coming into force of the Medicines for Human Use (Clinical Trials) Regulations 2004 (hereinafter the Clinical Trial Regulations), Cancer Research UK (CR-UK) reviewed and assessed its policies and procedures in relation to its involvement in the carrying out of clinical trials with medicinal products and decided to adopt the following principles.
- B This policy outlines the major principles that CR-UK will follow in deciding upon the extent of its involvement in and/or in undertaking any particular role in respect of, the initiation, management, funding or any other aspect of clinical trials. It is recognised that certain unusual or extraordinary circumstances may necessitate some departure from these principles. The policy therefore also sets out the basis upon which decisions will be reached by CR-UK in such exceptional or extraordinary circumstances.
- C This policy and these principles are based upon the existing policy of CR-UK that CR-UK and its employees, representatives, or holders of honorary or unremunerated positions with CR-UK acting for and on behalf of CR-UK (“CR-UK Representatives”) shall be reminded that they may not whilst acting in the course of their employment with CR-UK, or whilst acting on behalf of CR-UK, carry out any medical, surgical or clinical activity directly with a patient (including administering any products or treatment, recommending any treatment, or giving any diagnosis or medical advice.) In the event that any CR-UK Representatives, including any authorised medical professional, wishes to carry out such activities, it is their responsibility to ensure that they are acting in their professional capacity or under the terms of their employment or honorary employment with another party (e.g. the NHS) and that appropriate insurance, indemnity and liability arrangements are in place from that other party in respect of their activity.
- D CR-UK shall have no responsibility or liability for the action of the recipients of CR-UK grants. No recipients shall have any authority to act on behalf of or in the name of CR-UK unless they are CR-UK employees and act within their contract of employment.
- E The principles contained herein are also intended to extend to clinical trials which do not involve a medicinal product, and are therefore not covered by the Clinical Trial Regulations.

Principles

CR-UK and all CR-UK Representatives and any others for whose activities CR-UK is legally responsible shall adopt the following principles and procedures in respect of clinical trials from May 1st 2004.

1. CR-UK shall not be a Sponsor under the terms of the Clinical Trial Regulations for any clinical trial unless the initiation and management of the trial is conducted by the CR-UK Centre for Drug Development (CDD)
2. The CDD shall maintain its capability to carry out all aspects of the initiation, management and funding of clinical trials according to the procedures already in place and shall evidence this capability in order to ensure that it can comply with the standards required of the Charity pursuant to UK and EU law and binding regulations.

It is anticipated that each clinical trial for which CR-UK accepts responsibility as a Sponsor shall have undergone rigorous and expert analysis in the following aspects:

- the scientific and research case for such a trial;
- the details of the trial protocol;
- the ethical aspects of the trial;
- the risks and controls relating to the conduct of the trial;
- the contractual, legal and insurance framework that underlies the Charity's involvement in the trial

There is a streamlined process to ensure that such analysis is carried out and the results are clearly minuted.

The CDD procedures will also ensure that all regulatory and ethical approvals are in place before the trial can begin, that the clinical trials supplies are made, labelled and released according to Good Manufacturing Practice (GMP) requirements, that the trial is undertaken and run to Good Clinical Practice (GCP) requirements and that the prevailing pharmacovigilance requirements are followed.

3. CR-UK and CR-UK Representatives shall not act as a Sponsor in respect of any clinical trial not entirely managed by the CDD. All parties connected with trials which CR-UK is financing, or is otherwise involved with, shall be made aware of the position of CR-UK.
4. CR-UK shall at all times be aware of the identity of the Sponsor and of the Chief Investigator of each clinical trial approved for funding by Clinical Research Committee (CRC) and shall ensure that advice, assistance and support can be provided by CR-UK to such trials without the risk of incurring liability.
5. All CR-UK employees who are engaged in research or clinical trials activities shall be notified by CR-UK that they are not authorised to accept any of the obligations of a Sponsor or to submit any application to carry out a clinical trial to the Medicines and Healthcare Products Regulatory Agency (MHRA) or to any other national equivalent of the MHRA, in the name of CR-UK, except in the following circumstances:-

Where the carrying out of such activity or the submission of such application has been approved by either the New Agents Committee, CRC or the Scientific Executive Board (SEB) and where the management of such trial is to be conducted by the CDD or by an equivalent organisation with appropriate legal and regulatory clearance approved by the SEB and the Risk Management Department has been notified and has confirmed in writing the availability of insurance for such trial.

6. The supply of investigational and medicinal products, (as defined in the Clinical Trials Regulations) by any individual or function within CR-UK or by any person or institution acting or purporting to act for or on behalf of CR-UK is forbidden except in the following circumstances;
 - (i) the facility producing the investigational medicinal product must have a current and valid Investigational Medicinal Product Manufacturing License from the MHRA for the production of the product in question.
 - (ii) such products are supplied for use within trials that have been approved by any one of the New Agents Committee, CRC or the SEB;
 - (iii) IMP has been released by a suitable CR-UK appointed/designated QP.
7. Any:
 - activity in relation to clinical trials that is to be carried out outside of the United Kingdom
 - export from the United Kingdom by CR-UK of investigational medicinal products or other treatments,or
 - proposed activities in respect of clinical trials for which the Sponsor or Principal Investigator is located outside of the UK,

shall only proceed where the following procedure is followed:-

One of the following shall have been notified in writing and shall have confirmed their approval in writing:

- For early phase trial of novel investigational medicinal products – the Director of Drug Development,
- For late phase trials - the Director or Head of Clinical Research

In addition the Risk Management Department must be notified in writing and must confirm the availability of insurance in respect of this activity before it can proceed.

8. The procurement, for use within the EU, of investigational medicinal products manufactured outside of the EU will require an Authorising Qualified Person Certificate. Where this procurement is in relation to early phase trials of novel investigational medicinal products, the Director of Drug Development shall be notified.

9. Where CR-UK may act as a Sponsor or accept any delegations as a Sponsor, the expert panel, Protocol and Safety Review Board (PSRB) may be asked to advise upon any issues arising out of proposed trials and any other matter that the Executive Board, the SEB or the Director of Drug Development, the Director or Head of Clinical Research believe helpful in order to permit the Charity or the New Agents Committee or CRC to decide upon the appropriate course of action to adopt in respect of any clinical trial. The PSRB shall not however be constituted as a private ethics committee and neither the PSRB nor any individual member shall be authorised to act on behalf of CR-UK and shall not be relied upon by CR-UK in any capacity other than that of an expert adviser.

10. It is the policy of CR-UK to ensure that all CR-UK Representatives and any others acting for and on behalf of and with the authority of CR-UK do not become personally liable for their conduct in relation to any clinical trial activities that CR-UK has authorised in accordance with these principles. CR-UK Representatives and others shall not be expected to accept or to risk any personal liability, save for breach of their professional obligations. The Charity will endeavour to provide advice and reassurance on this aspect of these principles as and when requested by employees and others. Where available at reasonable cost, appropriate insurance will be put in place by the Charity, for all directors, officers, employees, trustees and others connected with and acting on behalf of the Charity in connection with clinical trials.

11. CR-UK shall not offer any indemnity or guarantee to any person in respect of their involvement in a clinical trial, including any patient involved in such trial, without having first obtained the written approval of the Director of the Centre for Drug Development or the Director of Clinical Research and Strategic Partnerships and (in both cases) the Director of Legal Services and the Risk Manager, who shall seek the advice of the CIRB if appropriate. However, CR-UK shall make available itself or via others a compensation scheme for patients participating in CR-UK sponsored clinical trials that is based on the ABPI no-fault compensation scheme.

Cancer Research UK will keep this policy under review.

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