Conflicts of Interest Policy
For
Investigators participating in CR-UK sponsored (DDO) clinical trials

1 Background

It is essential that there is public trust in the integrity of clinical trials sponsored by CR-UK and the results of such trials are robust and unbiased. The charity must ensure fair balance, independence, objectivity and scientific rigour in all of its clinical trials activities. CR-UK takes many precautions to ensure that this occurs, such as, peer review of project proposals and trial protocols; however, as part of this endeavour it also needs to avoid and/or manage real and perceived conflicts of interest.

Most of our investigators receive funding from CR-UK as all or part of their research funding, and in some cases, their personal salary comes from the charity. While this benefit will be declared, this is not perceived to be a ‘conflict’ as CR-UK is a non-commercial, charitable funding organisation. Unlike some commercial organisations, the Charity does not pay per-patient investigator fees which reduces another possible perceived conflict.

More obvious conflicts of interest could be perceived, if an investigator has certain relationships with a company or organisation that could lead them to benefit financially or commercially from the outcome of a trial. Similarly, if new agents arise from CR-UK funded or other academic research, investigators may be inventors and, hence, potentially benefit from milestone and royalty payments.

The following policy is intended to guide CR-UK’s management of potential conflicts of investigators on CR-UK-sponsored trials, primarily through disclosure of all financial or other interests that might be construed as resulting in actual, potential or apparent conflicts. It also recognises, however, that certain financial relationships are inconsistent with responsible/good clinical research practices and that investigators in positions of authority in a given clinical trial should not have ownership or hold other interests that could undermine confidence in the integrity of the trial or jeopardise the safety of trial participants.

It is assumed that many investigators on CR-UK (DDO) trials aim to present their data at ASCO meetings. ASCO has a conflicts of interest policy and so CR-UK has ensured that its policy (described here) is consistent with ASCO’s.

Certain regulatory authorities, e.g. the US Food and Drug Administration (FDA), also have concerns about conflicts of interests. For data to be acceptable for regulatory submissions to the FDA, the investigators from the study must comply with US Code of Federal Regulations Title 21, Part 54 (21 CFR 54). CR-UK wishes to ensure that in the event of identifying a successful drug, the data from its trials are acceptable to the FDA. Whilst responsibility for compliance lies with the investigators, CR-UK has ensured that its policy (described here) is consistent with 21 CFR 54.
Nothing in this policy should be viewed as the Charity making assumptions of impropriety where there are financial or other relationships of a commercial nature. Instead it should be taken as recognition of the many factors that can influence or be perceived to influence judgements about clinical research data.

2 Policy

2.1 Declaration of interests
CR-UK requires all clinical investigators in any CR-UK sponsored (DDO) trial to make written declarations of their relevant interests including those of their immediate family, spouses or partners and children. Declarations should include all financial interests and any other relationships with any company that owns or has licensed or has rights to licence the product or novel treatment being evaluated by CR-UK in clinical trial. This should include but not be limited to:

1. Employment, directorship or leadership position – any full or part time employment or service as an officer or board member
2. Advisory role – Consultant or advisory arrangements (paid or unpaid)
3. Stock ownership or options – any ownership interest or options in a start-up company, the stock of which is not publicly traded, or in a publicly traded company (unless in a diversified fund not controlled by the individual)
4. Any other direct or indirect financial interest (e.g. via CRT and Rewards to Inventors)
5. Honoraria – payments for specific speeches, seminar presentations or appearances
6. Research Funding
7. Expert testimony
8. Other remuneration – trips, gifts, in-kind payments etc.

Investigators must declare to CR-UK of any change in circumstances during the development of, or in the course of a trial that would mean that they or their spouse, partner or children would receive or hold any of the declarable items described here.

2.2 Restrictions
CR-UK recognises that investigators receive honoraria and payments for services such as membership of scientific advisory boards, giving talks or attending meetings and may also have other commercial relationships with companies. CR-UK also believes that the role of investigator is so pivotal that specific restrictions should apply in order to promote confidence in the clinical trial process and CR-UK’s trials in particular.

The charity has therefore decided that during the course of a clinical trial, i.e. from the opening of the study to publication of a substantial analysis of the trial results as a peer reviewed abstract and presentation or in a peer reviewed journal, the Principal clinical investigators at each site in its trials (and their spouse, partner or children) should not receive or hold any of the following:

1. Stock, stock options or other equity interest in any company that owns or has an express or implied license, or an option to a license to the product or novel treatment being evaluated in clinical trials by CR-UK (except when invested in a diversified fund not controlled by the covered individual).
2. Royalties or licensing fees (prospective or realised) from the product or novel treatment under investigation, unless the investigator is the inventor of a unique technology or treatment being evaluated in the CR-UK clinical trial.
3. Position as an officer, member of the board of directors or an employee of any company that owns or has an express or implied license or an option to a license to the product or novel treatment being evaluated by CR-UK in a clinical trial.
(The investigator can be on the Scientific Advisory Board as long as honoraria or payments for such service are declared and total no more than £5,000 per year (net of expenses), as described in point 5 below.)

4. More than £5,000 per year (net of expenses) in payments and honoraria from any company that owns or has an express or implied license or an option to a license to the product or novel treatment being evaluated by CR-UK in a clinical trial.

If, on review of an investigator’s Declaration of Interests or at any point in the conduct of a study, (1) CR-UK believes the investigator to be or have become conflicted, even if the reason for the conflict is not explicitly covered by this section 2.2 of the Policy or (2) the investigator fails to make the declaration according to the terms of this policy, CR-UK reserves the right to refuse or remove them as Principal Investigator on a trial.

3  Practicalities

3.1  Declarations of interest
CR-UK will ask all investigators to declare the financial and other relationships (as described in 2.1 above) that they and their family have with any company that owns or has licensed the product or novel treatment being evaluated by CR-UK in a clinical trial.
This will be done:
- At the outset when considering the investigator as a participant in the trial
- At the start of the trial (if there is more than 6 months between the initial declaration and the start of the trial).
- Annually thereafter for the duration of the trial

3.2  Restrictions
Any investigator with arrangements, relationships or payments, as described in section 2.2 above will not be accepted as an investigator in a CR-UK study of a drug to which payments or patents relate or which is owned or licensed by the company in question. Whilst CR-UK will request declarations on an annual basis, the participating investigators must inform CR-UK of any change of circumstance during the course of a clinical trial that would mean they or their spouse, partner or children would receive or hold any of the items listed in 2.2 above. At that time they or their family member will be asked divest themselves of the interests or they will be asked to stand down as an investigator in the trial.

3.3  Review of Interests
Before agreeing that an Investigator can participate in a CR-UK sponsored trial and during the course of the trial, the Investigator’s Declaration of Interests will be reviewed by the Drug Development Office and may be referred to the Scientific Executive Board (SEB). Even if a declared interest does not fall under section 2.2 of this policy, the SEB will decide whether, from CR-UK’s perspective, it causes sufficient conflict for the individual not to be an investigator on the particular study unless they divest themselves of the interest in question.
3.4 Record of interests
A record of investigators' interests will be kept on file and will be reviewed by CR-UK on an annual basis.

The information will be held in accordance with the Data Protection legislation.

Cancer Research UK will keep this policy under review.