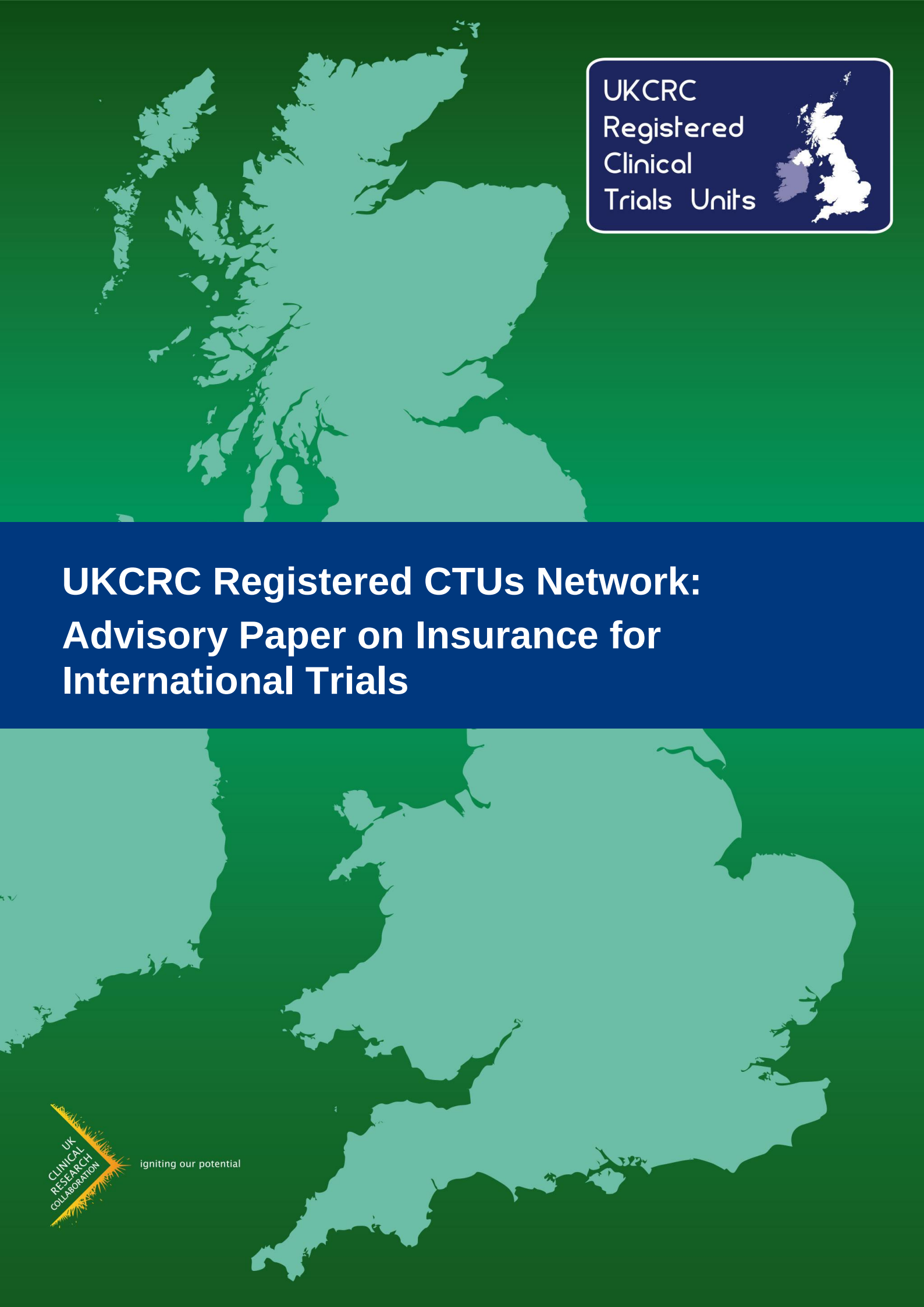

UKCRC Registered CTUs Network: Advisory Paper on Insurance for International Trials

UK CLINICAL RESEARCH COLLABORATION

igniting our potential

UKCRC Registered CTUs Network

Insurance for International Clinical Trials and Studies

This paper is intended to offer some advice to Sponsor institutions responsible for securing insurance in relation to international clinical trials. It lists some key questions that will need to be answered, and then offers a brief discussion of some considerations *to bear in mind. The information provided in this document is to be used as a guide only.*

Key Questions to ask about insurance:

- To what extent, if at all, does the protocol depart from that which is standard clinical care in that country?
- Has our institution recent experience of collaborating with sites in the country? If so, establish any 'lessons learnt'.
- What is the regulation/legislation which specifies insurance requirements in that country?
- Is there a legal requirement for a certain level or type of insurance provision in that country?
- Is there specific information which must be included in an insurance contract?
- Are the insurance requirements specified by the Ethics committee different to the regulations in that country?
- Does insurance have to be taken out in the specific country?
- Will your institutions insurance cover extend coverage to the specific country? If so, is there a limit to the cover provided?

Background

There are a various ways which those sponsoring or leading clinical research from the UK can consider, assess and accommodate the insurance and indemnity requirements associated with extending that research beyond the UK. Typically, these can include:-

- *An annual Clinical Trials policy of insurance* which operates 'world-wide' subject to the law and practical application in the country being considered permitting this.
- *Another form of legal liability insurance/insurances*, which provide for the participation in clinical trials and studies and which can apply outside the UK, where such is permitted in the country in question.
- *Individual clinical trials insurance policies issued specifically for a trial and for sites in the country/ies* into which the trial is being extended. These are ordinarily required where there is no annual clinical trials insurance provision in place, or in situations where the legislation and practical implementation in the country in question requires that such a local provision – so-called 'locally admitted' – be arranged.
- While it is for institutions to consider their preferred solution, doubtless mindful of their present and intended clinical research portfolio, and general risk appetite and profile, areas of common consideration are likely to include the expectations of considering ethics committees, and the extent to which there may be a wish that some or all clinical research beyond the UK have provisions which , as far as possible, can be ring-fenced from the insurance/indemnity arrangements in place for the core, UK-centred clinical research programmes.

Local arrangements

The requirements of some countries require that insurance, in a highly-prescribed form, be arranged. Depending upon local legislation, this may require contract terms in any site agreement to reflect the local requirements – i.e. in some cases it may influence the ability to introduce contract terms holding a negligent collaborator responsible, with local requirements requiring this as a Sponsor responsibility without any ability to seek a financial recovery from any negligent site. Any insurance which needs to be arranged by the Sponsor – and which may be required to include other covers, such as Medical Malpractice in relation to the research – will come at some considerable cost, necessitating that an appropriate budget source be identified at an early opportunity.

Key Personnel to be involved at an early stage

It is extremely helpful to identify those at the partner institutions responsible for: insurance/ indemnification; research governance, and research contracts (depending on the country and institution, very different terms may need to be applied). The Chief Investigator, with involvement of the overseas site's PI, can be helpful in introducing the site's contracts administration and research governance personnel.

Determining likely country-specific insurance/indemnity requirements

Generally, there is no single approach which will work for all cases, although there are several main avenues of enquiry which may individually, or in combination provide an answer in most cases:-

- *An international insurance guide*, such as that provided by Axco Insurance Information Services: http://www.axcoinfo.com/. This is often available through the insurance intermediary. However, while a most-useful resource, there are occasions particularly with countries where there may be limited number of enquiries, when the information appears to have been compiled reactively as a consequence of contributors' feedback, and not necessarily entirely proactively following examination of enacted or proposed legislation and its practical implementation. This is essentially a perception from some practical experience.
- *Seeking practical guidance from the collaborating institution*, which ought to be able to take a view based upon their requirements from cases where they sponsor or otherwise lead clinical trials. However, while beneficial in gathering information of likely practical requirements, it will be important to ensure that any offered opinion incorporates the views of those responsible at the organisation for agreeing contractual and related agreements, as well as those of the intended site Principal Investigator. The status of the site should also be considered: they may enjoy central funding or other support which includes a degree of government provided indemnification (which, subject to the terms and conditions connected with these, might well be acceptable in place of insurance).
- *Obtaining in-country legal opinion from lawyers authorised to practise in that country.* This may be a preferred route for particularly complex or challenging collaborations, or where the research being considered is anticipated to lead to other clinical research in that country. However, while this ought to be most-authoritative, this can be a complex area and one where it is unlikely that there will be many legal firms specialising.

- *The preferred form of insurance/indemnity has been considered and selected; what else may require consideration*? An essential component of any insurance/indemnity arrangement is to ensure that it is supported through contract terms which appropriately protect the insured, and by extension the insurer. For a UK HEI, this will align with charitable status to protect financial assets for the primary stated purpose of academic teaching and research, while for the insurer an ability to seek a recovery, or exercise rights of subrogation against a negligent third party will ordinarily be a condition of the insurance. The site agreement's terms and conditions will therefore be important. While a sensible starting point is to endeavour to introduce terms which mirror the position in the UK, this will not always be possible in practice. An example would be where the collaborating institutions' country has enacted legislation which, for example, requires that all participating parties – i.e. the Sponsor, local sites and any collaborating CROs – are protected by the same single provision, and where an ability to recover between the distinct legal parties which make-up this collaboration is prohibited.

  While information found in Axco, and other similar providers is helpful here, detailed and mostly authoritative guidance can be gleaned through additional sources of information, such as the European Observatory on Health Systems and Policies' *Health Systems in Transition – HiT* series: http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits. Taken from the WHO's site, these reports *"examine the specific approach of the organisation, financing and delivery of health services in a particular country and implementation of health, and health care policies."*

  HiT reports include sections relating to the organisational structure, financing and regulation, and planning within a reported country's healthcare system. They can therefore be particularly useful in enabling a better-understanding of the foundations of that country's healthcare systems, and the legislative and administrative structures which support this. In turn this can help to inform any insurance-based, or other indemnity provision (e.g. government-supported indemnity provision) and how this should be introduced contractually.