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| **NHS LOTHIAN CO-SPONSORSHIP CRITERIA** **(CTIMP STUDIES)** |
| NHS Lothian (Lothian Health Board) typically co-sponsors CTIMP studies with the University of Edinburgh. There may sometimes be situations where this is not possible and thus NHS Lothian may wish to co-sponsor these studies with another institution or legal entity. In order to determine whether co-sponsorship with another body is feasible and acceptable there are a number of criteria that NHS Lothian would wish to investigate before agreeing to co-sponsor CTIMP studies with the body in question.Each of the below requirements will be reviewed by the listed individual before a decision whether to co-sponsor with the proposed organisation will be finalised. Various methods including document review and interviews will be undertaken as part of this review process. A decision to enter into co-sponsorship will be the responsibility of the Deputy R&D Director.  |
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| **PROPOSED CO-SPONSOR INSTITUTION OR LEGAL ENTITY** |
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| **REQUIREMENTS** |
| 1. **QUALITY SYSTEM**

(Sponsorship Reviewer, or designee, to complete) |
| Does the proposed co-sponsor possess regulatory and GCP compliant SOPs and thoroughly defined processes for monitoring, pharmacovigilance, TMF maintenance and/or other responsibilities to be assumed by the proposed co-sponsor? Is there oversight of these processes? | ***Yes/No******(delete as appropriate)*** |
| ***Details:*** |
| 1. **INSPECTION RECORD**

(Sponsorship Reviewer, or designee, to complete) |
| When was the proposed co-sponsor last subject to MHRA GCP inspection?***Date:*** |
| Has the proposed co-sponsor been subject to any triggered MHRA inspections? | ***Yes/No******(delete as appropriate)*** |
| ***Date(s):*** |
| Are all actions from the proposed co-sponsor’s last two MHRA inspections closed?  | ***Yes/No******(delete as appropriate)*** |

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| 1. **INSURANCE**

(Sponsorship Reviewer, or designee, to complete on discussion with the Principal R&D Manager) |
| Can the proposed co-sponsor provide commercial clinical trial insurance or an acceptable alternative? | ***Yes/No******(delete as appropriate)*** |
| Required certificate(s) provided? | ***Yes/No******(delete as appropriate)*** |
| ***Details:***  |
| 1. **PREVIOUS EXPERIENCE**

(Sponsorship Reviewer, or designee, to complete) |
| ***Number of CTIMP studies sponsored / co-sponsored:***  |
| 1. **SPONSOR’S ROLE**

(Sponsorship Reviewer, or designee, to complete) |
| Can the proposed co-sponsor provide facilitation, pharmacovigilance? | ***Yes/No******(delete as appropriate)*** |
| Are the roles and responsibilities allocated to the proposed co-sponsor organisation described in the trial agreement? | ***Yes/No******(delete as appropriate)*** |
| Does the proposed co-sponsor possess the necessary research governance infrastructure? | ***Yes/No******(delete as appropriate)*** |

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| **OUTCOME**(Sponsorship Reviewer to complete) |
| Co-Sponsorship approved? | ***Yes/No******(delete as appropriate)*** |
| ***Comments:***  |
| ***If not approved, actions to be taken (pre-qualification audit, etc):***  |
| Signature |  | Date |  |

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| **AUTHORISATION** (Deputy R&D Director to complete) |
| Authorising Individual |  |
| Signature |  | Date |  |