**General VMIA Teletrial Information**

**As as 9 December 2019**

VMIA are happy to provide comments of proposed Schedule 7 language in the ‘Site Agreement’ or the Clinical Trial Research Agreement between the sponsor/primary site about the study being a teletrial study

VMIA response: VMIA is happy to review the insurance and indemnity clauses of any Agreements but does not provide advice in relation to the other components of the Agreement.

VMIA are happy to review and endorse the VCCC teletrials standard operating procedures

VMIA response: VMIA is happy to review the insurance and indemnity clauses of any Agreements but does not provide advice in relation to the other components of the Agreement.

VMIA will advise if any other teletrials supporting documentation would need to be provided to ensure compliance

VMIA response: VMIA is happy to review the insurance and indemnity clauses of any Agreements but does not provide advice in relation to the other components of the Agreement.  VMIA relies upon the guidelines and governance provided by NHMRC and/or DHHS as being level of governance required for the running of clinical trials/teletrials as we are not a regulator or developer of policies in the clinical trial environment.

**Type I: Primary Site (Public Hospital) 🡪 Satellite Site (Public Hospital)**

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| **Example** | **Scenario** | **VMIA Responses** |
| 1 | Employees of Victorian Public Hospitals who are appointed as a Principal Investigator (PI) on a teletrial will be covered by the VMIA’s policies of insurance for their negligent acts, errors and omissions in relation to the conduct of the teletrial, inclusive of providing guidance and/or advice to investigators at another public health organisation which is identified as a satellite site. | An employee of a Victorian Public Hospitals who is appointed as a PI on a teletrial will be covered by the VMIA’s policies of insurance for their conduct of the teletrial, subject to the terms conditions and exclusions of the policy wordings. |
| 2 | Employees of Victorian Public Hospitals who are appointed as a PI on a teletrial will still be covered by the VMIA’s policies of insurance for their negligent acts, errors and omissions in relation to the conduct of the teletrial, if they do not have practice privileges (e.g. honorary/VMO appointment) at a public health teletrial satellite site. | An employee of a Victorian Public Hospitals who is appointed as a PI on a teletrial will be covered by the VMIA’s policies of insurance for their conduct of the teletrial, subject to the terms conditions and exclusions of the policy wordings. The matter relating to ‘practice privileges’ is a decision of each and every hospital participating in the teletrial and it will be subject to their policies and procedures relating to employment/contractual privileges, credentialing etc. |

**Type II: Primary Site (Public Hospital) 🡪 Satellite Site (Private Hospital) or Independent PI (working in a private setting)**

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| **Example** | **Scenario** | **VMIA Responses** |
| 1 | Employees of Victorian Public Hospitals who are appointed as a PI on a teletrial will be covered by the VMIA’s policies of insurance for their negligent acts, errors and omissions in relation to the conduct of the teletrial, inclusive of providing guidance and/or advice to investigators at another public health organisation which is identified as a satellite site. | An employee of a Victorian Public Hospitals who is appointed as a PI on a teletrial will be covered by the VMIA’s policies of insurance for their conduct of the teletrial, subject to the terms conditions and exclusions of the policy wordings. |
| 2 | Will VMIA coverage be available (for both the primary and satellite site) if the primary site was a public hospital and the satellite site (private hospital) - and the research participant was going to the satellite site for say follow up visits and/or screening only? Note: PI is located at the public hospital and the UR number is generated at the public hospital. | The VMIA suite of products does not extend to private hospitals.  The private hospitals will be required to arrange their own insurance as per the requirements set out in the Agreement entered into by the various entities.  The public hospitals will be covered by their policies of insurance for their participation in the teletrial, subject to the terms conditions and exclusions of the policy wordings |
| 3 | Would the HREC (and RGO) be covered for their decision to include a private site as a satellite site, or does the private site need to provide “HREC Review Indemnity”? | The VMIA suite of products indemnifies the HREC within a public health service for their reviews, whether they are for public or private entities. It will be the decision of the private site as to whether they want to arrange any additional coverage to protect their own interests.  The Research Governance Officers (RGO) are also indemnified by the VMIA suite of products if they are employees of a public health service and acting on behalf of the public health service. |
| 4 | A Public Hospital teletrial PI will be covered by the suite of VMIA’s policies for their negligent acts, errors and omissions in relation to the conduct of the teletrial when providing advice/instruction to an investigator(s) at another private health organisation, which is identified as a satellite site. | An Employee of a Victorian Public Hospitals who is appointed as a PI on a teletrial will be covered by the VMIA’s policies of insurance for their conduct of the teletrial, subject to the terms conditions and exclusions of the policy wordings, including the provision of advice to an investigator at another private health organisation. |
| 5 | In the event that a research participant is participating in a teletrial at a private hospital and the PI (is at the public hospital), will the VMIA still cover the participant under the VMIA’s policies of insurance based on the assumption that the participant remains a patient of the primary sites, and as identified through the UR number allocated by primary site, for the purposes of the teletrial only. | *The VMIA suite of products does not cover ‘the participants of the clinical trials’ – it provides cover to the public health services running the teletrials and their vicarious liability for the actions of their employees.* |
| 6  A private entity hospital agreement will need to be signed between the public and private hospital. The public hospital HREC will require a copy of the Professional Indemnity Insurance Cover (which states research / clinical trials is covered) of the PI working privately or in a private hospital. This should be confirmed during the start up feasibility stage. | | |

**Type III: Primary Site (Private Hospital) 🡪 Satellite Site (Public Hospital)**

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| **Example** | **Scenario** | **VMIA Responses** |
| 1 | Will VMIA coverage be available if the primary site was a private hospital and the satellite site was a public hospital, the research participant is a patient at the primary site (and therefore has a UR number) but is going to the public hospital for 'activities' under the teletrial scenario? The principal investigator is located the private hospital. | The VMIA suite of products does not extend to private hospitals.  The private hospitals will be required to arrange their own insurance as per the requirements set out in the Agreement entered into by the various entities. The public hospitals will be covered by their VMIA’s policies of insurance for their participation in the teletrial, subject to the terms conditions and exclusions of the policy wordings. |
| 2 | Private Hospital’s Insurance has liability coverage and medical indemnity with no exclusions. i.e. includes clinical trials/teletrials | We expect the Agreement entered into by the various entities will outline the insurance requirements of the Primary site and the satellite sites, with a requirement/expectation that the policies will cover clinical trial/teletrial/research activities. |
| 3 | Should the reverse coverage extensions for PI coverage therefore apply from the private sector to the public sector, when the roles of primary and satellite site are reversed (private is primary and public is satellite site)? | We expect the Agreement entered into by the various entities will outline the insurance requirements of the Primary site and the satellite sites, with a requirement/expectation that the policies will cover clinical trial/teletrial/research activities. |