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Association of Australian
Medical Research Institutes

SUBMISSION

THE GOOD CLINICAL PRACTICE INSPECTIONS PROGRAM

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Response to the Good Clinical Practice Inspections Program consultation paper

Thank you for opportunity to contribute input on the development of a Good Clinical Practice (GCP) Inspections Program for clinical trials in the Clinical Trials Notification (CTN) and Clinical Trial Exemption (CTX) schemes.

AAMRI welcomes the pilot GCP Inspections program and the proposal to establish a routine inspections program. In the long term the program will address an oversight gap by identifying and managing risk under the CTN and CTX schemes. The program has the potential to greatly elevate the quality and integrity of clinical trials conducted in Australia.

In the following submission, AAMRI has provided feedback on:

the proposal to conduct a pilot program of GCP inspections and subsequent establishment of a routine inspection program

the proposed inspection process, including a proposal to release inspection findings to the approving HREC and/or Authorising Institution.

1 Feedback on the pilot GCP inspections program and the proposed routine GCP inspections program

AAMRI is supportive of the pilot and proposed routine inspection programs as outlined in the consultation paper. AAMRI recommends that in developing and implementing the inspection programs consideration should be given to the following areas:

- **Varied levels of readiness and resources available for an auditing process among organisations conducting clinical trials.** Significant staff, time and resources are required to prepare for and manage an inspection at a clinical trial site. For medical research institutes (MRIs) involved in clinical trials, available research governance resources are currently engaged in project oversight and managing successful trials. There are very limited additional resources available to undertake additional activities such as new requirements associated with quality assurance initiatives such as auditing, training and standard operating procedures (SOPs). Investigator-led clinical trials being undertaken in private practice rooms will also need special consideration.
- **Slowing clinical trials progress under the Clinical Trials Notification (CTN) scheme could decrease Australia's competitiveness as a clinical trials destination.** Currently the CTN scheme **is one of Australia's biggest drawcards as a place to conduct clinical trials because of the** advantages in speed, cost and access. An inspections program that slowed down the progress of clinical trials being conducted under CTN scheme could have a negative impact.
- **The potential for doubling up on auditing – for example through international audits of international clinical trials – will increase administrative load and place unnecessary strain on the research governance resources of organisations.**

Without sufficient alignment of regulatory processes and bodies there could be a large overlap in audits or inspections conducted by regulatory bodies, funding bodies the HREC and governance bodies.

- **The process for selecting clinical trials for the pilot inspections program is not clear.** While volunteers are requested during the consultation period it is unclear how other trials will be selected for the pilot program. During the pilot, AAMRI recommends consideration be given to the type of trials (e.g. drug, device), as well as targeting higher risk trials rather than selecting trials at random. For example, high budget publicly funded trials would be a high priority. As the pilots are exploratory the TGA should negotiate with selected institutions which trials to inspect. At least one device trial should be included in the pilot.
- **Introduction of auditing fees could be prohibitive for investigator-led clinical trials.** While the pilot inspections program will be funded by the TGA, it is unclear how the cost of a long-term routine inspections program would be covered. Investigator initiated studies, which would benefit most from an inspections program, are run on very tight budgets and can least afford to incur additional financial costs. AAMRI recommends that if established the cost of a routine inspection program should be included in the TGA budget.

2 Feedback on the proposal to release inspection findings to the approving HREC and/or Authorising Institution.

AAMRI agrees in principle that the Research Governance Office and the Human Research Ethics Committee would be appropriate mechanisms to receive the inspection findings and manage any issues in relation to the conduct of the trial or the data integrity. However, before any inspections program is rolled out greater clarity is needed in how the inspection findings will be reported and implemented.