**Checklist for Amendments or Addenda to Clinical Trial Research Agreements or Clinical Investigation Agreements**

The Amendment should be compared to the executed original. The indemnity should also be checked.

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| **Clause or Schedule** | **Please check** |
| Are the Parties listed in the Amendment the same as those in the original Agreement? If not, ask the Sponsor to correct. | Yes [ ]  |
| Is the “Effective Date” of the original Agreement correct? It should be the date specified or the date the last Party signed. | Yes [ ]  |
| Are there any terms such as “on behalf of”, “acting for”, “representing”? These are unacceptable as they imply an agency relationship. Each Party must act and sign in its own right. |  No [ ]  |
| Has the Principal Investigator been listed as a Party to the Amendment or Addendum to the Agreement? This is incorrect. |  No [ ]  |
| Is the name of the Institution “Alfred Health ABN 27 318 956 319 a body corporate established under the *Health Services Act 1988* (Vic) of Commercial Road, Melbourne 3004”?Just “Alfred Health” is also acceptable if the ABN is correct. | Yes [ ]  |
| If the original Agreement listed Bayside Health as the Party, a clause or recital should be added to state that the name of the Institution has changed to “Alfred Health”. Alternatively “Alfred Health formerly known as Bayside Health” is acceptable. The ABN remains unchanged. | Yes [ ]  N/A [ ]  |
| Are the changed terms acceptable to you? | Yes [ ]  |
| Has a revised budget been attached? | Yes [ ]  N/A [ ]  |
| Are the amounts inclusive or exclusive of GST? If inclusive, you will in effect receive 10% less. | Yes [ ]  N/A [ ]  |
| Are the amounts, terms and conditions of payment acceptable to you?  | Yes [ ]  N/A [ ]  |
| If there is a revised budget with additional expenses, will any revised Resource Centre Declarations be required?  | Yes [ ]  N/A [ ]  |
| Are there any changes to the indemnity or insurance clauses? If so, please notify the Office of Ethics and Research Governance. | Yes [ ]  No [ ]  |
| Have the International Sponsor or Local Sponsor changed? If so, please contact the Office of Ethics and Research Governance to discuss which other documents will be required. | Yes [ ]  No [ ]  |
| Is there a clause indicating that all other conditions apply such as "Except as provided herein, all other terms and conditions of the Agreement shall remain in full force and effect.”? | Yes [ ]  |
| Is there an execution section for each of the Parties? | Yes [ ]  |
| Is the execution section for the Principal Investigator prefaced with “Read and acknowledged by the Principal Investigator”? The words, “Agreed and accepted” are not appropriate as they imply the Principal Investigator is a Party and thus, personally liable. | Yes [ ]  |