Newcastle Private Hospital
Research Governance

Special Conditions for inclusion in
Medicines Australia Clinical Trial Research Agreement Templates.

Rationale:

Newcastle Private Hospital (NPH) is a private institution, as such the Principal Investigator (PI) is a Visiting Medical Officer (VMO) and not an employee of the institution.

Below are special conditions to be included in the 3 different versions of the Medicines Australia CTRA templates to note the NPH PI as a third party to the contract.

The following special conditions were reviewed and accepted by Healthscope Legal (in consultation with external lawyers; Aspen Legal) – November 2023.

NB: the special conditions are not subject to review and approval by the NSW Health SEBS Committee. NPH is a private hospital, and does not fall under the jurisdiction of SEBS (public health organisations only).

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1. Medicines Australia Standard CTRA: 8 March 2017 (revised)

1.1. Details of the parties (page 1)

Rationale: To include details of PI as a party of the contract.

Amended to include the following:

Name of Principal Investigator:	
Address:	
Fax for Notices:	
Phone Number:	

1.2. Signature Page

Rationale: To include details of PI as a party of the contract.

Amended to include the following signature block:

Signed by the **PRINCIPAL INVESTIGATOR**

Signed: _____

Name: _____

Position: _____

Date: ____/____/_____

1.3. Schedule 7: Special Conditions

Rationale: Principal Investigator to be added as a party to the contract:

Parties to the Agreement (Principal Investigator as Third Party)

1. In the Introduction, the opening sentence is deleted in its entirety and replaced with the following:

"This agreement is made between the Sponsor, Institution and Principal Investigator".

2. In the Purpose of the Agreement, clauses B and C are deleted in their entirety and replaced with the following:

"B. The Principal Investigator intends to conduct the Study sponsored by the Sponsor at the study site operated by the Institution.

C. The Institution will provide facilities, personnel and equipment to facilitate the conduct of the Study by the Principal Investigator.

D. The Study will be conducted on the terms and conditions set out below.

3. INTERPRETATION

Clause 1.1 is amended by:

3.1 Deleting and replacing the definition of “Personnel” to read:

“**Personnel** means employees, agents and/or authorised representatives. For clarity, the Principal Investigator is not an employee or an agent of the Institution.”

3.2 Deleting and replacing the definition of “Principal Investigator” to read:

“**Principal Investigator** is the person responsible for the conduct of the Study at the Study Site as identified on the first page of this Agreement and in **Schedule 1**.”

3.3 Deleting and replacing the definition of “Study Materials" to read:

“**Study Materials** means all the materials and information created for the Study or required to be submitted to the Sponsor including all data, imaging, results, Biological Samples, Case Report Forms (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed as a result of the Study, but excluding the Institution's and/or the Principal Investigator’s ordinary patient records.”

4. PRINCIPAL INVESTIGATOR

4.1 Clause 3.1 is deleted in its entirety and replaced with the following:

“The Principal Investigator is the person responsible for the supervision and management of the Study at the study site in accordance with the Protocol. The Principal Investigator is not an employee of the Institution but seeks to work with and use the facilities of the Institution to conduct this Study on behalf of the Sponsor. For the purposes of this agreement only, and between the Sponsor and the Institution only, the Institution agrees to use reasonable endeavours to ensure that the Study is conducted in accordance with the Study Protocol.”

4.2 Clause 3.2 is deleted in its entirety and replaced with the following:

“The Principal Investigator agrees to be responsible for his/her acts and omissions in relation to the conduct of the Study. Notwithstanding any other provisions in this agreement, the parties acknowledge and agree that the Principal Investigator is not an employee or an agent of the Institution and the Institution is not responsible for the acts and/or omissions of the Principal Investigator in relation to the conduct of the Study or the performance of the Principal Investigators obligations under this Agreement.”

4.3 The following sentence in clause 3.3 is deleted in its entirety:

“The Institution is responsible for ensuring that the Principal Investigator:”

and replaced with the following:

“The Institution will provide the Principal Investigator with all reasonable assistance to ensure that he or she is able to carry out his or her responsibilities in respect to this study, and that the study is conducted in accordance with the study protocol.

The Principal Investigator agrees to:”

4.4 In clause 3.3(8), the word “Institution” is deleted and replaced with “Principal Investigator”.

4.5 A new clause 3.3(16) is added as follows:

“take out and maintain sufficient insurance (including professional indemnity insurance) or other indemnity arrangements to cover any liabilities that may arise to them as a result of the conduct of the study, and to cover his or her activities as the Principal Investigator in respect to the study”

5. INSTITUTION AND PRINCIPAL INVESTIGATOR OBLIGATIONS AND RESPONSIBILITIES

5.1 In the heading of clause 4, the words “AND PRINCIPAL INVESTIGATOR” are added after the word “INSTITUTION”.

5.2 Clauses 4.1(1) and (2) are deleted in their entirety and replaced with the following:

“(1) the Institution and Principal Investigator must use reasonable endeavours to ensure that the replacement executes an appropriate agreement (approved by the Sponsor acting reasonably) binding him/her to the obligations imposed on the Principal Investigator by this Agreement; and

(2) if a replacement cannot be found who is acceptable to the Institution and Sponsor (acting reasonably), the Sponsor may require recruitment into the Study by the Institution and Principal Investigator to cease, and the Sponsor may terminate this Agreement in accordance with clause 14.4.”

5.3 In clause 4.3:

(a) The first sentence is replaced with the following: “The Institution and the Principal Investigator each warrant that to the best of their knowledge, it, its affiliates and any Personnel are properly registered with appropriate professional registration bodies, have not been disqualified from practice or disbarred or banned from conducting clinical trials by any Regulatory Authority for debarment.”

(b) In the second sentence, the words ‘and/or Principal Investigator’’ are added after the word “Institution”.

5.4 In clauses 4.4, 4.6, 4.7 and 4.11, the words “and Principal Investigator” are added after each instance of the words “The Institution”.

5.5 In clause 4.5, the words “warrants, represents and undertakes” are replaced with the words “and the Principal Investigator each warrant, represent and undertake”.

5.6 In clause 4.7, the words “its Personnel” are replaced with the words “their Personnel”.

5.7 In the first sentence of clause 4.9, the words “and the Principal Investigator” are added after the words “The Institution”. In the second sentence of clause 4.9, the words “and/or Principal Investigator” are added after the words “by the Institution”.

5.8 In clause 4.10, the words “and Principal Investigator” are added after each instance of the words “The Institution” and the word “agrees” is replaced with the word “agree”.

5.9 Clause 4.12 is deleted in its entirety and replaced with the following:

"If the Institution or Principal Investigator is contacted by the Regulatory Authority in connection with the conduct of the Study, the Institution or the Principal Investigator (as the case may be) shall immediately notify the Sponsor, unless prevented from doing so by law."

5.10 The first sentence of subclause 4.13 is replaced with the following:

"The Institution and the Principal Investigator will provide the Sponsor with all reasonable assistance and cooperation to rectify any matter raised by a Regulatory Authority or as the result of an audit of the Institution or Principal Investigator or Study Site."

5.11 In clause 4.14, the words "and Principal Investigator (as the case may be)" are added before the words "shall obtain approval".

5.12 A new clause 4.15 is added as follows:

"Notwithstanding clause 4.3, the Principal Investigator warrants that he or she is properly registered with appropriate professional registration bodies, has not been disqualified from practise or disbarred or banned from conducting clinical trials by any Regulatory Authority for debarment. Furthermore, the Principal Investigator shall notify the Sponsor as soon as practicable after he or she becomes aware of any such disqualification, disbarment or ban."

6. SPONSOR OBLIGATIONS AND RESPONSIBILITIES

6.1 Clause 5.1 is deleted in its entirety and replaced with the following:

"Prior to the Agreement being executed, the Sponsor or its designate must provide the Principal Investigator, the Institution and the Reviewing HREC, with all current and relevant information regarding the Investigational Product that is reasonably available to the Sponsor and required to justify the nature, scope and duration of the Study."

6.2 Clause 5.4 is deleted in its entirety and replaced with the following:

"The Sponsor will monitor the application of the Investigational Product in other places (both within and outside Australia) and advise the Institution, the Principal Investigator, and TGA of the cessation elsewhere of any relevant trial, or the withdrawal of the Investigational Product from any other market for safety reasons."

6.3 In clause 5.5 and 5.7, the words "and Principal Investigator" are added after each instance of the word "the Institution".

6.4 Clause 5.6 is deleted in its entirety and replaced with the following:

"The Sponsor will cooperate with the Institution, Principal Investigator and/or the Reviewing HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Study.

7. PROVISION OF EQUIPMENT & SOFTWARE

7.1 Clause 7.2 is deleted in its entirety and replaced with the following:

"If proper usage of the Equipment or Software requires training, the Institution and Principal Investigator each agree that:

(1) the Principal Investigator and the Personnel of the Institution and/or the Principal Investigator will make themselves available for training in using the Equipment and Software, at no cost to the Institution and the Principal Investigator; and

(2) the Equipment and Software will only be used as described in written directions provided by the Sponsor."

7.2 Clause 7.3 is deleted in its entirety and replaced with the following:

"The Equipment will be at the risk of the Sponsor, but the Institution and Principal Investigator will take reasonable care in the use and secure storage of the same and the Institution and/or Principal Investigator are responsible for damage caused to or by the Equipment by the negligence of its Personnel."

7.3 In clauses 7.4, 7.5, 7.6, the words "and Principal Investigator" are added after each instance of the word "Institution".

8. INVESTIGATIONAL PRODUCT & PRODUCT LIABILITY

In clauses 8.1 and 8.3, the words "and/or Principal Investigator (as applicable)" are added after each instance of the word "Institution"

9. CONFIDENTIALITY

9.1 In clause 9.2:

(a) The words "and the Principal Investigator each" are added before the words "may use or disclose"; and

(b) The words "or the Principal Investigator (as applicable)" are added after the words "the Institution" at paragraph (7).

(c) Clause 9.2 paragraph 9 is deleted in its entirety and replaced with:
"disclosure to their respective insurers."

9.2 The following sentence in clause 9.3 is to be deleted in its entirety:

"The Institution may use or disclose Sponsor Confidential Information in any of the following circumstances."

and replaced with the following:

"The Institution and Principal Investigator may use or disclose Sponsor Confidential Information in any of the following circumstances."

9.3 Clause 9.4 is deleted in its entirety and replaced with the following:

"The Sponsor may disclose Institution Confidential Information and Principal Investigator Confidential Information to its lawyers for the purposes of obtaining legal advice or to its Affiliates but only on a needs to know and confidential basis. The Sponsor may disclose Institution Confidential Information and/or Principal Investigator Confidential Information if required by law, with notice as soon as reasonably practical to the Institution and/or Principal Investigator (as the case may be), and subject to the Sponsor upon request providing reasonable assistance to enable the Institution and/or Principal Investigator (as the case may be) to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure."

10. In clause 10.2, the words "other party" are replaced with the words "other parties" at each instance.

11. STUDY MATERIALS AND INTELLECTUAL PROPERTY

11.1 Clause 12.1 is deleted in its entirety and replaced with the following:

"The Sponsor grants to the Institution, the Principal Investigator, and their Personnel the right to use the Background IP of the Sponsor and the Study Materials as required to carry out the Study and perform this Agreement. Except for this right, neither the Institution, the Principal Investigator nor any of its Personnel acquires any right or interest in any Intellectual Property provided by or on behalf of the Sponsor."

11.2 Clause 12.2 is deleted in its entirety and replaced with the following:

"In order to carry out the Study, the Institution or Principal Investigator may use Intellectual Property which is part of the Institution's or the Principal Investigator's Background IP. Any such Background IP remains the sole property of the Institution or the Principal Investigator (as applicable). The Institution and Principal Investigator each grants to the Sponsor a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) the Institution's or the Principal Investigator's (as applicable) Background IP for the purpose of using the Study Materials, including the commercialisation of the such Study Materials."

11.3 In clause 12.3:

(a) The words "presently assigns" are replaced with the words "and the Principal Investigator presently assigns";

(b) In the second sentence, the word "agrees" is replaced with the words "and the Principal Investigator each agree";

(c) In the second sentence, the word "its" is replaced with the word "their".

11.4 In clause 12.4, the words "or the Principal Investigator (as applicable)" are inserted before the words "must promptly disclose".

12. TERM AND TERMINATION

12.1 In the first sentence of clause 13.1:

(a) the word "either" is deleted; and

(b) the words ", or the Principal Investigator" are inserted after the words "the Institution"

12.2 In clause 13.2, the words “the other party” are replaced with the words “another party to this Agreement”.

12.3 In clause 13.3, the words “to the other party” are replaced with the words “to the other parties”.

12.4 In clauses 13.5, 13.6 and 13.8, the words “and the Principal Investigator” are inserted after each instance of the words “the Institution”.

13. ASSIGNMENT

13.1 In clauses 19.1, the words “other party” is replaced with the words “other parties” and the definition “Other Party” is replaced with the words “Other Parties”.

13.2 In clause 19.3, the word “its” is replaced with the word “their”.

14. In clause 25, the words “affected party” are replaced with the words “affected party or parties” the words “other party” are replaced with the words “other parties” and the word “either” is replaced with the word “any”.

15. The wording in clause 26 is deleted and replaced with the following:

“This Agreement may be executed in counterparts, each of which shall be an original and together shall constitute a single agreement. Counterparts may be electronically signed and exchanged in electronic form (including portable document format) by any party, and the receiving party may rely on the receipt of such document so executed and delivered electronically as if the original had been received.”

2. Medicines Australia CRO CTRA: 8 March 2017 (revised)

2.1 Details of the parties (page 1)

Rationale: To include details of PI as a party of the contract.

Amended to include the following:

Name of Principal Investigator:	
Address:	
Fax for Notices:	
Phone Number:	

2.2 Signature Page

Rationale: To include details of PI as a party of the contract.

Amended to include the following signature block:

Signed by the **PRINCIPAL INVESTIGATOR**

Signed: _____

Name: _____

Position: _____

Date: ____/____/_____

2.3 Schedule 7: Special Conditions

Rationale: Principal Investigator to be added as a party to the contract:

Parties to the Agreement (Principal Investigator as Third Party)

1. In the Introduction, the opening sentence is deleted in its entirety and replaced with the following:

"This agreement is made between the Local Sponsor, Institution and Principal Investigator".

2. In the Purpose of the Agreement, clauses C and D are deleted in their entirety and replaced with the following:

"C. The Principal Investigator intends to conduct the Study Local Sponsored by the Local Sponsor at the study site operated by the Institution.

D. The Institution will provide facilities, personnel and equipment to facilitate the conduct of the Study by the Principal Investigator.

E. The Study will be conducted on the terms and conditions set out below.

3. INTERPRETATION

Clause 1.1 is amended by:

3.1 Deleting and replacing the definition of “Personnel” to read:

“**Personnel** means employees, agents and/or authorised representatives. For clarity, the Principal Investigator is not an employee or an agent of the Institution.”

3.2 Deleting and replacing the definition of “Principal Investigator” to read:

“**Principal Investigator** is the person responsible for the conduct of the Study at the Study Site as identified on the first page of this Agreement and in **Schedule 1**.”

3.3 Deleting and replacing the definition of “Study Materials" to read:

“**Study Materials** means all the materials and information created for the Study or required to be submitted to the Local Sponsor including all data, imaging, results, Biological Samples, Case Report Forms (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed as a result of the Study, but excluding the Institution's and/or the Principal Investigator’s ordinary patient records.”

4. PRINCIPAL INVESTIGATOR

4.1 Clause 3.1 is deleted in its entirety and replaced with the following:

“The Principal Investigator is the person responsible for the supervision and management of the Study at the study site in accordance with the Protocol. The Principal Investigator is not an employee of the Institution but seeks to work with and use the facilities of the Institution to conduct this Study on behalf of the Local Sponsor. For the purposes of this agreement only, and between the Local Sponsor and the Institution only, the Institution agrees to use reasonable endeavours to ensure that the Study is conducted in accordance with the Study Protocol.”

4.2 Clause 3.2 is deleted in its entirety and replaced with the following:

“The Principal Investigator agrees to be responsible for his/her acts and omissions in relation to the conduct of the Study. Notwithstanding any other provisions in this agreement, the parties acknowledge and agree that the Principal Investigator is not an employee or an agent of the Institution and the Institution is not responsible for the acts and/or omissions of the Principal Investigator in relation to the conduct of the Study or the performance of the Principal Investigators obligations under this Agreement.”

4.3 The following sentence in clause 3.3 is deleted in its entirety:

“The Institution is responsible for ensuring that the Principal Investigator:”

and replaced with the following:

“The Institution will provide the Principal Investigator with all reasonable assistance to ensure that he or she is able to carry out his or her responsibilities in respect to this study, and that the study is conducted in accordance with the study protocol.

The Principal Investigator agrees to:"

4.4 In clause 3.3(8), the word "Institution" is deleted and replaced with "Principal Investigator".

4.5 A new clause 3.3(16) is added as follows:

"take out and maintain sufficient insurance (including professional indemnity insurance) or other indemnity arrangements to cover any liabilities that may arise to them as a result of the conduct of the study, and to cover his or her activities as the Principal Investigator in respect to the study"

5. INSTITUTION AND PRINCIPAL INVESTIGATOR OBLIGATIONS AND RESPONSIBILITIES

5.1 In the heading of clause 4, the words "AND PRINCIPAL INVESTIGATOR" are added after the word "INSTITUTION".

5.2 Clauses 4.1(1) and (2) are deleted in their entirety and replaced with the following:

"(1) the Institution and Principal Investigator must notify the local sponsor as soon as is practicable;

(2) the Institution and Principal Investigator must use reasonable endeavours to ensure that the replacement executes an appropriate agreement (approved by the local sponsor acting reasonably) binding him/her to the obligations imposed on the Principal Investigator by this Agreement; and

(3) if a replacement cannot be found who is acceptable to the Institution and local sponsor (acting reasonably), the local sponsor may require recruitment into the Study by the Institution and Principal Investigator to cease, and the local sponsor may terminate this Agreement in accordance with clause 14.4."

5.3 In clause 4.3:

(a) The first sentence is replaced with the following: "The Institution and the Principal Investigator each warrant that to the best of their knowledge, it, its affiliates and any Personnel are properly registered with appropriate professional registration bodies, have not been disqualified from practice or disbarred or banned from conducting clinical trials by any Regulatory Authority for debarment."

(b) In the second sentence, the words 'and/or Principal Investigator'' are added after the word "Institution".

5.4 In clauses 4.4, 4.6, 4.7 and 4.11, the words "and Principal Investigator" are added after each instance of the words "The Institution".

5.5 In clause 4.5, the words "warrants, represents and undertakes" are replaced with the words "and the Principal Investigator each warrant, represent and undertake".

5.6 In clause 4.7, the words "its Personnel" are replaced with the words "their Personnel".

5.7 In the first sentence of clause 4.9, the words "and the Principal Investigator" are added after the words "The Institution". In the second sentence of clause 4.9, the words "and/or Principal Investigator" are added after the words "by the Institution".

5.8 In clause 4.10, the words “and Principal Investigator” are added after each instance of the words “The Institution” and the word “agrees” is replaced with the word “agree”.

5.9 Clause 4.12 is deleted in its entirety and replaced with the following:

“If the Institution or Principal Investigator is contacted by the Regulatory Authority in connection with the conduct of the Study, the Institution or the Principal Investigator (as the case may be) shall immediately notify the Local Sponsor, unless prevented from doing so by law.”

5.10 The first sentence of subclause 4.13 is replaced with the following:

“The Institution and the Principal Investigator will provide the Local Sponsor with all reasonable assistance and cooperation to rectify any matter raised by a Regulatory Authority or as the result of an audit of the Institution or Principal Investigator or Study Site.”

5.11 In clause 4.14, the words “and Principal Investigator (as the case may be)” are added before the words “shall obtain approval”.

5.12 A new clause 4.15 is added as follows:

“Notwithstanding clause 4.3, the Principal Investigator warrants that he or she is properly registered with appropriate professional registration bodies, has not been disqualified from practise or disbarred or banned from conducting clinical trials by any Regulatory Authority for debarment. Furthermore, the Principal Investigator shall notify the Local Sponsor as soon as practicable after he or she becomes aware of any such disqualification, disbarment or ban.”

6. LOCAL SPONSOR OBLIGATIONS AND RESPONSIBILITIES

6.1 Clause 5.1 is deleted in its entirety and replaced with the following:

“Prior to the Agreement being executed, the Local Sponsor or its designate must provide the Principal Investigator, the Institution and the Reviewing HREC, with all current and relevant information regarding the Investigational Product that is reasonably available to the Local Sponsor and required to justify the nature, scope and duration of the Study.”

6.2 Clause 5.4 is deleted in its entirety and replaced with the following:

“The Local Sponsor will monitor the application of the Investigational Product in other places (both within and outside Australia) and advise the Institution, the Principal Investigator, and TGA of the cessation elsewhere of any relevant trial, or the withdrawal of the Investigational Product from any other market for safety reasons.”

6.3 In clause 5.5 and 5.7, the words “and Principal Investigator” are added after each instance of the word “the Institution”.

6.4 Clause 5.6 is deleted in its entirety and replaced with the following:

“The Local Sponsor will cooperate with the Institution, Principal Investigator and/or the Reviewing HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Study.

7. PROVISION OF EQUIPMENT & SOFTWARE

7.1 Clause 7.2 is deleted in its entirety and replaced with the following:

"If proper usage of the Equipment or Software requires training, the Institution and Principal Investigator each agree that:

(1) the Principal Investigator and the Personnel of the Institution and/or the Principal Investigator will make themselves available for training in using the Equipment and Software, at no cost to the Institution and the Principal Investigator; and

(2) the Equipment and Software will only be used as described in written directions provided by the Local Sponsor."

7.2 Clause 7.3 is deleted in its entirety and replaced with the following:

"The Equipment will be at the risk of the Local Sponsor, but the Institution and Principal Investigator will take reasonable care in the use and secure storage of the same and the Institution and/or Principal Investigator are responsible for damage caused to or by the Equipment by the negligence of its Personnel."

7.3 In clauses 7.4, 7.5, 7.6, the words "and Principal Investigator" are added after each instance of the word "Institution".

8. INVESTIGATIONAL PRODUCT & PRODUCT LIABILITY

In clauses 8.1 and 8.3, the words "and/or Principal Investigator (as applicable)" are added after each instance of the word "Institution"

9. CONFIDENTIALITY

9.1 In clause 9.3:

(a) The words "and the Principal Investigator each" are added before the words "may use or disclose"; and

(b) The words "or the Principal Investigator (as applicable)" are added after the words "the Institution" at paragraph (7).

(c) Clause 9.2 paragraph 9 is deleted in its entirety and replaced with:
"disclosure to their respective insurers."

9.2 The following sentence in clause 9.3 is to be deleted in its entirety:

"The Institution may use or disclose Local Sponsor or Organisation Confidential Information in any of the following circumstances."

and replaced with the following:

"The Institution and Principal Investigator may use or disclose Local Sponsor or Organisation Confidential Information in any of the following circumstances."

9.3 Clause 9.5 is deleted in its entirety and replaced with the following:

"The Local Sponsor may disclose Institution Confidential Information and Principal Investigator Confidential Information to its lawyers for the purposes of obtaining legal advice or to its Affiliates but only on a needs to know and confidential basis. The Local Sponsor may disclose Institution Confidential Information and/or Principal Investigator Confidential Information if required by law, with notice as soon as reasonably practical to the Institution and/or Principal Investigator (as the case may be), and subject to the Local Sponsor upon request providing reasonable assistance to enable the Institution and/or Principal Investigator (as the case may be) to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure."

10. In clause 10.2, the words "other party" are replaced with the words "other parties" at each instance.

11. STUDY MATERIALS AND INTELLECTUAL PROPERTY

11.1 Clause 12.1 is deleted in its entirety and replaced with the following:

"The Local Sponsor or organisation grants to the Institution, the Principal Investigator, and their Personnel the right to use the Background IP of the Local Sponsor and the Study Materials as required to carry out the Study and perform this Agreement. Except for this right, neither the Institution, the Principal Investigator nor any of its Personnel acquires any right or interest in any Intellectual Property provided by or on behalf of the Local Sponsor."

11.2 Clause 12.2 is deleted in its entirety and replaced with the following:

"In order to carry out the Study, the Institution or Principal Investigator may use Intellectual Property which is part of the Institution's or the Principal Investigator's Background IP. Any such Background IP remains the sole property of the Institution or the Principal Investigator (as applicable). The Institution and Principal Investigator each grants to the Local Sponsor, or at the Local Sponsor's request, to the Organisation, a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) the Institution's or the Principal Investigator's (as applicable) Background IP for the purpose of using the Study Materials, including the commercialisation of the such Study Materials."

11.3 In clause 12.3:

(a) The words "presently assigns" are replaced with the words "and the Principal Investigator presently assigns";

(b) In the second sentence, the word "agrees" is replaced with the words "and the Principal Investigator each agree";

(c) In the second sentence, the word "its" is replaced with the word "their".

11.4 In clause 12.4, the words "or the Principal Investigator (as applicable)" are inserted before the words "must promptly disclose".

12. TERM AND TERMINATION

12.1 In the first sentence of clause 13.1:

(a) the word "either" is deleted; and

(b) the words ", or the Principal Investigator" are inserted after the word " Institution"

12.2 In clause 13.2, the words “the other party” are replaced with the words “another party to this Agreement”.

12.3 In clause 13.3, the words “to the other party” are replaced with the words “to the other parties”.

12.4 In clauses 13.5, 13.6 and 13.8, the words “and the Principal Investigator” are inserted after each instance of the words “the Institution”.

13. ASSIGNMENT

13.1 In clauses 19.1, the words “other party” is replaced with the words “other parties” and the definition “Other Party” is replaced with the words “Other Parties”.

13.2 In clause 19.3, the word “its” is replaced with the word “their”.

14. In clause 25, the words “affected party” are replaced with the words “affected party or parties” the words “other party” are replaced with the words “other parties” and the word “either” is replaced with the word “any”.

15. The wording in clause 26 is deleted and replaced with the following:

“This Agreement may be executed in counterparts, each of which shall be an original and together shall constitute a single agreement. Counterparts may be electronically signed and exchanged in electronic form (including portable document format) by any party, and the receiving party may rely on the receipt of such document so executed and delivered electronically as if the original had been received.”

3. Medicines Australia CRG CTRA: 8 March 2017 (revised)

3.1 Details of the parties (page 1)

Rationale: To include details of PI as a party of the contract.

Amended to include the following:

Name of Principal Investigator:	
Address:	
Fax for Notices:	
Phone Number:	

3.2 Signature Page

Rationale: To include details of PI as a party of the contract.

Amended to include the following signature block:

Signed by the **PRINCIPAL INVESTIGATOR**

Signed: _____

Name: _____

Position: _____

Date: ____/____/_____

3.3 Schedule 4: Special Conditions

Rationale: Principal Investigator to be added as a party to the contract:

1. In the Introduction, the opening sentence is deleted in its entirety and replaced with the following:

"This agreement is made between the CRG, Institution and Principal Investigator".

2. In the Purpose of the Agreement, clauses B, C and D are deleted in their entirety and replaced with the following:

"B. The Principal Investigator intends to conduct the Study sponsored by the CRG at the study site operated by the Institution.

C. The Institution will provide facilities, personnel and equipment to facilitate the conduct of the Study by the Principal Investigator.

D. The Study will be conducted on the terms and conditions set out below.

E. The parties acknowledge that they are not for profit organisations and the Study will be conducted in the spirit of cooperation and collaboration."

3. INTERPRETATION

Clause 1.1 is amended by:

3.1 Deleting and replacing the definition of “Personnel” to read:

“**Personnel** means employees, agents and/or authorised representatives. For clarity, the Principal Investigator is not an employee or an agent of the Institution.”

3.2 Deleting and replacing the definition of “Principal Investigator” to read:

“**Principal Investigator** is the person responsible for the conduct of the Study at the Study Site as identified on the first page of this Agreement and in **Schedule 1**.”

3.3 Deleting and replacing the definition of “Study Materials" to read:

“**Study Materials** means all the materials and information created for the Study or required to be submitted to the CRG including all data, imaging, results, Biological Samples, Case Report Forms (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed as a result of the Study, but excluding the Institution's and/or the Principal Investigator’s ordinary patient records.”

4. PRINCIPAL INVESTIGATOR

4.1 Clause 3.1 is deleted in its entirety and replaced with the following:

“The Principal Investigator is the person responsible for the supervision and management of the Study at the study site in accordance with the Protocol. The Principal Investigator is not an employee of the Institution but seeks to work with and use the facilities of the Institution to conduct this Study on behalf of the CRG. For the purposes of this agreement only, and between the CRG and the Institution only, the Institution agrees to use reasonable endeavours to ensure that the Study is conducted in accordance with the Study Protocol.”

4.2 Clause 3.2 is deleted in its entirety and replaced with the following:

“The Principal Investigator agrees to be responsible for his/her acts and omissions in relation to the conduct of the Study. Notwithstanding any other provisions in this agreement, the parties acknowledge and agree that the Principal Investigator is not an employee or an agent of the Institution and the Institution is not responsible for the acts and/or omissions of the Principal Investigator in relation to the conduct of the Study or the performance of the Principal Investigators obligations under this Agreement.”

4.3 The following sentence in clause 3.3 is deleted in its entirety:

“The Institution is responsible for ensuring that the Principal Investigator:”

and replaced with the following:

“The Institution will provide the Principal Investigator with all reasonable assistance to ensure that he or she is able to carry out his or her responsibilities in respect to this study, and that the study is conducted in accordance with the study protocol.

The Principal Investigator agrees to:"

4.4 In clause 3.3(8), the word "Institution" is deleted and replaced with "Principal Investigator".

4.5 A new clause 3.3(16) is added as follows:

"take out and maintain sufficient insurance (including professional indemnity insurance) or other indemnity arrangements to cover any liabilities that may arise to them as a result of the conduct of the study, and to cover his or her activities as the Principal Investigator in respect to the study"

5. Clauses 3.3(5), 3.3(6), 5.8 and 9.2(2) are amended by replacing the words "Responsible HREC" with "Reviewing HREC".

6. INSTITUTION AND PRINCIPAL INVESTIGATOR OBLIGATIONS AND RESPONSIBILITIES

6.1 In the heading of clause 4, the words "AND PRINCIPAL INVESTIGATOR" are added after the word "INSTITUTION".

6.2 Clauses 4.1(1), (2) and (3) are deleted in their entirety and replaced with the following:

"(1) the Institution and Principal Investigator must notify the CRG as soon as is practicable;

(2) the Institution and Principal Investigator must use reasonable endeavours to ensure that the replacement executes an appropriate agreement (approved by the CRG acting reasonably) binding him/her to the obligations imposed on the Principal Investigator by this Agreement; and

(3) if a replacement cannot be found who is acceptable to the Institution and CRG (acting reasonably), the CRG may require recruitment into the Study by the Institution and Principal Investigator to cease, and the CRG may terminate this Agreement in accordance with clause 14.4."

6.3 In clause 4.3:

(a) The first sentence is replaced with the following: "The Institution and the Principal Investigator each warrant that to the best of their knowledge, it, its affiliates and any Personnel are properly registered with appropriate professional registration bodies, have not been disqualified from practice or disbarred or banned from conducting clinical trials by any Regulatory Authority for debarment."

(b) In the second sentence, the words 'and/or Principal Investigator'' are added after the word "Institution".

6.4 In clauses 4.4, 4.6, 4.7 and 4.11, the words "and Principal Investigator" are added after each instance of the words "The Institution".

6.5 In clause 4.5, the words "warrants, represents and undertakes" are replaced with the words "and the Principal Investigator each warrant, represent and undertake".

6.6 In clause 4.7, the words "its Personnel" are replaced with the words "their Personnel".

6.7 In the first sentence of clause 4.9, the words "and the Principal Investigator" are added after the words "The Institution". In the second sentence of clause 4.9, the words "and/or Principal Investigator" are added after the words "by the Institution".

6.8 In clause 4.10, the words “and Principal Investigator” are added after each instance of the words “The Institution” and the word “agrees” is replaced with the word “agree”.

6.9 Clause 4.12 is deleted in its entirety and replaced with the following:

“If the Institution or Principal Investigator is contacted by the Regulatory Authority in connection with the conduct of the Study, the Institution or the Principal Investigator (as the case may be) shall immediately notify the CRG, unless prevented from doing so by law.”

6.10 The first sentence of subclause 4.13 is replaced with the following:

“The Institution and the Principal Investigator will provide the CRG with all reasonable assistance and cooperation to rectify any matter raised by a Regulatory Authority or as the result of an audit of the Institution or Principal Investigator or Study Site.”

6.11 In clause 4.14, the words “and Principal Investigator (as the case may be)” are added before the words “shall obtain approval”.

6.12 A new clause 4.15 is added as follows:

“Notwithstanding clause 4.3, the Principal Investigator warrants that he or she is properly registered with appropriate professional registration bodies, has not been disqualified from practise or disbarred or banned from conducting clinical trials by any Regulatory Authority for debarment. Furthermore, the Principal Investigator shall notify the CRG as soon as practicable after he or she becomes aware of any such disqualification, disbarment or ban.”

7. CRG OBLIGATIONS AND RESPONSIBILITIES

7.1 Clause 5.1 is deleted in its entirety and replaced with the following:

“Prior to the Agreement being executed, the CRG or its designate must provide the Principal Investigator, the Institution and the Reviewing HREC, with all current and relevant information regarding the Investigational Product that is reasonably available to the CRG and required to justify the nature, scope and duration of the Study.”

7.2 Clause 5.6 is deleted in its entirety and replaced with the following:

“The CRG will, as soon as it becomes aware, advise the Institution, Principal Investigator and TGA of the cessation elsewhere of any relevant trial, or the withdrawal of the Investigational Product from any other market for safety reasons.”

7.3 In clause 5.7, the words “and Principal Investigator” are added after the words “the Institution”.

7.4 Clause 5.8 is deleted in its entirety and replaced with the following:

“The CRG will cooperate with the Institution, Principal Investigator and/or the Reviewing HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Study.

8. PROVISION OF EQUIPMENT & SOFTWARE

8.1 In clause 7.2, the words “and Principal Investigator” are added after the words “the Institution”.

8.2 Clause 7.3 is deleted in its entirety and replaced with the following:

"If proper usage of the Equipment or Software requires training, the Institution and Principal Investigator each agree that:

(1) the Principal Investigator and the Personnel of the Institution and/or the Principal Investigator will make themselves available for training in using the Equipment and Software, at no cost to the Institution and the Principal Investigator; and

(2) the Equipment and Software will only be used as described in written directions provided by the CRG."

8.3 In clauses 7.4, 7.5, 7.8, the words "and Principal Investigator" are added after each instance of the word "Institution".

9. INVESTIGATIONAL PRODUCT & PRODUCT LIABILITY

In clauses 8.2 and 8.3, the words "and/or Principal Investigator (as applicable)" are added after each instance of the word "Institution"

10. CONFIDENTIALITY

10.1 In clause 9.2:

(a) The words "and the Principal Investigator each" are added before the words "may use or disclose"; and

(b) The words "or the Principal Investigator (as applicable)" are added after the words "the Institution" at paragraph (7).

(c) Clause 9.2 paragraph 9 is deleted in its entirety and replaced with:
"disclosure to their respective insurers."

10.2 The following sentence in clause 9.3 is to be deleted in its entirety:

"The Institution may use or disclose CRG Confidential Information in any of the following circumstances."

and replaced with the following:

"The Institution and Principal Investigator may use or disclose CRG Confidential Information in any of the following circumstances."

10.3 Clause 9.4 is deleted in its entirety and replaced with the following:

"The CRG may disclose Institution Confidential Information and Principal Investigator Confidential Information to its lawyers for the purposes of obtaining legal advice or to its Affiliates but only on a needs to know and confidential basis. The CRG may disclose Institution Confidential Information and/or Principal Investigator Confidential Information if required by law, with notice as soon as reasonably practical to the Institution and/or Principal Investigator (as the case may be), and subject to the CRG upon request providing reasonable assistance to enable the Institution and/or Principal Investigator (as the case may be) to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure."

11. In clause 10.2, the words “other party” are replaced with the words “other parties” at each instance.

12. Clause 11 is amended to insert a new clause 11.4 after clause 11.3, with the new clause to read as follows:

“11.4 CRG may upon request by Institution and where the CRG is permitted to do so, provide aggregated and/or de-identified data reports for Institution’s internal, non-commercial use. Notwithstanding clause 11.1, any use of such reports by Institution shall be at its own risk, and Institution must comply with all applicable laws (including privacy laws) in connection with any use of such reports and must not engage in any act or practice which would breach or cause CRG to breach such applicable laws. Institution must not try to identify Study Participants and must not try to link any data in such reports to other public data, CRG data (including that held by different institutions or by Institution for different projects) or data held by Institution (except where such linkage is permitted by applicable laws).”

13. In the second sentence of clause 12.2, the word “agrees” is replaced with the phrase “and Principal Investigator each agree”.

14. STUDY RESULTS AND INTELLECTUAL PROPERTY

14.1 Clause 13.1 is deleted in its entirety and replaced with the following:

“The CRG grants to the Institution, the Principal Investigator, and their Personnel the right to use the Background IP of the CRG and the Study Materials as required to carry out the Study and perform this Agreement. Except for this right, all Intellectual Property created and provided by the CRG remains the sole property of the CRG or the CRG’s designate. Nothing in this agreement transfers any Intellectual Property (other than the right to use where expressly stated in this Agreement) to the Institution or the Principal Investigator.”

14.2 Clause 13.2 is deleted in its entirety and replaced with the following:

“In order to carry out the Study, the Institution or Principal Investigator may use Intellectual Property which is part of the Institution’s or the Principal Investigator’s Background IP. Any such Background Intellectual Property remains the sole property of the Institution or the Principal Investigator (as applicable). The Institution and Principal Investigator each grants to the CRG a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) the Institution’s or the Principal Investigator’s (as applicable) Background IP for the purpose of using the Study Materials, including the commercialisation of the such Study Materials.”

14.3 In clause 13.3:

(a) The words “presently assigns” are replaced with the words “and the Principal Investigator presently assigns”;

(b) In the second sentence, the word “agrees” is replaced with the words “and the Principal Investigator each agree”;

(c) In the second sentence, the word “its” is replaced with the word “their”.

14.4 In clause 13.5, the words "or the Principal Investigator (as applicable)” are inserted before the words “must promptly disclose”.

15. TERM AND TERMINATION

15.1 In the first sentence of clause 14.1:

(a) the word “either” is deleted; and

(b) the words “, or the Principal Investigator” are inserted after the words “the Institution”

15.2 In clause 14.2, the words “the other party” are replaced with the words “another party to this Agreement”.

15.3 In clause 14.3, the words “to the other party” are replaced with the words “to the other parties”.

15.4 Clause 14.5 is deleted in its entirety and replaced with the following:

“The CRG or Institution may terminate this Agreement immediately by giving notice if the Principal Investigator ceases to be accredited or credentialed with the Study Site(s) and acceptable replacement cannot be found, or the replacement does not agree to the provisions of this Agreement, in accordance with clause 4.1(3).”

15.5 In clauses 14.6, 14.7 and 14.9, the words “and the Principal Investigator” are inserted after each instance of the words “the Institution”.

16. ASSIGNMENT

16.1 In clauses 20.1, the words “other party” is replaced with the words “other parties” and the definition “Other Party” is replaced with the words “Other Parties”.

16.2 In clause 20.3, the word “its” is replaced with the word “their”.

17. In clause 25, the words “affected party” are replaced with the words “affected party or parties” the words “other party” are replaced with the words “other parties” and the word “either” is replaced with the word “any”.

18. The wording in clause 26 is deleted and replaced with the following:

“This Agreement may be executed in counterparts, each of which shall be an original and together shall constitute a single agreement. Counterparts may be electronically signed and exchanged in electronic form (including portable document format) by any party, and the receiving party may rely on the receipt of such document so executed and delivered electronically as if the original had been received.”