****

**MEMORANDUM OF AGREEMENT**

**between**

**THE UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG**

**and**

**Sponsor/Applicant ………………………………………**

**and**

**External Site/Principal Investigator (PI) ………………………………………**

**TABLE OF CONTENTS**

1. parties 3

2. introduction 3

3. objectives 3

4. DEFINITIONS 4

5. Ethical Standards: 5

6. Reporting Obligations by external SITE AND SPONSOR 5

7. Site Access for wits hrec: medical 5

8. Data Security 6

9. Informed Consent 6

10. Duration of Agreement 6

11. BREACH AND TERMINATION 6

12. confidentiality 6

13. DISPUTES 8

14. indemnity 8

15. LIMITATION OF LIABILITY 9

16. FORCE MAJEURE 10

17. MISCELLANEOUS MATTERS 10

|  |  |
| --- | --- |
| ANNEXURE 1 | Project Proposal |
| ANNEXURE 2 | Approved Ethics Certificate |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**MEMORANDUM OF AGREEMENT**

# parties

## The University of the Witwatersrand, Johannesburg, (“the University”);

## …………………… (“External Site/PI”); and

## ……………………………. (“Sponsor/Applicant”).

# introduction

## This Memorandum of Agreement ("Agreement") is entered into between the University, the Sponsor/Applicant and the External Site/PI under the ethics approval as provided by the Wits Human Research Ethics Committee: Medical (“Wits HREC: Medical”).

## The External Site/PI is conducting research titled, “………………………… ” [Title of the Research] (“the Project”) as per Annexure 1 attached hereto and has applied for ethical approval from the Wits HREC: Medical as per the ethics approval certificate as attached hereto as Annexure 2.

## The Wits HREC: Medical has the responsibility to review and approve research applications to ensure the protection of human subjects and compliance with ethical standards and principles.

# objectives

## The External Site/PI and the Sponsor/Applicant agree that the approved research will be conducted off-campus at an external site, namely “…………………………” and any modifications to the research ethics applications will be communicated promptly to the Wits HREC: Medical for review and approval.

# DEFINITIONS

Unless the context clearly indicates otherwise, the following terms will bear the following meanings:

|  |  |
| --- | --- |
| “Agreement” | this agreement together with all annexures and schedules hereto |
| “Applicant” | Means organisation/company acting on behalf of the Sponsor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| “Business Day” | any day which is not a Saturday, Sunday or official public holiday in South Africa |
| “External Site” | means \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ a for profit / non-profit organisation duly incorporated in the Republic of South Africa with registration number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, PBO registration number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and Trust Registration Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |
| “External Research Site” | means where the External Site/PI is conducting its research at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| “Party” | The University, External Site or Sponsor/Applicant |
| “Project” | means “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” and as more fully described in the attached proposal marked as Annexure A |
| “Signature Date” | the date on which this Agreement is signed by the last Party to do so |
| “Sponsor” | means \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ a for-profit / non-profit organisation duly incorporated in the Republic of South Africa with registration number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, PBO registration number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and Trust Registration Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |
| “PI” | Principal Investigator |
| “University” | the University of the Witwatersrand, Johannesburg, a public higher education institution recognised as such in terms of the Higher Education Act 101 of 1997 |

# Ethical Standards:

## The External Site/PI agrees to adhere to the ethical standards outlined in the approved research application and any additional guidelines provided by the Wits HREC: Medical.

## The Parties agree that if for any reason ethics approval is revoked, then the Agreement will be suspended until and if the ethics approval is provided by the Wits HREC: Medical.

# withdrawal or suspension of ethics approval

## In the event that the Wits HREC determines, in its sole discretion, that there are grounds of concern regarding the ethical conduct of the Project, the Wits HREC: Medical reserves the right to withdraw or suspend its ethical approval for the Project.

## Grounds for withdrawal or suspension will include but are not limited to:

### the discovery by the Wits HREC: Medical of a serious violation or violations of ethical principles, regulations, or guidelines governing human research;

### material changes by the External Site/PI and the Sponsor/Applicant to the research application that were not submitted for prior approval by the Wits HREC: Medical or were not approved, if submitted;

### the failure by the External Site/PI and the Sponsor/Applicant to comply with reporting requirements, including but not limited to adverse events, changes to the protocol, or any other information required by the Wits HREC: Medical; and / or

### Any unforeseen circumstances or developments that raise ethical concerns and jeopardize the well-being or rights of research participants.

## The Wits HREC: Medical will notify the External Site/PI and the Sponsor/Applicant in writing of its decision to withdraw or suspend ethics approval, along with the reasons for such action. The PI will have the opportunity to respond to the concerns raised by the Wits HREC: Medical and take corrective actions, as deemed necessary within 14 (fourteen) calendar days.

## Upon resolution of the concerns to the satisfaction of the Wits HREC: Medical and upon submission and approval of any necessary amendments to the research application, the Wits HREC: Medical may reinstate ethics approval for the Project.

## Notwithstanding the withdrawal or suspension of ethics approval, the obligations of the Parties under this Agreement will continue to be binding to the extent feasible, unless the Parties agree otherwise in writing.

## This clause is subject to any applicable laws, regulations, and institutional policies governing human research and ethics review.

# Reporting Obligations by external SITE AND SPONSOR

## The External Site/PI and the Sponsor/Applicant will

### promptly report any adverse events, deviations from the approved application, changes in the research plan, changes in investigators or any complaints to the Wits HREC: Medical; and

### designate a person as its representative (usually the Principal Investigator), who will be responsible for liaising with the University and / or the Wits HREC: Medical representative at all times for the purposes of this Agreement.

## The Sponsor agrees that it is responsible for covering all reasonable costs associated with audits and / or site visits conducted at private research sites involved in the execution of this Agreement. Such audits may be carried out by regulatory authorities, third-party auditors, representatives or nominees of the Wits HREC: Medical or representatives designated by the Sponsor

# Site Access AND COSTS for wits hrec: medical

## The Wits HREC: Medical reserves the right to request and/or gain access to the external research site of the External Site/PI for the purpose of monitoring the research and ensuring compliance with ethical standards and principles which access will not be denied.

## The External Site/PI agrees to provide such access to the External Site as requested by the Wits HREC: Medical.

## The Sponsor will cover the costs of such site visits by the Wits HREC: Medical.

# Data Security

## The External Site/PI will implement appropriate measures to ensure the security and confidentiality of all research data collected at the external research site.

# Informed Consent

## The External Site/PI will obtain informed consent and/or assent if applicable from all research participants in accordance with the approved ethics application and provide a copy of the consent and/or assent (if applicable) form to the Wits HREC: Medical.

# Duration of Agreement

## This Agreement will remain in full force and effect for the duration of the research project unless terminated earlier by agreement of the Parties.

# BREACH AND TERMINATION

## An event of a material breach will occur should either Party breach any of the material terms or conditions of this Agreement and fail to remedy that breach within a period of 7 (seven) calendar days of being called upon in writing to do so;

## Upon the occurrence of an event of breach the aggrieved party will be entitled, in addition to any other rights which it may have in law, to cancel this agreement on written notice to the defaulting party and to claim from the defaulting party such damages as the aggrieved party may suffer.

## Any termination of this agreement shall not absolve the Parties from the obligation to observe the confidentiality measures and other restraints as set out herein.

# confidentiality

## The Parties shall not use, directly or indirectly, for their own benefit or that of any other person, and shall keep confidential and not disclose, any Confidential Information of the other Party other than to those persons connected with the companies who are required to have such information.

## The Parties shall ensure that all reasonable security measures are taken in order to safeguard all Confidential Information from access to and use by any third party.

## The Parties undertake to instruct their employees, agents, subcontractors or representatives concerning the obligations of confidentiality set forth in this Agreement.

## The Parties shall not use the name, logos, trademarks, or trade names, whether registered or not, of the other Parties concerned in publicity releases or advertising or in any other manner, including client lists, without having secured the prior written consent of the other Party, which consent shall not be unreasonably withheld.

## The provisions of this clause shall survive the termination of this Agreement for any reason whatsoever.

## The Party who has received Confidential Information from the disclosing Party undertakes to promptly return or destroy such confidential information on request from the disclosing Party and promptly confirm in writing to the disclosing Party that such action has been taken.

## Upon termination, for whatever reason, both Parties shall return to each other, all Confidential Information, as well as all relevant confidential documentation in their possession, 2 (two) calendar days after such termination.

## The Parties hereto shall fully comply with the statutory obligations contained in the Protection of Personal Information Act N0. 14 of 2013 (“POPIA”) and the Regulations issued in terms thereof and shall process all Personal information and/or personal data in respect of this Agreement in accordance with POPIA and only for the purpose of fulfilling their obligations in terms of this Agreement. The definitions as used in section 1 of POPIA and the Electronic Communications and Transactions Act (ECT) shall apply to this clause and the Parties warrant they are fully conversant with POPIA as at the date of signature hereof.

# DISPUTES

## The Parties will negotiate in good faith to resolve any disputes that may arise out of this Agreement.

## Each Party shall inform the other in the event of any perceived or potential dispute occurring.

## The Parties’ respective Representatives shall first attempt to resolve the dispute.

## If the Parties fail to resolve the dispute in terms of clause 13.3 within ten (10) Business Days after receipt of the notice referred to in 13.2, either Party may submit the dispute for resolution to the University’s Deputy Vice-Chancellor: Research and Innovation or his / her nominee and the External Site’s chief executive officer or his / her nominee.

## Any disputes which cannot be resolved by the Parties in terms of clauses 13.1 to 13.4 inclusive within seven (7) Business Days shall at the instance of either Party be adjudicated by the South Gauteng High Court, Johannesburg, unless the Parties agree to refer the dispute to arbitration in terms of a separate arbitration agreement. The Parties irrevocably consent and submit to the exclusive jurisdiction of the South African courts for the adjudication of such disputes.

## The decision of the arbitrator will be final and binding on the Parties, and may at the request of either Party be made an order of court of competent jurisdiction, and each of the Parties hereby agrees to submit itself to the jurisdiction of such court.

# indemnity

## In consideration of the External Site/PI’s participation in the Project, the External Site and/or the Sponsor/Applicant hereby indemnifies and holds harmless the University and in turn the Wits HREC: Medical and its employees and agents against all liability for claims and proceedings made or brought (whether successfully or otherwise):

### by or on behalf of a Project participant, by their dependents, parent(s) or legally appointed guardian against the University and the Wits HREC: Medical or any of its employees or agents, for costs or damages for personal injury (including death) to such Project participant resulting from, arising out of or relating to Wits HREC: Medical’s review or approval of the Project. Wits HREC: Medical shall not be liable for any administration of the investigational medicinal product or device under investigation or any clinical intervention or procedure provided for or required by the Application to which the Project participant would not have been exposed but for their participation in the Project;

### by the External Site/PI, or any of its employees or agents or by or on behalf of a Project participant for a declaration concerning the treatment of a Project participant who has suffered such personal injury; and

### by the Sponsor/Applicant, or any of its employees or agents or by or on behalf of a Project participant for a declaration concerning the treatment of a Project participant who has suffered such personal injury.

# LIMITATION OF LIABILITY

## The University has insured itself against the acts and omissions of persons acting on its behalf and its registered students and staff are insured during the course and scope of their registered courses and individuals who are subject to the University’s Rules and Regulations are insured during the course and scope of their registered courses and/or within the course and scope of the University’s business. The University’s maximum liability will be limited, whether for a single or multiple events, to the extent of its insurance cover herein.

# Other insurance

## The External Site/PI is insured by either the Sponsor or the Applicant against the acts and omissions of persons acting on its behalf and within the course and scope of its business in terms of their public liability.

## The Parties agree that the insurance obtained by the Sponsor / Applicant will be in terms of Association of the British Pharmaceutical Industry / ABPI 2014 covering any adverse event or serious adverse event occurring due to the participant being on the Project.

## Indemnification of the Site and the investigators is required by the Applicant / Sponsor for any other adverse events related to the Project.

## Investigators’ personal malpractice insurance and / or professional indemnity insurance via MPS etc. in case of negligence and / or malpractice.

# FORCE MAJEURE

## An event of a material breach will occur should either Party breach any of the material terms or conditions of this Agreement and fail to remedy that breach within a period of 7 (seven) days of being called upon in writing to do so;

## Upon the occurrence of an event of breach the aggrieved party will be entitled, in addition to any other rights which it may have in law, to cancel this agreement on written notice to the defaulting party and to claim from the defaulting party such damages as the aggrieved party may suffer.

## Any termination of this agreement shall not absolve the Parties from the obligation to observe the confidentiality measures and other restraints as set out herein.

# MISCELLANEOUS MATTERS

## **Address for correspondence**

### Any correspondence (other than a notice contemplated in 17.2) in connection with this Agreement may be addressed:

#### in the case of the University, to:

Physical Address

Research Development Office

10th Floor, Senate House

1 Jan Smuts Avenue

Braamfontein

Johannesburg

Republic of South Africa

Postal Address

10th Floor, Senate House

Private Bag 3

Wits 2050

Republic of South Africa

Electronic mail address: ………………………….

marked for the attention of the ………………………….

#### in the case of the External Site/PI to:

Physical Address

…………………………………….

…………………………………….

…………………………………….

Postal Address

…………………………………….

…………………………………….

…………………………………….

Electronic mail address: …………………………………

marked for the attention of the …………………………….

#### in the case of the Sponsor/Applicant to:

Physical Address

…………………………………….

…………………………………….

…………………………………….

Postal Address

…………………………………….

…………………………………….

…………………………………….

Electronic mail address: …………………………………

marked for the attention of the …………………………….

### The notice will be deemed to have been duly given:

#### on hand delivery or courier, if delivered to the Party's physical address set out in 17.1.1;

#### on despatch, if sent to the Party's then fax number or electronic mail address set out in 17.1.1 and confirmed by registered letter posted no later than the next business day;

unless the addressor is aware, at the time the notice would otherwise be deemed to have been given, that the notice is unlikely to have been received by the addressee through no act or omission of the addressee.

### A Party may change its address for this purpose to another address in the Republic of South Africa, by notice to the other Party.

### Notwithstanding anything to the contrary herein contained a written notice or communication actually received by a Party will be an adequate written notice or communication to it notwithstanding that it was not sent to or delivered at its chosen address in terms of 17.1.1.

### All notices and correspondence in connection with this Agreement will be in the English language.

## **Address for Service of Legal Documents**

### The Parties choose the following physical addresses at which documents in legal proceedings in connection with this Agreement may be served (i.e. their *domicilia citandi et executandi*):

#### The University:

Office of the Director: Legal Services

5th Floor, Senate House

1 Jan Smuts Avenue

Braamfontein

Johannesburg

#### External Site:

..........................................

..........................................

..........................................

#### Sponsor:

..........................................

..........................................

..........................................

### A Party may change its address for this purpose to another physical address in the Republic of South Africa at which legal process can be served, by notice to the other Party.

## **Entire Agreement**

This Agreement contains all the express provisions agreed on by the Parties with regard to the subject matter of the Agreement and the Parties waive the right to rely on any alleged express provision not contained in the Agreement.

## **No Representations**

No Party may rely on any representation which allegedly induced that Party to enter into this Agreement, unless the representation is recorded in this Agreement.

## **Variation, Cancellation and Waiver**

No addition to or variation of any clause of this Agreement (including this clause 17.5), consensual cancellation or novation of this Agreement and no waiver of any right arising from this Agreement or its breach or termination will be of any force or effect unless reduced to writing and signed by both Parties or their duly authorised representatives.

## **Indulgences**

If either Party at any time breaches any of its obligations under this Agreement, the other Party ("the Aggrieved Party"):

### may at any time after that breach exercise any right that became exercisable directly or indirectly as a result of the breach, unless the Aggrieved Party has expressly elected in writing or by clear and unambiguous conduct, amounting to more than mere delay, not to exercise the right. In particular, acceptance of late performance will be provisional only, and the Aggrieved Party may still exercise that right during that period;

### will not be estopped (i.e. precluded) from exercising its rights arising out of that breach, despite the fact that it may have elected or agreed on one or more previous occasions not to exercise the rights arising out of any similar breach or breaches.

## **Applicable Law**

This Agreement will be interpreted and implemented in accordance with the law of the Republic of South Africa.

## **Jurisdiction**

The Parties consent to the jurisdiction of the South Gauteng High Court, Johannesburg.

## **Successors in title**

Without prejudice to any other provision of this Agreement, any successor‑in‑title, including any executor, heir, liquidator, judicial manager, curator or trustee, of a Party will be bound by this Agreement.

## **Severability**

If any provision of this Agreement is invalid, unenforceable or illegal, the remaining provisions of this Agreement will be deemed to be severable therefrom and will continue in full force and effect unless such invalidity, unenforceability or illegality goes to the root of this Agreement.

## **Counterparts**

This Agreement may be executed in any number of counterparts and by the Parties hereto on separate counterparts, each of which when executed and delivered will be an original and each of the counterparts will together constitute one and the same instrument.

## **Costs**

Each Party will bear its own costs relating to the negotiation, preparation and signature of this Agreement.

**Signed on behalf of the University:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signed on behalf of External Site/PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signed on behalf of Sponsor/Applicant**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ANNEXURE 1**

**Project Proposal**

**ANNEXURE 2**

**Approved Ethics Certificate**