THIS INVESTIGATION AGREEMENT is made on 2015

BETWEEN:

(1) **OXITEC LIMITED** (Company number 4512301) whose registered office is at 2nd Floor, Park Gate, 25 Western Avenue, Milton Park, Oxford, OX14 4SH, United Kingdom (**"Oxitec"**);

AND

(2) **FLORIDA KEYS MOSQUITO CONTROL DISTRICT, a special taxing district of the state of Florida,** having its principal office at 5224 College Road, Key West, Florida 33040, United States of America (**"FKMCD"**)

BACKGROUND

(A) Oxitec has developed proprietary technology known as self-limiting gene technology and has created a genetically engineered (GE) strain of *Aedes aegypti* that is known as OX513A and which is intended to be used as a New Animal Drug to control wild mosquitoes of the same species.

(B) Oxitec, has applied to the United States Food and Drug Administration - Center for Veterinary Medicine ('FDA-CVM') for Regulatory Clearance (as defined below) for Investigational Use of the New Animal Drug.

(C) The purpose of the Investigation (defined below) is to evaluate the effectiveness of the New Animal Drug to reduce the local *Aedes aegypti* mosquito population in Key West, Monroe County, Florida, USA. Oxitec is the sponsor of the Investigation and is responsible for its overall management.

(D) FKMCD is interested to see the New Animal Drug progress towards being available commercially and has therefore agreed to cooperate with Oxitec and the Investigation in accordance with and on the terms set out in this Agreement.

THE PARTIES HEREBY AGREE AS FOLLOWS:

1. DEFINITIONS

1.1 In this Agreement the following words shall have the following meanings:

Agreement	This Investigation Agreement
CDC	The Center for Disease Control of the United States of America.
Claims	All demands, claims, and liability (whether criminal or civil, in contract, tort, or otherwise) for losses, damages, legal costs, and other expenses of any nature whatsoever and all costs and expenses (including legal costs) incurred in connection therewith.

Commencement Date	The date this Agreement is executed by both Parties.
Confidential Information	All information, including technical, scientific, and commercial information, provided by Oxitec to the Recipient or to which the Recipient has access as a result of this Agreement, that: (a) in respect of information provided in documentary or by way of a model or in other tangible form, at the time of provision is marked or otherwise designated to show expressly or by implication that it is imparted in confidence; and (b) in respect of information that is imparted orally, any information that Oxitec or its representatives informed the Recipient at the time the disclosure was imparted in confidence; and (c) any copy of any of the foregoing.
Equipment	Equipment for use in connection with the Investigation as detailed in Schedule 2.
Monitoring Laboratory	A secure, lockable space of at least 15 square metres provided by FKMCD on the ground floor of its Marathon office for use by Oxitec as an ACL2 (Arthropod Containment Level 2) laboratory for evaluating field samples in accordance with the Protocol. Access to the space shall be controlled to ensure Oxitec is able to protect the fidelity of the space and those accessing the space.
Indemnified Parties	The directors, officers, employees, agents and representatives of Oxitec or FKMCD as the context requires and Oxitec's licensors.
Insectary	A secure, lockable space of at least 30 square metres provided by FKMCD on the upper floor of its Marathon office for use by Oxitec as an ACL2 (Arthropod Containment Level 2) laboratory for producing and holding the New Animal Drug. Access to the space shall be controlled to ensure Oxitec is able to protect the fidelity of the space and those having access to the space.
Investigation	The investigation comprises both: (a) The testing and evaluation of the New Animal Drug by Oxitec as described in the Protocol and (b) The work set out in the Work Plan.
Losses	All losses, including financial losses, damages, legal costs and other expenses of any nature whatsoever.
Materials	The biological materials and associated information and documentation to be supplied by Oxitec under this Agreement including the New Animal Drug together with know-how and Confidential Information relating to the New Animal Drug as detailed in Schedule 3.
New Animal Drug	A genetically engineered strain of *Aedes aegypti* referred to as OX513A with repressible lethality (known as self-limiting gene

	technology).
Project Manager	An employee of Oxitec appointed to manage the Investigation. The Project Manager will initially be Derric Nimmo.
Protocol	The protocol set out in Schedule 1 as submitted to the FDA-CVM and as amended from time to time by agreement with the FDA-CVM (where required).
Results	All data generated as a result of the Investigation.
Regulatory Clearance	Notification from the FDA-CVM that it does not object to the Investigation being undertaken and/or notification from the FDA-CVM that it does not object to the New Animal Drug being marketed as the context requires.
Secondee	A suitably qualified employee of FKMCD designated to work as part of the Project Team under the oversight of the Project Manager for the duration of the Investigation. For the avoidance of doubt the Secondee will at all times remain an employee of FKMCD and Oxitec shall not at any point in time or under any circumstances be regarded as the employer of the Secondee but the Secondee will report to and be accountable to the Project Manager for the duration of the Investigation.
Sponsor Representative	An employee of Oxitec appointed to be responsible for the Protocol and all interactions with the regulator under this Agreement. The Sponsor Representative shall initially be Camilla Beech.
Term	The period from the Commencement Date until the completion of all aspects of the Protocol and Work Plan unless terminated earlier in accordance with clause 11. Not to exceed to 22 months after initial release of mosquitoes.
Territory	The whole of the Keys area within Monroe County in the State of Florida, USA including the Upper, Middle and Lower Keys.
Third Party	Any person other than the Parties.
USDA	United States Department of Agriculture.
Work Plan	The tasks specified in Schedule 4 and the timetable for performing them.

2. THE INVESTIGATION

2.1 The Parties agree that the Investigation shall not begin until Oxitec has:

(a) received Regulatory Clearance from the FDA-CVM that the Investigation may be undertaken in an agreed upon location within the Territory;

(b) received authorization from the FDA-CVM, USDA and CDC to import and deliver a shipment of the New Animal Drug to the Insectary.

2.2 The Parties shall undertake and perform their respective roles in the Investigation in accordance with the Protocol and as described in this Agreement and shall ensure that all directions from the FDA-CVM, whether given at the time of Regulatory Clearance or subsequently, are followed by all those involved in the conduct of the Investigation.

2.3 Both Parties recognize the importance commercially of the Investigation to Oxitec and that the Investigation is of no value to Oxitec if it is terminated early or conducted outside of the Protocol. The Parties therefore agree to use their best efforts to ensure that the Investigation takes place strictly in accordance with the Protocol and that time shall be of the essence.

2.4 Notwithstanding the foregoing, the release of GM mosquitoes may not commence between July through October without the consent of the FKMCD staff.

3. ORGANISATION OF THE INVESTIGATION

3.1 The Parties will establish a Steering Committee with responsibility for overseeing the management and conduct of the Investigation. The Steering Committee shall consist of two or three members from each Party. The initial members from Oxitec shall be Hadyn Parry, Camilla Beech and Andrew McKemey. The initial members from FKMCD shall be Michael Doyle and his Designee. Either Party may vary its member(s) of the Steering Group by giving written notice to the other Party.

3.2 The Steering Committee shall:

(a) receive regular reports from the Project Manager on the progress of the Investigation including the implementation of the Work Plan, and shall monitor the conduct, nature, progress and results of the Investigation (recognising that day-to-day monitoring of data and results from the Investigation shall be the responsibility of the Project Manager);

(b) amend the Work Plan as required and consider amendments to the Protocol as described in clause 5;

(c) allocate resources and tasks in relation to the Work Plan and the Investigation between the Parties and record such allocation in revisions to the Work Plan from time to time;

(d) meet monthly or at such intervals as it considers appropriate to undertake its obligations. Such meetings may be in person, by video or telephone conference as agreed by the Steering Committee; and

(e) perform any other functions specified in this Agreement.

3.3 The meetings of the Steering Committee shall be chaired by a member of the Steering Committee employed by Oxitec. Meetings shall be convened by the chairman with at least seven (7) days prior notice, accompanied by an agenda. The agenda shall be deemed to be accepted unless one of the Steering Committee members notifies the chairman and the other members in writing, which notice may be given by e-mail, of additional points to add to the agenda at the latest two (2) days before the date of the meeting. At meetings of the Steering Committee decisions shall be made by a majority of the votes cast and the chairman shall have a deciding vote on all issues in case of a tie.

3.4 The Parties agree that FKMCD shall retain control and authority over the quantity of resources allocated to the project. Such control and authority will be discussed with the Steering Committee for any concerns or input. While every effort will be made to accommodate the recommendations of the Steering Committee, the Parties expressly recognize that the primary mission of the FKMCD remains the abatement and control of arthropods.

3.5 **PROJECT TEAM**

3.6 The day-to-day implementation and management of the Work Plan and Investigation shall be carried out by the Project Team under the management and control of the Project Manager. The Project Team shall comprise the Project Manager, another employee of Oxitec, three (3) Secondees (as nominated by FKMCD and approved by the Steering Committee in its absolute discretion) and any further resources that may be approved by the Steering Committee. Should the Steering Committee decide at any stage that any Secondees of FKMCD are unsuitable FKMCD will use its best endeavours to replace them with more suitable Secondees.

3.7 The functions of the Project Team shall include:

(a) conducting the Investigation in accordance with the terms of the Protocol and in accordance with the law;

(b) collecting and reviewing the data and results from the Investigation and compiling and agreeing to the content of reports to the Steering Committee;

(c) allocating project tasks in accordance with the Work Plan and resource availability;

(d) informing the Steering Committee of any disagreement among the members of the Project Team with regard to any matter requiring a decision and affecting the progress of the project in order that the Steering Committee may determine how to resolve the issue;

(e) reviewing and considering whether any changes might be needed to the Work Plan or Protocol or any changes to releases specified in the Protocol and making recommendations to the Steering Committee concerning changes to the Work Plan and/or Protocol and any other matters affecting the Investigation.

3.8 The Project Team shall seek to operate by consensus but the Project Manager shall have the authority to allocate roles, tasks and methods and shall refer to the Steering Committee any matter requiring decision about which agreement cannot be reached within the Project Team.

4. ALLOCATION OF SPECIFIC RESPONSIBILITIES

4.1 For the purposes of obtaining Regulatory Clearance and conducting the Investigation in compliance with 21 C.F.R. § 511.1 Oxitec shall be the Sponsor of the Investigation and shall therefore be responsible for performing the actions specified in 21 C.F.R. § 511.1.

4.2 FKMCD shall be identified as the US legal entity responsible for the importation of the New Animal Drug on the CDC and USDA application forms and employee(s) or agent(s) of Oxitec shall be nominated as the authorised user(s). The Parties shall collaborate to obtain and comply with these permits.

4.3 FKMCD agrees to be named jointly with Oxitec as the study monitor on the FDA Notice of Claimed Investigational Use form, which Oxitec shall submit as Sponsor.

4.4 FKMCD shall:

(a) Assist Oxitec in carrying out diligently the work detailed in the Protocol in accordance with the provisions of the Protocol and accompanying Standard Operating Procedures (SOPs) with the highest current scientific and technological standards;

(b) Provide on secondment at least three (3) suitably qualified personnel to assist Oxitec with the Investigation as Secondees to work as part of the Project Team;

(c) Provide Oxitec unrestricted access to the Insectary for Oxitec to adapt and fit out at Oxitec's cost (estimated to be USD 40,000) and for the purposes of producing and holding the New Animal Drug;

(d) Provide Oxitec unrestricted access to the Monitoring Laboratory for Oxitec to adapt and fit out at Oxitec's cost (estimated to be USD 15,000) and for the purposes of analysing field samples;

(e) Provide the Equipment listed in Schedule 2 to Oxitec to enable Oxitec to conduct the Investigation in accordance with the Protocol;

(f) Provide certain resources required to undertake the community engagement program identified in the Work Plan, including materials and opinion surveys but excluding Third Party advisers/consultants.

4.5 FKMCD shall use its best endeavours to ensure that all work carried out under this Agreement by it or by any of its employees, officers, agents or representatives complies with all relevant laws, regulations, practices, operating procedures, codes, and all relevant guidelines, including without limitation legislation appropriate to new animal drug investigations, the processing of data and the requirements of the FDA-CVM. Any additional requirements Oxitec may reasonably require.

4.6 Apart from the analysis required by the Protocol, or requested by Oxitec, FKMCD shall not carry out or permit any Third Party to carry out any other studies relating to unpublished Results or data or samples arising from or taken in the course of the Investigation without the prior written permission of Oxitec. Notwithstanding the foregoing, the Parties recognize that no such prohibition exists for public engagement survey studies.

4.7 Each Party shall perform its obligations in connection with the Investigation including all steps taken to obtain Regulatory Clearance for the Investigation at its own expense and in accordance with all applicable laws, regulations, industry norms and standards.

4.8 The Parties acknowledge that the regulations applicable to the Investigation will be those for a New Animal Drug and follow Guidance for Industry 187 for GE animals, but noting this guidance is subject to change. The Parties agree to work closely together, to be flexible and to cooperate fully with one another to accommodate any changes in the regulatory environment in accordance with both the spirit and the letter of this Agreement. To that end FKMCD shall disclose all Investigation data to Oxitec and shall assist and support Oxitec in any application Oxitec may make for authorisation, approval or clearance in connection with the use of the New Animal Drug on a commercial basis based on the Investigation results.

4.9 FKMCD recognizes and agrees to comply with Florida Statute § 119.0701 (as may be amended from time to time) regarding the need to keep public records and provide the public with access to those records. FKMCD warrants that Oxitec is not required under the said statute to maintain public records but Oxitec acknowledges that information supplied to FKMCD relating to the Investigation may be subject to the requirements of disclosure under the said statute.

4.10 The Parties recognize the majority of Oxitec's activities will not involve Oxitec acting on behalf of the FKMCD and thus not subject to Florida Chapter 119. However, to the extent Oxitec submits documents to the FKMCD for approval, or is acting on behalf of the FKMCD, such documents would be subject to 119 and Oxitec agrees to comply with Florida Statute § 119.0701, set forth herein, as may be amended from time to time:

(1) For purposes of this section, the term:
(a) "Contractor" means an individual, partnership, corporation, or business entity that enters into a contract for services with a public agency and is acting on behalf of the public agency as provided under s. 119.011(2).
(b) "Public agency" means a state, county, district, authority, or municipal officer, or department, division, board, bureau, commission, or other separate unit of government created or established by law.
(2) In addition to other contract requirements provided by law, each public agency contract for services must include a provision that requires the contractor to comply with public records laws, specifically to:
(a) Keep and maintain public records that ordinarily and necessarily would be required by the public agency in order to perform the service.

5. AMENDMENT OF THE PROTOCOL

5.1 The Protocol shall be amended solely by the Sponsor Representative, who shall communicate such amendments in writing to the FDA-CVM.

5.2 Before making any material amendment to the Protocol (as that term is defined in the Protocol), including to the Protocol's Standard Operating Procedures, Oxitec will make reasonable efforts to present the amendment and its rationale to the Steering Committee to permit discussion before finalising the amendment. The Sponsor Representative will notify in writing (including by email) the Project Manager and all members of the Steering Committee of all amendments, whether or not material and whether or not discussed by the Steering Committee, within 3 working days of the amendment being made.

5.3 If FKMCD is dissatisfied with or would like to change any aspect of the Protocol, it will raise the concern and/or any proposed amendment with the Steering Committee.

5.4 Any amendment shall be deemed to be incorporated into the Protocol and/or Standard Operating Procedures only after the Sponsor Representative notifies the Project Manager as provided in this Section 5.

6. USE OF THE MATERIALS

6.1 Oxitec shall be responsible for maintaining the Materials within the Insectary, for transporting the New Animal Drug to the field and releasing it there, and for transporting field samples to the Monitoring Laboratory, all in accordance with the Protocol.

6.2 FKMCD shall:

(a) use the New Animal Drug and the Equipment only in accordance with the Protocol, and as directed by the Project Manager and shall comply with all reasonable instructions given by Oxitec and/or its Project Manager from time to time in relation to the use of the Materials;

(b) not provide the New Animal Drugs or the Equipment to any Third Party except as contemplated in this Agreement;

(c) not perform any compositional, structural or other analysis of the New Animal Drug, the Materials or the Equipment or undertake any reverse engineering in relation to the New Animal Drugs, the Materials or the Equipment, without Oxitec's prior written consent;

(d) not remove the New Animal Drug from the Insectary nor provide access to the Insectary or the Monitoring Laboratory to any employee of FKMCD or to Third Party without the prior written authorisation of Oxitec or the Project Manager;

(e) nothing in this clause 6.2 prevents FKMCD permitting access to the Insectary or Monitoring Laboratory without prior written authorisation in circumstances where preventing such access would contravene legislation and Oxitec is informed as soon as reasonably possible.

6.3 FKMCD shall ensure that all employees of FKMCD assigned to work with the Project Manager cooperate fully with the Project Manager and give the Project Manager advance notice of any planned absences from work and notification of absences due to illness as soon as is practical to do so. Oxitec reserves the right to exclude individual employees of FKMCD from the Project Team in its absolute discretion.

6.4 The Equipment, Materials and any copies thereof made by or in the possession of or under the control of FKMCD pursuant to this Agreement shall at all times remain the property of Oxitec (or its licensors) and no transfer of title shall occur under the terms of this Agreement. The Equipment, Materials and any copies thereof made by or in the possession of or under the control of FKMCD shall be immediately returned or, if Oxitec so requests, destroyed.

6.5 Except as expressly provided by this Agreement, no licence under any of Oxitec's intellectual property is granted or implied by this Agreement.

6.6 FKMCD understands and acknowledges that the Material incorporates the valuable intellectual property, know-how and Confidential Information of Oxitec and its licensors, and that Oxitec and its licensors own all such intellectual property rights in and to the Material. FKMCD further recognises that nothing contained in this Agreement shall be construed as granting to FKMCD any rights to such intellectual property or such confidential information, or to any invention or patent right that has issued or may issue based on the Material, or anything contained therein or derived there from. Further, FKMCD shall not remove, amend, alter or obscure any notices relating to intellectual property on any packaging, documents or material accompanying or forming part of the Material and/or Equipment.

7. INTELLECTUAL PROPERTY & CONFIDENTIALITY OBLIGATIONS

7.1 FKMCD hereby assigns to Oxitec, with full title guarantee, all rights in and to any intellectual property created or arising from the Investigation for the full duration of such rights, wherever in the world enforceable, and shall procure such an assignment from any employees of FKMCD who are engaged in the Investigation. FKMCD agrees to execute (or ensure that any other party it shall engage in the Investigation executes) all documents and assignments and do all such things as may be necessary to perfect Oxitec's title to the Intellectual Property or to register Oxitec as owner of any registrable rights.

7.2 As between Oxitec and FKMCD, all Confidential Information belongs solely to Oxitec. FKMCD shall not, during the Term and for a period of five (5) years thereafter, disclose to any Third Party nor use for any purpose except the Investigation any Confidential Information.

7.3 The obligations of confidentiality and non-use set out in Clause 7.2 shall not apply to any information, whether Confidential Information or not, that FKMCD can show by way of written record:

(a) is required to be disclosed by FKMCD to comply with the applicable laws or governmental regulations provided that FKMCD, where possible, notifies Oxitec, of such requirement prior to any such disclosure, and FKMCD takes whatever steps it can to limit the disclosure of commercially sensitive information relating to or disclosed by Oxitec;

(b) was known to FKMCD before the information was imparted by Oxitec;

(c) is in or subsequently becomes publicly known through no fault, act, or omission on the part of FKMCD;

(d) is received by FKMCD without restriction on disclosure or use from a Third Party lawfully entitled to make the disclosure to FKMCD without such restrictions.

7.4 FKMCD warrants that all of its employees will be made aware of the obligations of confidentiality that it has agreed to above in connection with the Investigation and this Agreement and will ensure that all such employees are subject to equally stringent terms of confidentiality as regards the same as if they were each named as parties to this Agreement.

8. COMMUNICATION, PUBLICATION & ANNOUNCEMENTS

8.1 The Parties may from time to time wish to make press statements or publish materials including or referring to the work carried out under this Agreement, and the results or other data created during performance of the Investigation. The Parties recognise the importance of collaboration with regard to communication and the publication of information related to the Investigation and agree that they shall consult with one another regarding the communication and publication process.

8.2 The Parties shall create and maintain a document setting out agreed public statements regarding all aspects of the Investigation, which shall be approved by the Steering Committee.

8.3 The Parties agree to notify one another and provide a copy of any intended press release or public statement 24 hours before the release of any such statement, interview or publication. All press releases are to be agreed by both Parties wherever possible prior to publication. Where there is disagreement as to the content the Parties agree to provide one another with 48 hours' notice of their intention to proceed with the release of the statement so that the other Party can make an independent statement on the same material.

8.4 Each Party undertakes and agrees not to make any individual press release, public statement or comment that is at variance with the agreed statements referred to in clause 8.2 without the other Party's prior written agreement.

8.5 FKMCD shall make available, at the request of Oxitec, any raw data generated relating to the Investigation including any survey of public opinion, and Oxitec shall be entitled to use all such data, and any reports, publications, and disclosures reviewed by Oxitec for any purpose. FKMCD will notify Oxitec in writing at least 7 calendar days before the publication of any data or survey results and will at that time provide Oxitec with a copy of the proposed publication. If Oxitec objects to the proposed publication it will refer the matter to the Steering Group who will determine how best to proceed.

8.6 Notwithstanding the foregoing, nothing in this Agreement is intended to limit comments by Board members at public meetings or when speaking in their official capacity as Commissioners of the FKMCD.

8.7 Nothing in this Agreement is intended to circumvent requirements of FKMCD by Florida Sunshine Law.

8.8 Nothing in this Agreement is intended to limit comments by FKMCD staff regarding operational and budgetary issues.

8.9 Notwithstanding the foregoing, both Parties recognise the importance of maintaining the independent nature of the other under this Agreement. Both Parties will endeavour to work with the other, including through the steering committee, to maintain a consistent approach to communications with the Public. However, should the situation require a response, or should the need arise for either Party to communicate with the public, constituents or others regarding the matters covered by this Agreement, such communication will not result in a violation and/or breech of this Agreement, regardless of the requirements of this Section 8 of the Agreement.

9. LIABILITY

9.1 Oxitec agrees to take out and maintain for the duration of the Investigation until the termination of this Agreement in accordance with clause 11 the following insurance policies, adding FKMCD as an additional insured, to meet Third Party Claims and Losses for which Oxitec is held to be liable by a court of competent jurisdiction in respect of activities undertaken by Oxitec pursuant to the terms of this Agreement:

(a) Public liability insurance to the value of five (5) million dollars (USD);

(b) Product liability insurance to the value of five (5) million dollars (USD);

(c) Pollution and contamination liability insurance to the value of three (3) million dollars (USD).

9.2 Each Party shall indemnify and hold harmless the other Party from all Claims and Losses arising from the failure of that Party, its employees or agents to conduct the Investigation in accordance with the Protocol and/or with clauses 6.1 and 6.2.

9.3 FKMCD and Oxitec (the 'Indemnifying Party') shall each indemnify and hold the other Party (the 'Other Party') harmless in addition to the Indemnified Parties from and against all Claims and Losses for which the Indemnifying Party is held liable by a court of competent jurisdiction including Claims and Losses arising from: (a) injury to the Other Party's employees, directors, officers, agents and representatives and/or Third Parties, and/or (b) the use, keeping or treatment of the Materials (for which the Indemnifying Party was responsible) outside the scope of the Protocol and/or (c) access gained to the Insectary by any Third Party without Oxitec's prior written permission.

9.4 FKMCD and Oxitec recognize and agree that Director Michael Doyle shall at all times be acting and performing as the agent and servant of FKMCD and the Director shall exercise exclusive control or direction over the method and manner by which Director performs his services and functions on behalf of FKMCD.

9.5 Oxitec undertakes to make no claim in connection with this Agreement or its subject matter against the Director Michael Doyle (apart from claims based on fraud or wilful misconduct). This undertaking is intended to give protection to the individual director: it does not prejudice any right which Oxitec might have to claim against FKMCD for any breach of this Agreement including without limitation as a consequence of any direction, action, inaction or negligence on the part of any of its directors including Michael Doyle.

9.6 Nothing in this Agreement shall, as between the Parties, exclude the liability of Oxitec for any loss or damage suffered by a Third Party as a direct consequence of the release of the New Animal Drug in the Territory in accordance with the Protocol.

9.7 Nothing in this Agreement shall exclude or restrict the liability of a Party for death or personal injury caused by the negligence of that Party or for fraud.

9.8 To the extent that Oxitec has any liability in contract, tort or otherwise under or in connection with this Agreement, including any liability for breach of warranty, Oxitec's liability shall not exceed the amount of insurance cover provided by its insurers as set out in clause 9.1.

9.9 Neither Party shall be liable to the other for any consequential or economic loss including but not limited to loss of profit, business goodwill, turnover or any other loss arising from its performance or non-performance of its obligations in connection with this Agreement whether arising from breach of contract, tort, breach of duty, negligence or any other cause of action.

10. **WARRANTIES**

10.1 The Parties warrant that they shall each abide by all applicable governmental regulations and guidelines when handling and using the Material and shall ensure that all employees of either Party handling or using the Materials on behalf of either Party behalf are technically qualified to do so.

10.2 Oxitec is the owner of, applicant for and/or the registered proprietor of, a number of intellectual property rights (including patents) around the world relating to aspects of its self-limiting gene technology incorporated within or forming part of the Materials however Oxitec makes no warranty regarding the existence and/or validity of such rights in the USA.

Oxitec agrees to indemnify and hold FKMCD harmless in the event that legal action is brought or threatened against FKMCD alleging infringement of third party rights as a result of the use of the Materials in the Territory in accordance with the Protocol. FKMCD shall promptly provide Oxitec with full details of any such legal action or threatened legal action and the Parties shall discuss and agree the best way to respond. Oxitec shall have the right but not the obligation to defend such suit to the extent that it relates to activities undertaken as part of the Investigation and shall have the right to settle with such third party or to terminate the Investigation if it considers it appropriate.

10.3 The Materials made available by Oxitec include biological materials that are experimental in nature, and Oxitec makes no representation and gives no warranty as to the performance of the Materials in any particular manner, that they are fit for any particular purpose or that the Material will not have any latent or other defect.

11. DURATION AND TERMINATION

11.1 This Agreement, and the licences granted hereunder, shall come into effect on the Commencement Date and, unless terminated earlier in accordance with this Clause 11, or as a result of the refusal by the FDA-CVM of the application for Regulatory Clearance of the Investigation or notification of a decision by the FDA-CVM that the Investigation must cease, it shall continue in force until the end of the Term, and on such date this Agreement shall terminate automatically by expiry.

11.2 The Parties may terminate this Agreement at any time by mutual written agreement signed by the authorised signatories of the Parties.

11.3 Upon termination of this Agreement for any reason (and unless otherwise agreed by the Parties in a subsequent, written agreement):

(a) FKMCD shall return to Oxitec, or at Oxitec's request, destroy any and all Equipment, Materials (including biological materials) and any documents or other materials that are in FKMCD's possession (excluding those held within the Insectary which Oxitec shall be responsible for removing and/or destroying) or under its control incorporating Confidential Information belonging to Oxitec and shall within fourteen (14) days of so doing provide Oxitec with a sworn statement confirming that all Materials (including those stored electronically) have been destroyed or delivered up, as directed by Oxitec, and that it no longer has any such materials in its possession or under its control.

(b) All rights and licences granted by Oxitec under this Agreement shall cease to have effect.

(c) The Parties shall discuss and agree the basis upon which Oxitec may continue to use the Insectary, Monitoring Laboratory and any Equipment provided by the FKMCD in the event they are still required by Oxitec following termination.

12. DISPUTE RESOLUTION

12.1 If any dispute arises in connection with this Agreement, the Parties will endeavour to resolve it by direct discussion between the Chief Executive Officer or leader(s) of each Party authorised to bind the Party. If the dispute is not resolved the Parties will attempt to settle the issue by mediation conducted in accordance with the Centre for Effective Dispute Resolution

(CEDR) Model Mediation Procedure. Unless otherwise agreed between the Parties, the mediator will be nominated by CEDR, the location of the mediation will be Washington DC and the language of the mediation will be English. To initiate the mediation a party must give notice in writing ("ADR notice") to the other party to the dispute requesting mediation. A copy of the request should be sent to CEDR. The mediation will start not later than fourteen (14) days after the date of the ADR notice.

12.2 In the event that a Third Party issues legal proceedings against Oxitec or FKMCD in an attempt to stop or challenge the performance of the Investigation the Parties shall liaise and, acting in good faith, resolve how best to handle the legal proceedings, and how the cost of the litigation should be met by the Parties.

12.3 Should the Investigation be terminated prematurely as a result of an event of Force Majeure (as defined in clause 13.3) or by agreement of the Parties pursuant to Clause 11.2, Oxitec may continue to use the Insectary if the FKMCD Board determines it is in the best interest(s) of the District and may charge a fair market rate for rental of the space by Oxitec for the purposes of rearing and supplying the New Animal Drug to one or more Third Parties or otherwise.

13. GENERAL

13.1 This Agreement may only be amended in writing signed by duly authorised representatives of each Party.

13.2 No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude a further exercise of such right or remedy.

13.3 Neither Party shall have any liability or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement that results from an event or circumstances beyond the reasonable control of that Party, including without limitation civil protests or Third Party litigation directed against a Party with a view to bringing the Investigation to a premature end (an event of "Force Majeure"). The Party affected by such an event of Force Majeure shall:

(a) notify the other Party in writing when such event or circumstances cause a delay or failure in performance and when they cease to do so; and

(b) use its reasonable endeavours to avoid or remove the causes of non-performance and shall continue performance as expeditiously as possible as soon as such causes have been removed;

(c) liaise with the other Party regarding the event or circumstances and the action to be taken by the Parties as a consequence.

If any Force Majeure event prevents a Party from performing its material obligations under this Agreement for three (3) months, that Party shall refer the issue to the Steering Group which will be responsible for determining how the Parties will resolve matters.

13.4 If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the

invalid part of provision that otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under applicable law.

13.5 In this Agreement the headings are used for convenience only and shall not affect its interpretation; references to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine; references to Clauses and Schedules mean clauses of, and schedules to, this Agreement; references in this Agreement to termination shall include termination by expiry; and where the word "including" is used it shall be understood as meaning "including without limitation".

13.6 Except for the rights of the Indemnified Parties, this Agreement does not create any right enforceable by any person who was not a party to it. Furthermore, no person except a Party to this Agreement has any right to prevent the amendment of this Agreement or its termination.

13.7 This Agreement and its Schedule sets out the entire agreement between the Parties relating to the subject matter and supersedes all prior oral and/or written agreements, arrangements or understandings between them relating to such subject matter except the letter signed on 02 September 2014 relating to building works. Subject to Clause 10, the Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

13.8 Neither Party shall act or describe itself as the agent or representative of the other, nor shall it make or represent that it has authority to make any commitments on the other's behalf.

13.9 The validity, construction and performance of this agreement shall be governed by the laws of the State of Florida and the Parties submit to the non-exclusive jurisdiction of the courts of Florida in respect of any matter arising hereunder and not resolved in accordance with clause 12.1 except that a Party may seek an interim injunction in any court of competent jurisdiction.

Accepted and agreed by the Parties through their authorised signatories:

For and on behalf of **Oxitec Ltd**

Signature ……

Print name …….

Title ……..

Date ……

For and on behalf of **Florida Keys Mosquito Control District**

Signature …….

Print name …….

Title ……..

Date ……

Schedule 1

[*Insert a copy of the Protocol]*

Schedule 2

Both Parties will provide certain equipment to enable the Project to proceed. The lists for each Party below cover the main items but are not intended to be exhaustive.

Provided by Oxitec

Item	Quantity
Hatching	
Vacuum chambers	2
Vacuum pump	1
Aliquoting	
Magnetic stirer	2
Automatic pipettor	2
2 litre jug	2
2 litre glass beaker	4
Magnetic flee (large)	2
Sieves (v-fine)	2
Pippette Gilson (1ml)	2
Rearing Larvae	
Trays (600x400x10cm)	600
Aliquoting spoons - diet set (5)	4
Fodo blender	1
Temperature loggers (button logger) Starter kit	1
Temperature loggers (button logger) Starter kit + 20 buttons	20
Sorting males	
Aliquoting spoons - Pupae	4
Turkey baisters	3
Squirty bottles for flushing larvae and pupae 500ml	8

Sorting sink (shallow 3meter long sink)	1
Larval/pupal separator (LPS)	1
Digital camera	1
Wire sorter	2
Large containers for LPS	1
Large container for wire sorter	1
Sieves (large, made from trays)	6
Releases	
Releases devices by foot	500
Ovitraps	200
Sticky Ovitraps	200
QC and monitoring	
Mosquito aspirator	2
Fluorescent scope	1
Stereo scope (egg counting)	2
Graticules	3
General	
Scales (accurate to .000g)	1
Fridge	1
Freezer (chest type)	1
Computer	1
Double sieve for containment	1

Provided by FKMCD

- A truck of suitable size to transport the release devices to the release site, for example a Ford F150 or equivalent.
- An incubator will also be provided in the monitoring laboratory for the rearing of larvae from the field.

Schedule 3

Oxitec shall supply the following tangible components of the Materials plus intangible know-how.

- Eggs of genetically engineered OX513A *Aedes aegypti* mosquito.
- Standard Operating Procedures relating to the use of OX513A in the Protocol including without limitation the production and release of this strain.

Schedule 4

The main elements of the Work Plan with indicative dates are:

- Regulatory approvals: up to January 2015
- Building works: Up to 31 October 2014
- Training the project team: Up to 30 November 2014
- Community engagement: Ongoing, including town hall meeting 4 December 2014
- Production: From about 17 November 2014
- Release: After regulatory approval and successful public engagement; not before January 2015.

An example weekly plan for the production, release and monitoring tasks is shown in the following tables; the Project Manager will determine the actual activity plan at the time of the project in light of all the circumstances.

Basic verview of tasks							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Release	✓		✓		✓		
Wash up RD's	✓		✓		✓		
Hatch eggs	✓		✓		✓		
Aliquot		✓		✓		✓	
Larval feeding (AM and PM)	✓	✓	✓	✓	✓	✓	✓
Sort male pupae			✓		✓		✓
Draining RD's		✓		✓			✓
Ovipaddles				✓ (counting/hatching and setup penetrance study)			
Penetrance study	✓	✓	✓	✓ (setup pots for study)	✓	✓	✓
Ovipots (collect) + analyse sticky ovitraps	✓						

The table below translates the above table into the FTEs required on each day; obviously this will change if the plan is modified.

	Summary of people required							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total FTE or work days
Actual FTE required	2.24	0.73	2.92	1.15	2.85	0.62	1.79	1.76
Number of people required	2.5	1	3	1.5	3	1	2	2.00
	Rota for 4 staff							
Work week person one	0.5	0	0	1	1	0.5	1	4
Work week person two	1	0	1	0	0.5	0	0	2.5
Work week person three	1	1	1	0	1	0	1	5
Work week person four	0	0	1	0.5	0.5	0.5	0	2.5