

RESEARCH USE LICENCE

This Agreement is made on the day of, 20..

BETWEEN

(1) The **Secretary of State for Health**, acting through the National Institute for Biological Standards and Control as part of the Medicines and Healthcare Products Regulatory Agency with a place of business at UKSCB, NIBSC, Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG, UK (hereinafter called NIBSC).

and

(2) [*Depositor*] whose principal place of business is situated at [*address*] (hereinafter called "the Depositor").

and

(3) [*Requestor*] whose principal place of business is situated at [*address*] (hereinafter called "the Requestor") and whose Principal Investigator is [*name*].

In respect of the following material;

[Name/Number of Cell Line designated by the Depositor]

In respect of the following study;

The research project entitled "....." details of which are set out in the attached Approval Documents.

WHEREAS

- (A) NIBSC is responsible for managing the UK Stem Cell Bank (the "Bank") (as defined below) which receives funding from the Medical Research Council (the "MRC") and the Biotechnology and the Biological Sciences Research Council together referred to as "Grant Donor";
- (B) The Depositor at the Effective Date owns the laboratory grade stem cell line and has allowed NIBSC to hold deposited samples in the Bank, hereunder referred to as the Material;
- (C) NIBSC has used the Material to establish cell banks, samples of which are available for distribution, hereunder referred to as the Banked Material;
- (D) Requestor wishes to obtain samples of the Banked Material to use in the Research (as defined below) and has obtained the necessary permission from the Steering Committee for such use; and
- (E) The Secretariat to the Steering Committee acts on behalf of the Steering Committee and communicates the Steering Committee's decisions, as appropriate to the parties to this Agreement.

This Agreement sets out the terms and conditions between NIBSC, the Depositor and the Requestor under which NIBSC will supply samples of the Banked Material to the Requestor.

NOW IT IS HEREBY AGREED AS FOLLOWS

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement the following words and phrases shall have the following meanings unless the context requires otherwise:

- (a) "Application" shall mean the Application made by the Requestor to the Steering Committee requesting access to samples of Banked Material for use in the Research.
- (b) "Approval Date" shall mean the date stated in the Approval Documents which are sent by the Secretariat to the Steering Committee to the Depositor, the Requestor and NIBSC.
- (c) "Approval Documents" means written evidence of Steering Committee approval which allows the Requestor to access samples of the Banked Material for use in the Research, a copy of which is attached to this Agreement at Schedule 1.
- (d) "Banked Material" shall mean the cell banks of the laboratory-grade stem cell lines, including any cell lines or progeny that NIBSC has established from the Material.
- (e) "Code of Practice" shall mean the Steering Committee's code of practice for the use of Human Stem Cell Lines as may be amended from time to time.
- (f) "Depositor" shall mean the party to this Agreement, who at the Effective Date owns the stem cell lines and who has entered into a Material Deposit and Distribution Agreement with NIBSC, to allow NIBSC to hold and use deposited sample(s) of the Material.
- (g) "Derivative Materials" shall mean any other materials or products, other than the Material and Banked Material that are derived from, are produced by the use of, or that wholly or partially incorporate the Material or Banked Material.
- (h) "Effective Date" shall mean the date of last signature of this Agreement.
- (i) "Expiry Date" shall mean five years after the Effective Date.
- (j) "Information" shall mean any information, including instructions, provided in writing by NIBSC to the Requestor, including but such information and instructions as may have been provided to NIBSC by the Depositor.
- (k) "Intellectual Property" means patents, trade marks, service marks, registered designs, copyrights, database rights, design rights, confidential information, applications for any of the above, and any similar right recognised from time to time in any jurisdiction, together with all rights of action in relation to the infringement of any of the above.
- (l) "Material" shall mean the laboratory grade stem cell line material provided to NIBSC by the Depositor for deposit in the Bank under the terms of the Material Deposit and Distribution Agreement between NIBSC and the Depositor.

- (m) "Principal Investigator" means the individual who has received approval from Steering Committee to undertake the Research.
 - (n) "Requestor" means the party to his Agreement and host Institution of the Principal Investigator wishing to obtain samples of the Banked Material.
 - (o) "Research" means the laboratory based non commercial *in vitro* preclinical research to be undertaken by the Requestor and described in the Application.
 - (p) "Secretariat to the Steering Committee" shall mean the Secretariat acting on behalf of the Steering Committee for the UK Stem Cell Bank and the Use of Stem Cell Lines to communicate Steering Committee decisions to Depositor, Requestor and NIBSC, as appropriate.
 - (q) "Steering Committee" shall mean the UK Steering Committee for the UK Stem Cell Bank and the Use of Stem Cell Lines, established to supervise the use of stem cell lines. The membership and terms of reference of the Steering Committee can be found on the MRC website (www.mrc.ac.uk).
- 1.2 Clause, schedule and paragraph headings shall not affect the interpretation of this Agreement.
- 1.3 The schedules form part of this Agreement and shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the schedules.
- 1.4 Words in the singular shall include the plural and vice versa.
- 1.5 A reference to one gender shall include a reference to the other genders.
- 1.6 A reference to a statute, statutory provision or any subordinate legislation made under a statute is to such statute, provision or subordinate legislation as amended or re-enacted from time to time whether before or after the date of this Agreement and, in the case of a statute, includes any subordinate legislation made under that statute whether before or after the date of this Agreement.
- 1.7 A reference to writing or written includes faxes but not e-mail.
- 1.8 Any obligation in this Agreement on a person not to do something includes an obligation not to agree or allow that thing to be done.
- 1.9 A reference to an agreement is a reference to that agreement as varied or novated (in each case, other than in breach of the provisions of this Agreement) at any time.
- 1.10 References to clauses and schedules are to the clauses and schedules of this Agreement; references to paragraphs are to paragraphs of the relevant schedule.
- 1.11 Any phrase introduced by the terms including, include, in particular or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

2. ACCESS TO AND USE OF MATERIALS

- 2.1 Requestor will have submitted an Application to and have received approval from the Steering Committee to access samples of the Banked Material for use in the Research

specified in the Application, before samples of the Banked Material can be released to Requestor by NIBSC. A copy of the Approval Documents is attached as Schedule 1 to this Agreement.

- 2.2 Upon execution of this Agreement, NIBSC agrees to supply Requestor with samples of the Banked Material.
- 2.3 Requestor undertakes to obtain all necessary local permissions prior to any use of the Banked Material outside the UK.
- 2.4 NIBSC will invoice the Requestor according to NIBSC's prevailing tariffs and the Requestor agrees to pay the invoice within thirty (30) days of the invoice date. The current prevailing tariffs can be found on the Bank web-site (www.ukstemcellbank.org.uk).
- 2.5 The Depositor hereby grants the Requestor a non-exclusive royalty free licence to use the Banked Material in the Research during the term of this Agreement. The Requestor will not use the Banked Material for any purpose other than the Research.
- 2.6 Any use of the Banked Material and/or any Derivative Materials must comply with the Law of England and Wales if in the UK or with any applicable local Law if abroad, with all other applicable laws, government regulations, codes and guidelines and with the Code Of Practice.
- 2.7 The Requestor must obtain written approval from the Steering Committee before using the Banked Material for any other purpose including but not limited to modifications to the Research or any deviation from the Application and the Approval Documents.
- 2.8 Requestor undertakes not to use the Banked Material or any Derivative Material for the purposes of reproductive cloning under any circumstances and in any manner whatsoever.
- 2.9 Requestor undertakes only to use the Banked Material and any Derivative Materials including cells which are progeny of the Banked Material in the Research and not for (i) research in humans, including clinical trial; (ii) creation of human admixed embryos; and (iii) any commercial purpose, unless otherwise agreed in writing by the Steering Committee, the Depositor and NIBSC.
- 2.10 The Requestor acknowledges that no right or licence is being granted under this Agreement to the Requestor to sell or make any other commercial use of the Banked Material or Derivative Materials or any product made on the basis thereof. To the extent that any such rights or licenses are required, the Requestor acknowledges that Requestor is solely responsible for obtaining such rights or licences from the Depositor or any relevant third party.
- 2.11 Unless agreed otherwise in writing by the Steering Committee, NIBSC and/or the Depositor, the Requestor undertakes that the Banked Material and/or Derivative Materials will not be made available by the Requestor to any person other than the Principal Investigator and those who are under the direct supervision of the Principal Investigator.
- 2.12 Notwithstanding that the Banked Material and any Derivative Materials may only be used in non-commercial *in vitro* preclinical scientific research, Requestor agrees to notify NIBSC of any property of the laboratory-grade stem cell line that he discovers which would have the potential to affect the quality, safety or efficacy of the cells if they were to be used in human medicine. In this event NIBSC may be required to report on

such properties to appropriate authorities, the Depositor and others with access to Banked Material.

- 2.13 The Requestor acknowledges that release of the Banked Material may be embargoed for a period of time in a specified field, at the request of the Depositor and as agreed by the Steering Committee and the Banked Material may therefore be unavailable until such embargo terminates.
- 2.14 Requestor undertakes not to use the Banked Material or the Information, whether alone or in conjunction with any other information, in any effort to establish the identity of the individual from whom the Banked Material was derived.
- 2.15 The Requestor shall ensure that the Banked Material is at all times kept secure at the Requestor's facilities located at the above address and protected against loss, damage and contamination.
- 2.16 The Requestor shall ensure that the Banked Material is at all times clearly labelled as the property of the Depositor.
- 2.17 The Requestor shall maintain complete, accurate and up to date records to ensure that the Banked Material can be traced at all times and that details of all uses and processes relating to the Banked Material are documented.
- 2.18 For the avoidance of doubt any breach by Requestor of this Article 2, shall constitute a material breach of this Agreement.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 The Requestor will inform Depositor of the results of the Research at the request of the Depositor. Any such disclosure would be in confidence unless otherwise agreed in writing by the Depositor and the Requestor.
- 3.2 All Intellectual Property rights in the Material and any Information developed by or on behalf of the Depositor shall remain the property of the Depositor and no rights therein are granted to the Requestor save as expressly set out in this Agreement. All Intellectual Property rights in any Information developed by or on behalf of NIBSC shall remain the property of NIBSC and no rights therein are granted to the Requestor save as expressly set out in this Agreement.
- 3.3 Any Intellectual Property arising out of the Requestor's use of the Banked Material will be owned by the Requestor and Requestor agrees that it will grant a non-exclusive, royalty-free licence without the right to sublicense to the Depositor and NIBSC to use any Intellectual Property or results or discoveries or inventions or Derivative Materials whether patentable or not, made as a result of the Requestor's use of the Banked Materials for non-commercial research.
- 3.4 The Depositor and the Requestor acknowledge that NIBSC's role in the distribution of Banked Material is solely to facilitate improvements in public health and NIBSC is not liable for the use of the Banked Material and/or Derivative Materials by Requestor. To the fullest extent permissible by Law, NIBSC will not become involved in disputes between the Depositor and Requestor relating to the transfer and use of the Banked Material or Derivative Materials.

4. CONFIDENTIALITY

- 4.1 The parties agree not to use or disclose any information provided to it pursuant to this Agreement save as expressly provided for herein or to use or refer to this Agreement in any promotional activity or use the names or trademarks of the other parties without express written permission.
- 4.2 The obligations of confidence referred to in this Clause 4 shall not extend to any information which:
- (a) is or becomes generally available to the public otherwise than by reason of a breach by the recipient party of any provision of this Clause 4; or
 - (b) the recipient party can show was in its possession and is at its free disposal prior to its receipt from the other; or
 - (c) is subsequently disclosed to the recipient party without obligations of confidence by a third party owing no such obligations to the disclosing party in respect thereof; or
 - (d) is required to be disclosed in accordance with applicable law or by appropriate regulatory authorities.
- 4.3 Notwithstanding the foregoing, the Depositor and the Requestor acknowledge that there is an obligation to publicly report the identity of the Requestor and its Research and to provide on its own initiative or upon NIBSC written request, regular (approximately annually) information summaries of the results of Research undertaken with Banked Material, in order to fulfill:
- (a) the requirement of the Grant Donor funders to make research results publicly available (as set out in MRC's Supplementary Terms and Conditions for Grants, Unit programmes and Training Awards in stem cell research, which can be found on the MRC website - www.mrc.ac.uk)
 - (b) the requirement of the Grant Donor funders to be able to evaluate the performance and outputs of the Bank
 - (c) the requirement of each Depositor to have access to information concerning recipients of their Material and Derivative Materials, their use and published Research
- and the Depositor and the Requestor hereby agree to use their reasonable efforts to do all such things necessary to put these requirements into effect. For the avoidance of doubt, the Depositor and Requestor agree that this information will be made publicly available on the Bank web-site (www.ukstemcellbank.org.uk).
- 4.4 The Requestor will obtain prior written permission from the Depositor before submitting any publication reporting the Research such permission not to be unreasonably withheld or delayed. The Requestor shall provide the Depositor with copies of any proposed publications or public presentation making reference to the Research no less than forty (40) days prior to the submission date for publication or date of presentation. The Depositor shall have the right to delay disclosure for a period not to exceed thirty five (35) days after receipt of such material. Failure of the Depositor to request a delay in disclosure within thirty five (35) days shall constitute permission to publish or disclose as submitted.
- 4.5 The Requestor will acknowledge the Bank and NIBSC as the source of the Banked Material and the Depositor as the originator of the Material in any publication or public

disclosure of the Research and inform the Bank and NIBSC and the Depositor when such a publication or public disclosure is to be made.

- 4.6 Requestor(s) will provide NIBSC with copies of published Research within thirty (30) days of publication.

5. LIABILITIES AND WARRANTIES

- 5.1 Nothing in this Agreement shall operate to limit or exclude the liability of either party for death or personal injury caused by negligence of that party or any other liability which may not lawfully be excluded.
- 5.2 The Banked Material is supplied without warranty of merchantability or fitness for any particular purpose and without representation or warranty that it is free of extraneous agents or biologically active contaminants (including but not limited to TSE's) or that the use or supply of the Banked Material will not infringe the intellectual property or other right of any third party and NIBSC and the Depositor shall – subject to Clause 5.1 – not be liable for any loss, damage, cost or expense arising out of or in connection with the Research or any use the Requestor makes of the Banked Material or Derivative Materials.
- 5.3 The Requestor warrants that it has obtained the full approval from the Steering Committee and all information provided in the Application is accurate.
- 5.4 The Requestor undertakes to indemnify and hold harmless NIBSC and the Depositor and their trustees, directors, officers, employees and affiliates against all claims, proceedings, demands and liabilities including, without limitation, any claim etc. arising from or connected with the use, handling or storage of the Banked Material or Derivative Materials or of any products or information resulting from the Research, as well as any claim that the use of such materials, products or information will infringe the rights of third parties, except to the extent that such claim etc. is a result of the wilful misconduct or gross negligence of the Depositor or NIBSC.
- 5.5 NIBSC shall not be liable for any acts or omissions of the other parties who shall take all reasonable steps to decide or settle any dispute in respect of such acts or omissions among themselves and without involving NIBSC.

6. TERM

- 6.1 This Agreement will come into force on the Effective Date and shall (subject to the provisions for earlier termination in Clause 6.2 below) continue in force until the Expiry Date. Thereafter, the parties may at their sole discretion extend this Agreement by mutual agreement in writing.
- 6.2 NIBSC may terminate this Agreement without liability to the Requestor or the Depositor by giving notice in writing to the Requestor if:
- (a) the Requestor commits a material breach of any term of this Agreement or (where such breach is capable of remedy) fails to remedy the breach within a period of thirty (30) days after having been notified in writing to do so; or
 - (b) the Steering Committee withdraws its approval for the Banked Material's use; or
 - (c) the Requestor ceases to do business, becomes unable to pay its debts as they fall due, becomes or is deemed insolvent, has a receiver, liquidator, manager, administrator, administrative receiver or similar officer appointed in respect of the

whole or any part of its assets or business (or is the subject of a filing with any court for the appointment of any such officer), makes any composition or arrangement with its creditors, takes or suffers any similar action in consequence of debt or an order or resolution is made for its dissolution or liquidation (other than for the purpose of solvent amalgamation or reconstruction), or any equivalent or similar action or proceeding is taken or suffered in any jurisdiction and the same is not dismissed or discharged within thirty (30) days thereafter.

- 6.3 The termination of this Agreement shall be without prejudice to the rights and remedies of either party which may have accrued up to the date of termination.
- 6.4 Upon termination of this Agreement for any reason whatsoever the Requestor shall immediately cease to use the Intellectual Property rights licensed under 2.5.

7. CONSEQUENCES OF TERMINATION OR EXPIRY

- 7.1 Upon termination or expiry of this Agreement for any reason whatsoever:
- (a) the rights or licences granted under or pursuant to this Agreement will cease to have effect;
 - (b) the provisions of any provision which expressly or by implication is intended to come into or remain in force on or after termination shall continue in full force and effect.
 - (c) the Requestor shall immediately return to NIBSC all Information and remaining Banked Material, including all copies of such Information and Banked Material or, if NIBSC so requests, the Banked Material shall be destroyed at the Requestor's expense and authenticated certificates of their destruction shall be provided to NIBSC.
 - (d) the Requestor shall cease using the Derivative Materials until a further agreement is reached with the Depositor and NIBSC is informed that such an agreement is in place.

8. ASSIGNMENT

- 8.1 The Requestor may not assign, delegate, sub-contract, transfer, charge or otherwise dispose of any of its rights and responsibilities under this Agreement without the written consent of NIBSC and the Depositor provided, however, that such consent shall not be unreasonably withheld in the event that the Agreement is assigned in connection with the transfer of the entire business of the Requestor and the assignee undertakes to be bound by the provisions of this Agreement. In case of any changes in respect of the details of the Principal Investigator(s) which materially affect their involvement in this Agreement, the Requestor must immediately inform NIBSC thereof. Another individual may then be substituted, subject to agreement with the Steering Committee and NIBSC.
- 8.2 In the event that the Depositor transfers ownership of any of the human embryonic stem cell lines used to establish the Material or of the part of its business controlling the ownership thereof to a third party, the rights and obligations under this Agreement will automatically novate to the transferee. The Depositor undertakes to ensure that the transferee is notified of the existence of this Agreement and to notify NIBSC and the Requestor of the transfer.

8.3 In case of the transfer of all or a substantial part of NIBSC's activities to another body, NIBSC shall, notwithstanding any provision to the contrary in this Agreement, be entitled to transfer its rights and obligations hereunder to such other body.

9. NOTICES

9.1 Any notice given under this Agreement shall be in writing and signed by or on behalf of the party giving it and shall be served by delivering it personally, or sending it by pre-paid recorded delivery or registered post to the relevant party at its registered office for the time being or by sending it by fax to the fax number notified by the relevant party to the other party.

10. VALIDITY

10.1 If any provision of this Agreement is or becomes for any reason whatsoever invalid, illegal or unenforceable, it shall be divisible from this Agreement and shall be deemed to be deleted from it and the validity of the remaining provisions shall not be affected in any way.

11. VARIATION

11.1 No variation of or amendment to this Agreement shall bind any party unless made in writing and signed by all parties.

12. WAIVERS

12.1 Failure of either party to enforce or exercise, at any time or for any period, any term of this Agreement does not constitute, and shall not be construed as, a waiver of such term and shall not affect the right to enforce such term, or any other term contained in this Agreement, at a later date.

12.2 No delay or failure of any party in exercising or enforcing any of its rights or remedies whatsoever shall operate as a waiver of those rights or remedies or so as to preclude or impair the exercise or enforcement of those rights or remedies. No single or partial exercise or enforcement of any right or remedy by any party shall preclude or impair any other exercise or enforcement of that right or remedy by that party.

13. COUNTERPARTS

13.1 This Agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute the one Agreement.

13.2 No counterpart shall be effective until each party has executed at least one counterpart.

14. GOVERNING LAW AND JURISDICTION

14.1 The validity, construction and performance of this Agreement (including any non-contractual dispute or claim) shall be governed by the Law of England and Wales and the jurisdiction of the English courts.

This document has been duly signed by authorised representatives of the parties:

Signed on behalf of Depositor

Signature:

Name:

Title:

Signed on behalf of Requestor

Signature:

Name:

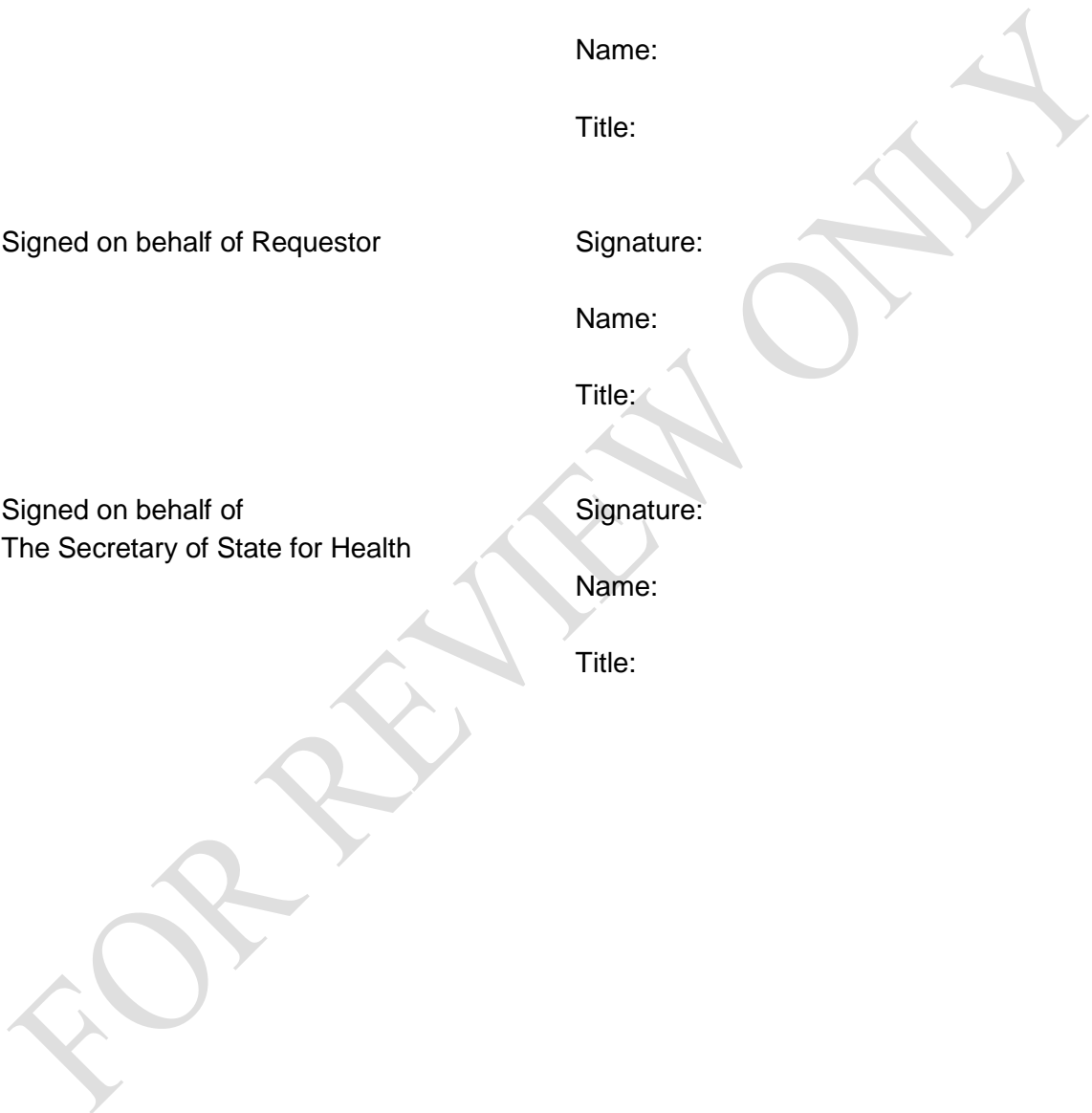
Title:

Signed on behalf of
The Secretary of State for Health

Signature:

Name:

Title:



SCHEDULE 1

Approval Documents

FOR REVIEW ONLY