

# LICENCE AGREEMENT

This licence agreement (the "Agreement") is made:

## BETWEEN

- (1) **MEDICAL RESEARCH COUNCIL**, a public body established by Royal Charter and incorporated under the laws of England having a head office address at 2<sup>nd</sup> Floor David Phillips Building, Polaris House, North Star Avenue, Swindon SN2 1FL (the "**MRC**"); and
- (2) **KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST**, whose registered address is at Denmark Hill, London SE5 9RS (the "**TRUST**").

## WHEREAS

- A. The MRC, specifically its employee Professor Tim Cole, has developed certain statistical tables and MRC owns or is the beneficial owner of such tables.
- B. The MRC wishes, in furtherance of its mission to ensure knowledge generated by its employees is disseminated for the improvement of human health, to have such tables made widely available for public use and benefit.
- C. The TRUST wishes to acquire certain rights to use such tables for the purpose of developing its in-house electronic Growth Charts.
- D. The MRC is prepared to grant the TRUST such a licence, subject always to the terms of this Agreement.

**NOW IT IS HEREBY AGREED** as follows:-

## 1 DEFINITIONS

- 1.1 In this Agreement the following terms shall have the following meanings:-

**"Effective Date"** means the 01/01/2013

**"LMS Method"** shall mean the method for smoothing reference centile curves described in *Cole and Green (1992) Smoothing reference Centile Curves: The LMS Method and Penalized Likelihood; Statistics in Medicine Vol. 11 pp1305-1319*.

**"LMS Tables"** means those tables, developed by Professor Tim Cole, produced to date (i) using the LMS Method, showing the values of L, M and S for the blood pressure of populations of children of varying ages in Great Britain, where M is the median figure, S is the coefficient of variation and L is a measure of skewness of the data relative to a normal distribution;

(ii) from the UK90 data, as well as any future dates to those tables, showing the value of L, M and S for the monthly weight, height, BMI and other variables for populations of children of varying ages from birth to 20 years (standardised to year 1990), where M is the median figure, S is the coefficient of variation and L is a measure of skewness of the data relative to a normal distribution and any re-issues, updates and amendments to those tables or the data in them;

(iii) by amalgamating WHO data from age 2 weeks with recalculated British 1990 birth data and as referenced in the publication: Wright CM, Williams AF, Elliman D, et al. Using the new UK-WHO growth charts. *BMJ*. 2010;340:c1140., as well as any future dates to those tables, showing the value of L, M and S for the monthly weight, height, BMI and head circumference for populations of children of varying ages from birth to 4 years, where M is the median figure, S is the coefficient of variation and L is a measure

of skewness of the data relative to a normal distribution and any re-issues, updates and amendments to those tables or the data in them.

**"Growth Charts"** are electronic charts developed and used in-house by the TRUST that report centiles and SDS.

**"Party"** means either the MRC or the TRUST and **"Parties"** shall mean both of them.

**"Permitted Purpose"** means the use of the LMS Tables by the TRUST for in-house use only to develop Growth Charts for human clinical diagnostic use, research and teaching activities with an objective for the furtherance of public health.

1.2 In this Agreement, any reference to:-

- (i) a statutory provision includes a reference to any modifications or re-enactment of it from time to time;
- (ii) Clause(s) is to clause(s) of this Agreement; and
- (iii) the singular includes the plural and vice versa.

1.3 The headings used in this Agreement shall not affect the interpretation of this Agreement.

## **2 LICENCE**

- 2.1 Subject to the other Clauses of this Agreement, the MRC hereby grants the TRUST a non-exclusive, non-sublicensable licence to use, reproduce, copy, display and distribute the LMS Tables solely for the Permitted Purpose. For the avoidance of doubt, this licence does not include the right to alter or delete any of the coefficients contained in the LMS Tables.
- 2.2 Following the development of the Growth Charts using the LMS Tables, the TRUST acknowledges and agrees that it is not permitted to make either the LMS Tables or the Growth Charts available to any third party, without the prior written consent of the MRC.
- 2.3 It is expressly understood and agreed by the TRUST that the LMS Tables and Growth Charts will at all times be used in accordance with the provisions of this Agreement plus all applicable laws and regulations. For the avoidance of doubt, this shall include compliance with: (i) the restrictions and obligations shown in Schedule 1; and (ii) all legal requirements relating to the supply and use of *in vitro* diagnostic medical devices as set out in the Medical Devices Regulations 2002 (SI No 618), as amended by the Medical Devices (Amendment) Regulations 2008.
- 2.4 The TRUST shall not claim any right to prevent others from using the LMS Tables.
- 2.5 The Parties acknowledge and agree that Professor Cole has not waived any moral rights which he has in the LMS Tables. The TRUST further acknowledges and agrees that the MRC is the copyright holder of the LMS Tables and agrees that it will not remove any copyright or other notices from the LMS Tables.
- 2.6 The TRUST shall not subcontract any work related to the development of the Growth Charts to a third party who is not party to this Agreement.

## **3 MATERIALS TRANSFER**

- 3.1 MRC agrees to supply the LMS Tables in electronic form to the TRUST as soon after the Effective Date as is reasonably possible.

#### **4 CONSIDERATION**

- 4.1 The licence granted pursuant to Clause 2 shall be free of charge. The TRUST hereby further agrees that it will not use the LMS Tables and/or its Growth Charts to advertise, endorse or promote products, brands, services or companies.

#### **5 WARRANTY AND LIABILITY**

- 5.1 The MRC warrants that:
- (a) the LMS Tables were produced by Professor Cole in the course of his employment by the MRC;
  - (b) the LMS Tables are an original work in the copyright sense (i.e. not copied from any other source) and that as a result, as far as the MRC knows, the MRC owns the copyright in such work.
  - (c) it has the right to grant the licences granted under this Agreement; and
  - (d) it has the right to enter this Agreement.
- 5.2 Other than the limited warranty provided under Clause 5.1, the TRUST understands and agrees that the LMS Tables are provided without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied, and without representation or warranty that the use or supply of the LMS Tables will not infringe any patent, copyright, trademark or other right of any third party.
- 5.3 The TRUST warrants that it is entitled to enter into this Agreement and to fully comply with the relevant terms of this Agreement.
- 5.4 Save in relation to circumstances which would amount to a breach of the limited warranty provided under Clause 5.1 above, MRC shall not be liable to the TRUST in respect of any claim of infringement of any third party intellectual property rights, occasioned by any direct or indirect use of the LMS Tables permitted under this Agreement.
- 5.5 Subject to the limitations shown in Clause 5.7, the MRC shall indemnify and hold harmless the TRUST against all costs, damages, claims, expenses and liabilities brought against the TRUST by third parties to the extent they directly arise from a breach of the limited warranty provided under Clause 5.1 above. This indemnification is provided on the condition that the TRUST promptly informs the MRC upon receipt of any applicable claim, the MRC handles all proceedings relating to the claim, the TRUST provides the MRC with reasonable assistance at MRC's cost in relation to such legal proceedings, including in relation to access to documents and to individuals, as MRC shall reasonably request, and the TRUST shall not make any agreement, settlement or claim in respect thereof without the written permission of the MRC. Furthermore, the MRC reserves the right to terminate this Agreement immediately following receipt of such a claim by the TRUST. The Parties agree that the indemnity provided under this Clause 5.5 shall not extend to any such claims to the extent said claims arise from the TRUST's wilful misconduct or negligent acts or omissions.
- 5.6 Subject to the indemnity provided under Clause 5.5 and the limitations shown in Clause 5.7, the TRUST agrees to indemnify and hold harmless the MRC for any loss, claim, damage or liability, of whatsoever kind or nature, which may arise from, or in connection with this Agreement or the use of the LMS Tables or the Growth Charts by the TRUST, except to the extent that such loss or damages arises out of the MRC's

wilful misconduct or negligent acts or omissions. This indemnification is provided on the condition that the MRC promptly informs the TRUST upon receipt of any applicable claim, the TRUST handles all proceedings relating to the claim, the MRC provides the TRUST with reasonable assistance at TRUST's cost in relation to such legal proceedings, including in relation to access to documents and to individuals, as TRUST shall reasonably request, and MRC shall not make any agreement, settlement or claim in respect thereof without the written permission of the TRUST. Furthermore, the TRUST reserves the right to terminate this Agreement immediately following receipt of such a claim by the MRC. The Parties agree that the indemnity provided under this Clause 5.6 shall not extend to any such claims to the extent said claims arise from the MRC's wilful misconduct or negligent acts or omissions.

- 5.7 The liability of either Party to the other under this Clause 5 will not extend to any indirect damages or losses, including any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity, even if the Party bringing the claim has advised the other of the possibility of those losses, or if they were within the other Party's contemplation.

## **6 TERM AND TERMINATION**

- 6.1 This Agreement shall come into force on the Effective Date and, unless terminated earlier in accordance with the other provisions of this Clause 6, shall remain in full force and effect until the copyright in the LMS Tables expires.
- 6.2 Either Party may terminate this Agreement without cause by giving notice in writing to the other Party.
- 6.3 MRC may terminate this Agreement forthwith by notice in writing to the TRUST if the TRUST enters into liquidation, whether compulsory or voluntarily, or compounds with, or convenes a meeting of, its creditors or has a receiver appointed over all or part of its assets or takes or suffers any similar actions in consequence of a debt or ceases for any reason to carry out its business.
- 6.4 Upon termination of this Agreement and unless the TRUST comes to a further agreement with MRC relating to the LMS Tables, the TRUST shall forthwith:
- (a) cease to use the LMS Tables and any version of the Growth Charts that contains or otherwise incorporates any form of the LMS Tables;
  - (b) destroy all copies of the LMS Tables in the TRUST's possession or control;
  - (c) destroy any versions of the Growth Charts that contain or otherwise incorporate any form of the LMS Tables, which the TRUST has in its respective possession or control;
  - (d) deliver to the MRC a statement, signed by an authorised representative of the TRUST, certifying that such items have been so destroyed and that only one (1) copy of the LMS Tables and one (1) copy of any such Growth Charts has been retained by the TRUST in a secure location solely for the purpose of enabling the TRUST to comply with the provisions of this Agreement.

For the avoidance of doubt, nothing in this Clause 6.4 shall prevent the TRUST from retaining in a secure location one (1) copy of any version of the Growth Charts as is strictly required to ensure compliance of that party with any applicable law or statutory regulation.

- 6.5 The expiration or earlier termination of this Agreement for whatever reason shall not affect the accrued rights of the Parties arising in any way out of this Agreement as at the date of such expiration or termination. In addition, all provisions of this Agreement that are expressed to survive this Agreement shall remain in full force and effect after said date. For the avoidance of doubt, the expiry or termination of this Agreement shall not affect the accrued obligations under Clauses 2, 4 and 5, including in relation to any rights granted by the TRUST to third parties as permitted by this Agreement, before the date of such expiry or termination.

## **7 ASSIGNMENT**

- 7.1 Without prejudice to Clause 2 and subject to Clause 7.2 below, neither Party shall assign, transfer or in any other manner make over to any other party the benefit and/or burden of this Agreement without the prior written consent of the other Party.
- 7.2 The TRUST shall be entitled to assign or transfer in the manner prohibited by Clause 7.1 above to an affiliate or to any other legal entity with which it may transfer its assets and undertaking, provided that such affiliate or other legal entity undertakes and agrees in writing to observe the rights and obligations of the TRUST under the provisions of this Agreement being assigned or otherwise being made over. The TRUST shall promptly inform the MRC in writing of any such assignment or transfer.

## **8 GENERAL PROVISIONS**

- 8.1 This Agreement shall be governed by and construed in accordance with the laws of England. The Parties hereby submit to the exclusive jurisdiction of the courts of England in relation to any dispute arising out of this Agreement.
- 8.2 No modification of this Agreement shall be binding upon either Party unless approved in writing by an authorised representative of each of the Parties.
- 8.3 If any Clause or any part of any Clause is declared invalid or unenforceable by the judgment, decree, consent or otherwise of a court of competent jurisdiction:
- (a) such invalidity or unenforceability shall not affect the validity and enforceability of the rest of this Agreement, which shall survive in full force and effect;
  - (b) such provision shall be deemed deleted and severed from this Agreement; and
  - (c) such deleted provision shall be replaced by such modified provision as shall have the closest effect to the deleted provision but shall at the same time be valid, practicable and enforceable.
- 8.4 No failure or omission by either Party to carry out or to observe any of the terms or conditions of this Agreement will, except in relation to obligations to make payments hereunder, give rise to any claim against the Party in question or be deemed a breach of this Agreement if such failure or omission arises from any cause beyond the reasonable control of that Party.
- 8.5 No relaxation, forbearance, delay or indulgence by either Party in enforcing any of the terms or conditions of this Agreement or the granting of time by either Party to the other shall prejudice, affect or restrict the rights and powers of that Party nor shall any waiver by either Party of any breach of this Agreement operate as a waiver of or in relation to any subsequent or any continuing breach of this Agreement.
- (a) This Agreement embodies the entire agreement between the Parties as to the subject matter hereof and merges all prior discussions in relation thereto.

- 8.6 MRC and the TRUST shall first attempt to settle by mutual agreement all disputes and differences arising under this Agreement.
- 8.7 The TRUST may not use the name of the Medical Research Council or of its research establishments or staff for any promotional or publicity purposes, other than under terms expressly agreed by the MRC. The MRC will be supplied with copies of all such material for approval prior to publication.
- 8.8 A person who is not a Party to this Agreement shall have no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.

## **9 NOTICES**

- 9.1 Any notice or document given by a Party to the other Party under this Agreement shall be in writing and will be deemed to have been duly given if:
- (a) in the case of delivery by hand, when delivered; or
  - (b) in the case of sending by post:
    - (i) where posted in the country of the addressee, on the second working day following the day of posting, and
    - (ii) where posted in any other country, on the fifth working day following the day of posting; or
  - (c) in the case of facsimile or other electronic transmission, on acknowledgement by the recipient's facsimile/electronic receiving equipment on a business day if the acknowledgement occurs before 17.00 hours local time of the recipient and in any other case on the following business day.
- 9.2 Unless and until otherwise advised by a Party, any notice or document given by a Party to the other Party under this Agreement shall be sent to:

In the case of the MRC:

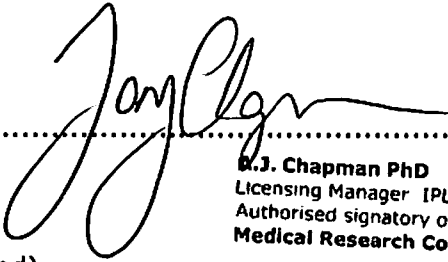
Director of Intellectual Property and Licensing  
Medical Research Council Technology,  
Lynton House, 7-12 Tavistock Square,  
London WC1H 9LT, UK  
FAX 0207 391 7200

In the case of the TRUST:

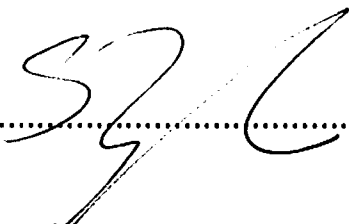
Commercial Solicitor  
Legal Services  
King's College Hospital NHS Foundation Trust  
Denmark Hill  
London SE5 9RS  
FAX 0203 299 3706

IN WITNESS WHEREOF this Agreement has been signed by the duly authorised representatives of the MRC and the TRUST.

Signed for and on behalf of the **MEDICAL RESEARCH COUNCIL**

Signature.......... Date.....01-AUGUST-2014.....  
Name (Printed).....**Dr. J. Chapman PhD**.....  
Licensing Manager IPL, MRCT  
Authorised signatory on behalf of  
Medical Research Council..... Title.....

Signed for and on behalf of **KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST**

Signature.......... Date.....12 AUGUST 2014.....  
Name (Printed).....SIMON TAYLOR..... Title.....CFO.....

**Schedule 1 – Restrictions and obligations applying to:**

**A. blood pressure centile charts**

- a) Charts should reference: Jackson, L. V., Thalange, K.S. and Cole, T. J. Blood pressure centiles for Great Britain. Arch. Dis. Child (2007); **92**: 298-303.
- b) Charts should not be used for the purposes of advertising or promoting other products.
- c) Chart design should be sufficiently different from the design of any existing third party charts so as to avoid being mistaken for such charts.

**B. UK90 data and WHO data charts**

- a) Charts should not be used for the purposes of advertising or promoting other products.
- b) Chart design should be sufficiently different from the design of any existing third party charts so as to avoid being mistaken for such charts.

