H. Lundbeck A/S
9 Ottiliavej DK-2500 Valby
Copenhagen Denmark
Tel +45 3643 2769
Fax +45 3643 8292
E-mail rwb@lundbeck.com
www.lundbeck.com

110405

Department of Pharmacology
Institute of Neuroscience and Physiology
Sahlgrenska Academy
University of Gothenburg
POB 431
SE 405 30 Gothenburg
Sweden
Attn.: Elias Eriksson

Date 28 March, 2011

Our ref

Dear Elias

Re.: Collaboration Agreement for signoff.

Please find enclosed 2 samples of above for your perusal. Kindly ensure sign-off on both samples, retain one sample for your files, and return one sample to me at your earliest convenience.
Thank you

Kind regards
H. Lundbeck A/S

pp. Rikke Winther,
Divisional Director
Outsourcing Management

Collaboration Agreement

between

University of Gothenburg
Department of Pharmacology
Institute of Neuroscience and Physiology
University of Gothenburg
POB 431
SE 405 30 Gothenburg
Sweden

(hereinafter referred to as "University")

and

H. Lundbeck A/S
Ottiliavej 9
DK-2500 Copenhagen-Valby,
Denmark

(hereinafter referred to as "**Lundbeck**")

University and Lundbeck may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

The Parties hereby agree as follows:

1. Objective

1.1 This Collaboration Agreement ("Agreement") shall set out the general terms and conditions under which the University shall perform and supervise a research project ("Research Project") proposed by the University. The Research Project shall be based on the University's existing expertise, facilities and know-how pertinent to the subject of each Research Project.

2. Conduct of the Research Project

2.1 The University shall perform the Research Project at its own premises. Professor Elias Eriksson, MD. shall be the principal researcher at the University to perform the Research Project (the "Principal Researcher"). Company agrees that the Principal Researcher may not be substituted without the prior written approval of Lundbeck. In the event the Principal Researcher becomes either unwilling or unable to perform the duties required by this Agreement, the University shall endeavour, in good faith and expeditiously, to find a replacement researcher acceptable to Lundbeck. In the event an

acceptable substitute is not found, Lundbeck may terminate this Agreement in accordance with Article 6.3

2.2 Upon Lundbeck's request the Parties shall discuss and liaise regarding the present status and results of the Research Project in order to optimise the completion hereof.

2.3 The University shall upon completion of the Research Project submit a final concluding report to Lundbeck ("Final Report"). The Final Report shall be provided to Lundbeck as soon as practicably possible following completion of the Research Project and in all cases prior to any publication by University allowing Lundbeck a peer review of the Final Report.

2.4 The University undertakes to conduct the Research Project with all due diligence within the time schedule agreed between the Parties and in accordance with the highest professional standards and in a timely, competent and efficient manner.

2.5 For the performance of the Research Project Lundbeck will deliver to the University selected analysis datasets from a selected group of studies for Lundbeck's proprietary compound Citalopram. Such datasets will be unblinded by Lundbeck, although necessary precautions will be taken by Lundbeck to ensure that the data are anonymous at the individual patient level allowing anonymous transfer of the data ("Analysis Datasets"). The University warrants that (i) the Analysis Datasets will be used by the University exclusively for the Research Project, and (ii) the University will not make the Analysis Datasets available or in any other way accessible to any of the University personnel not responsible for the Research Project or to any third party without the prior written and express consent from Lundbeck in each case. In addition the University acknowledges and accepts that the Analysis Datasets are provided "as is" and that Lundbeck provides no warranty, express or implied, as to the accuracy, completeness or usefulness of the Analysis Datasets.

3. Confidentiality

3.1 Each Party shall keep the other Party's scientific, technical or other information and/or know-how, which they may gain access to during the performance of the Agreement, including the Analysis Datasets ("Project Information"), confidential. Each Party further undertakes to keep confidential (i) all Research Results (as defined below) belonging to the other Party as set out in Article 5, and (ii) information gained in connection with an arbitration as set forth in Article 9.2, including the award rendered by the Arbitration Institute.

3.2 The confidentiality obligation set out in Article 3.1 above shall not apply to (i) Project Information published with the prior written consent of the other Party, or (ii) Project Information made available to the public by a third party who did not acquire directly or indirectly the Project Information from the other Party, (iii) Project Information which was, is or become part of the public domain without breach of the Agreement by a Party, or (iv) Project Information which is required by law to be disclosed, in which case the Party receiving such request shall promptly notify the other party of such request.

3.3 The Parties agree to disclose the other Party's Project Information and Research Results only to those of their employees who for the proper performance of the Research Project must be granted access to such, provided that such employees are obligated to hold the Project Information and Research Results confidential as set forth herein.

3.4 Notwithstanding the above Lundbeck or any Lundbeck affiliate or sub-contractor shall be entitled to any and all commercial or non-commercial use whatsoever of any results, findings, Research Results (as defined below) or conclusions pertinent to a Research Project or of any Project Information at any time.

3.5 Neither Party shall be entitled to use the other Party's name, nor the name of any member of the other Party's staff, in any publicity, advertising or news release without the other Party's prior written approval.

4. Payment

4.1 The Parties agree that the University's shall not receive any remuneration for the performance of the Research Project.

5. Intellectual Property Rights

5.1 Ownership to the results achieved by the University during the University's work with the Research Project, including the Final Report, (the "Research Results") shall be vested in the University ("University Proprietary Information") provided, however, that the University grants to Lundbeck a perpetual, world-wide, royalty free, non-exclusive right, with a right to grant multiple tiers of sublicenses, to use the Final Report for any purpose.

5.2 Notwithstanding the foregoing, University acknowledges that Lundbeck has a proprietary interest in the Analysis Datasets, including its proprietary compound Citalopram, (collectively "Lundbeck Proprietary Information"). The Parties agree that any improvements to Lundbeck Proprietary Information are the sole property of Lundbeck.

6. Term and Termination

6.1 The Agreement shall become effective as from the date of signature of the Party last to sign ("Effective Date") and shall, unless terminated as set forth herein, continue in full force and effect until the completion of the Research Project and Lundbeck's receipt of the Final Report(s), c.f. Article 2.3.

6.2 Lundbeck shall, however, be entitled to terminate the Agreement in its entirety at any time and for any reason with immediate effect upon written notice. If Lundbeck so terminates the Agreement, the University shall return to Lundbeck the Analysis Datasets, destroy any copies hereof and refrain from any further use hereof.

6.3 The Agreement may upon written notice from the non-defaulting Party be terminated forthwith by the non-defaulting Party in case of material breach remaining unremedied for more than seven (7) days. The filing for bankruptcy, insolvency or payment suspen-

sion proceedings against either Party shall entitle the other Party to terminate the Agreement with written notice to take effect forthwith.

7. Assignment

7.1 Without Lundbeck's prior written approval the University shall not be entitled to assign, transfer or subcontract any of the University's rights or obligations hereunder to any third party. The University shall ensure that any accepted subcontractors shall adhere to the provisions of the Agreement and the University shall be responsible towards Lundbeck for any performance under the Agreement by said subcontractors. Lundbeck may assign, transfer or subcontract its rights or obligations hereunder to any Lundbeck affiliate.

8. Liabilities

8.1 The University shall be liable for all losses, damages, liabilities, reasonable attorney fees, court costs and expenses, including personal injury losses (collectively "Losses") incurred by Lundbeck arising from or relating to the University's performance under the Agreement to the extent said Losses are caused by the University's negligent or intentional acts or omissions.

8.2 Lundbeck shall be liable for all Losses incurred by the University arising from or relating to Lundbeck's performance under the Agreement to the extent said Losses are caused by Lundbeck's negligent or intentional acts or omissions.

9. Applicable law and Arbitration

9.1 Any dispute arising from or relating to the Agreement shall be settled in accordance with Danish law.

9.2 In the event of any controversy or claim arising out of or relating to any provision of the Agreement or the breach, termination or invalidity thereof, the Parties shall try to settle the problem amicably between themselves. Should they fail to agree, the matter in dispute shall be settled by arbitration in accordance with the Rules of Procedure of the Danish Institute of Arbitration ("The Arbitration Institute"). The award rendered shall be final and binding and enforceable by any court having jurisdiction. The Arbitration Court shall consist of one (1) member and shall have its seat in Copenhagen. The language of the proceedings shall be English. The Arbitration Institute shall appoint the arbitrator on request by a Party hereto.

10. Miscellaneous

10.1 Any amendment to the Agreement shall be agreed upon in writing and signed by the Parties hereto.

10.2 The appendices to the Agreement shall form an integral part of the Agreement and shall be regarded as incorporated into the Agreement in every respect. In case of inconsistency between the terms and conditions of the appendices and the Agreement, the latter shall prevail to the extent of such inconsistency but no further.

10.3 Failure of either Party to insist upon a strict performance of any of the provisions of the Agreement or to enforce its rights under the Agreement at any time for any period shall not be construed as a waiver of any such rights. Time is of the essence in respect of all issues governed by the Agreement.

10.4 In the implementation of and performance under the Agreement, each Party shall comply with any and all relevant and applicable laws. Such compliance shall be the sole responsibility of such Party requiring no supervision, direction, responsibility or liability on behalf of the other Party.

10.5 The Agreement shall supersede all previous agreements and amendments written or oral between the Parties on the subject matter hereof.

10.6 The University warrants to process all personal data, including the data in the Analysis Datasets, in accordance with a separate agreement on "Personal Data Processing" which is attached to the Agreement as Appendix 2.

10.7 The Agreement has been made in duplicate and signed by the Parties hereto.

Appendix 1 Description of the Research Project

Appendix 2 Agreement between the Parties regarding Personal Data Processing

Place: Hillerød 1/4 2011

H. Lundbeck A/S

Helle Mengel
Vice President
Biometric Science & Pharmacovigilance

Place: Gothenburg 5/4 2011

University of Gothenburg

Elias Eriksson
Professor, MD

Appendix 1 to
to Collaborator Agreement
between H. Lundbeck A/S ("Lundbeck") and
Department of Pharmacology, Institute of Neuroscience and Physiology, University of Gothenburg ("University")
executed version dated 28 March 2011
hereinafter ("the Agreement")

SIGNATURE PAGE

RETROSPECTIVE ANALYSIS OF THE POSSIBLE RELATIONSSHIP BETWEEN BASELINE SYMPTOM PROFILE AND RESPONSE TO PHARMACOLOGICAL TREATMENT IN DEPRESSION

Date: 1 April 2011
H. Lundbeck A/S

Helle Mengel
Vice President
Biometric Science & Pharmacovigilance

Date: 5/4 2011
Department of Pharmacology
Institute of Neuroscience and Physiology
Sahlgrenska Academy
University of Gothenburg

Elias Eriksson, Professor, MD.

Appendix 1 to
to Collaborator Agreement
between H. Lundbeck A/S ("Lundbeck") and
Department of Pharmacology, Institute of Neuroscience and Physiology, University of Gothenburg ("University")
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RETROSPECTIVE ANALYSIS OF THE POSSIBLE RELATIONSSHIP BETWEEN BASELINE SYMPTOM PROFILE AND RESPONSE TO PHARMACOLOGICAL TREATMENT IN DEPRESSION

Background:

Many large antidepressant trials have failed to reveal a significant difference between the tested drug and placebo. This has led some authors even to question if these drugs exert any antidepressant effect, and it has also influenced clinical practice, in the sense that authorities in many countries haveconcluded that cognitive behavioural therapy is as effective as pharmacological treatment for the treatment of depression, and that antidepressants drugs should hence not be regarded as first line of treatment.

Contrasting the negative outcome of many trials, there are however also many studies showing a clear-cut and statistically significant superiority of the tested antidepressant drug versus placebo. Whereas a negative outcome of a study can be attributed methodological problems (=type II-error), a significant difference between active drug and placebo should not appear by chance. In a situation where some studies suggest a drug to be clearly superior to placebo, and other studies fail to find such a difference, it is hence reasonable to assume that the outcome of the positive trials is more trustworthy than that of the negative studies. Most authors of treatment recommendations, however, do not argue along these lines, but regard positive and negative studies as equally informative, and believe that the sum effect of all available studies (calculated e.g. by using meta-analyses) reflects the true efficacy of the drug.

A key issue for the interpretation of the current literature in the depression field, and for the design of future antidepressant trials, hence must be to clarify why trials assessing the efficacy of a certain substance often yield very different results; i.e. why there are so many failed trials in spite of the fact that most antidepressants clearly have an antidepressant effect. One possibility, that in our view is the most likely one, is that a factor of major importance in this context is that of inclusion: i.e. that the outcome of a study to a great extent depends on the clinical characteristics of the included patients.

Description of project:

Many companies have conducted post-hoc analyses of the outcome of their antidepressant trials in order to search for response predictors, but these analyses (or at least those that have been published) have mainly focussed on the issue of baseline severity. The scope of the current project is much broader, in the sense that many parameters, apart from severity, will be assessed.

The aim of step 1 of this project is to conduct post-hoc analyses of 3-4 trials in which (preferably different) selective serotonin reuptake inhibitors (SSRIs) have been compared to placebo (or to placebo and an active comparator) with respect to the possible relationship (on the individual level) between baseline symptom profile and outcome. These initial analyses will be hypothesis-generating, and include the testing of numerous possibilities, focussing on if the absence or presence of certain symptoms (or symptom constellations) at baseline predict response (or non-response) to active drug and placebo, respectively, but also addressing issues such as age, gender, onset of action, drop-out etc.

Since findings obtained at step 1 may probably not survive correction for multiple comparisons, given the large number of analyses that will be undertaken, our project will also comprise a step 2, in which we will use the data from 3-4 other trials in order to assess if the hypotheses emanating from step 1 are possible to replicate in independent samples

Required contributions from pharmaceutical companies:

Although it is likely that attempts similar to those outlined above have been undertaken within different drug companies, an advantage of this study is that we will request data from different companies, concerning different drugs, and that we hence hopefully will be able to identify predictors of importance for the efficacy of all antidepressant drugs, or all drugs belonging to a certain class (such as the SSRIs). To or knowledge, such attempts have not been made before, or at least never been published.

We are well aware of the fact that many drug companies have traditionally been reluctant to disclose raw data from their studies to extramural researchers. On the other hand, within the scientific community, there are today increased demands for openness, and for public access to data, not least within the field of drug trials, which has led many companies to reconsider their previous policy never to make raw data available for scrutiny by external researchers. In order to increase the willingness of the companies that we approach for this project to give us access to their data files, this study will only comprise drugs that are no longer under patent protection, such as the first-generation SSRIs.

Request:

For the reasons discussed above, we would be very grateful if H Lundbeck would give us access to raw data from a number of studies comparing citalopram (*not* escitalopram) with placebo (or with placebo plus an active comparator) for the treatment of depression. The individual data, for all included participants, that we would need, is the following: *i)* baseline rating, *ii)* symptom assessments throughout the treatment period, *iii)* CGI-data (and/or other global response assessments), *iv)* information regarding drop-out (and, if available, reason for drop out), *v)* age, *vi)* gender,*vii)* treatment arm, *viii)* centre (in case the study is a multicentre one) and *ix)* order of inclusion (if not equivalent to the code number). Studies where HAM-D or BDI have been used for baseline assessment are more useful than those in which inclusion has been based on MADRS only. If the study has been a failed trial, not showing a difference between citalopram orplacebo, or if such a difference was obtained, is not important; ideally, we would like to include trials of both type. Needless to say, for integrity reasons, the data files should be completely de-identified.

Elias Eriksson
phone: +709 55 50 55
email: elias.eriksson@neuro.gu.se

Appendix 2
to Collaborator Agreement
between H. Lundbeck A/S ("Lundbeck") and
Department of Pharmacology, Institute of Neuroscience and Physiology,
University of Gothenburg ("University") hereinafter ("the Agreement")
executed version dated 28 March 2011

Data Protection Agreement regarding processing of personal data

WHEREAS the parties have entered into the Agreement,

WHEREAS this Appendix 2 sets out the obligations of the UNIVERSITY relating to the protection of Clinical Research Data relating to or deriving from the conduct of clinical studies,

WHEREAS the terms defined in the Agreement shall have the same meaning herein as therein unless otherwise explicitly indicated,

WHEREAS "the Definitions" shall mean the terms defined in the list at the end of this Appendix,

WHEREAS this Appendix shall form an integral part of the Agreement and shall be regarded as incorporated into the Agreement in every respect as from the date this Appendix is executed by both parties. All other terms and conditions of the Agreement shall remain in force unchanged. In case of inconsistency between the terms and conditions of the Agreement and this Appendix the Agreement shall prevail as set out in the Agreement.

1. Introduction to this Appendix

1.1 The background for this Appendix is that when Lundbeck is processing Clinical Research Data as defined in the Definitions, Lundbeck is according to the Danish Act on Processing of Personal Data [1] (Act no. 429 of May 31 2000 as amended from time to time hereinafter "the Danish Act on Processing of Personal Data ") acting as Data Controller ("hereinafter CONTROLLER"), and must therefore comply with certain terms and conditions issued by the Danish Data Protection Agency (hereinafter referred to as "the Danish Conditions") and any other regulation on safety measures with regard to data processors, that may be in force in the member state where the data processing takes place (together named as: "CONDITIONS") on behalf of Lundbeck.

1.2 As part of the obligation incumbent on the CONTROLLER according to the Danish Conditions the CONTROLLER must ensure that the PROCESSOR

[1] Implementing Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Data Protection Agreement regarding processing of personal data

can and will comply with the Danish Conditions, which are incumbent on the CONTROLLER, and furthermore must ensure that the PROCESSOR when processing Clinical Research Data for the CONTROLLER complies with the CONDITIONS.

1.3 When UNIVERSITY is processing Clinical Research Data on behalf of the CONTROLLER, UNIVERSITY is according to the above Danish Act on Processing of Personal Data, acting as the PROCESSOR as defined in the Definitions.

1.4 For the sake of clarity the PROCESSOR should note that it is the current interpretation of the Danish Act on Processing of Personal Data by The Danish Data Protection Agency, that Clinical Research Data will not be anonymous, as long as the Subject Identification Code List is kept by the Investigator. During the processing of Clinical Research Data all Clinical Research Data Subjects are identified by the Subject Identification Code to protect the identity of the Clinical Research Data Subjects. Neither the CONTROLLER nor the PROCESSOR are able or permitted to identify the Clinical Research Data Subjects when the Clinical Research Data has been removed from the Trial Site. Only Clinical Research Data which in accordance with applicable laws and regulations is required to be retained on the Trial Site after the completion or termination of the clinical study may be retained by the Processor, but only to the extent necessary to comply with the said applicable laws and regulations.

1.5 Further the Danish Data Protection Agency holds the CONTROLLER responsible for requesting sufficient information from the PROCESSOR, to enable the CONTROLLER to ensure that the PROCESSOR will comply with these Conditions at any time during the Clinical Research Data processing.

1.6 If the PROCESSOR is established in a different member state of the EU than Denmark (hereinafter a "Member State") or an Approved Country, the PROCESSOR warrants that it will fulfil any such additional provisions on technical and organisational security measures, as laid down by the relevant local legislation and/or authorities in the Member State or the Approved Country incumbent on the PROCESSOR.

1.7 It is a prerequisite for use of this Appendix, that the clinical research, in which the Clinical Research Data are provided for or produced in, is conducted according to the applicable guidelines, if relevant.

2 General conditions

2.1 The PROCESSOR is only permitted to process Clinical Research Data included under the Agreement and for, which the CONTROLLER is responsible throughout the duration of the data processing services described in the Agreement and such processing shall only be performed in compliance with the instructions given by the CONTROLLER including but not limited to the content of this Appendix, and any applicable Conditions.

2.2 The PROCESSOR must not use, process or disclose the Clinical Research Data related to the CONTROLLER for any other purpose than as set out in the Agreement including but not limited to for its own purposes or disclose Clinical Research Data to a third party or transfer Clinical Research Data to a third country (as defined in the Definitions) without the explicit prior written approval of the CONTROLLER.

2.3 The PROCESSOR is not permitted to publish and/or in any way present any part of the Clinical Research Data without prior written approval by the CONTROLLER or as set out in the Agreement. If publication of results from the Clinical Trials is permitted by the CONTROLLER or mandatory according to local law such must be done in a way ensuring against disclosing the identity of the Clinical Research Data Subjects").

2.4 The PROCESSOR must provide the CONTROLLER with any and all information as deemed necessary by CONTROLLER about the technical and organisation security measures and/or equipment and procedures related to the processing of Controller's Clinical Research Data.

2.5 The PROCESSOR warrants that it will at any time permit CONTROLLER's Quality Assurance Department and/or any relevant Data Protection Agency access to audit/inspect the facilities of the PROCESSOR and/or the Clinical Research Data processing services for compliance with the CONDITIONS. The PROCESSOR further warrants that it will assist such adequately in order to conduct the audit.

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2.6 If the PROCESSOR cannot provide compliance with the CONDITIONS and/or any other relevant data protection legislation, for whatever reason, the PROCESSOR must promptly inform the CONTROLLER hereof in writing for the attention of the person signing the Agreement.

2.7 The PROCESSOR agrees to deal promptly and properly with all inquires from the CONTROLLER relating to the processing of the CONTROLLER´s Clinical Research Data.

2.8 The PROCESSOR agrees to promptly notify the CONTROLLER in writing about:

- any legally binding request for disclosure of Clinical Research Data,
- any accidental or unauthorised access to Clinical Research Data,
- any request received directly from the Clinical Research Data Subjects or from Investigators.

2.9 Regarding the processing of the CONTROLLER´s Clinical Research Data the PROCESSOR warrants that the Clinical Research Data will at any time:

- be processed fairly and lawfully,
- not be processed in a way incompatible with those purposes they are collected for as specified in the clinical research/trial protocol attached to the Agreement,
- the Clinical Research Data is only disclosed to UNIVERSITY personnel, which are participating in the Clinical Research.

2.10 The PROCESSOR warrants that it will not to the extent such is legally possible respond to requests from the Clinical Research Data Subjects or any other request for disclosure of the data unless prior written approval has been obtained from the CONTROLLER.

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3 Disclosure to a third party/transfer to a third country

3.1 The PROCESSOR must not disclose Clinical Research Data to any third party, and/or transfer Clinical Research Data to Third countries unless prior specifically written agreement is obtained from the CONTROLLER.

4 Technical and organisational security measures:

4.1 All facilities used for storage and processing of Clinical Research Data, must have access control and/or restricted access to prevent access by non-authorised persons.

4.2 The processing of Clinical Research Data should be organised in a way, so that the necessary checks are made to ensure that no inaccurate or misleading Clinical Research Data are processed.

4.3 The PROCESSOR may only access the Clinical Research Data using a secure and controlled IT system, which includes but is not limited to confidential passwords and, which ensures that unauthorized access to Clinical Research Data cannot take place. Such password has to be changed at least every three (3) months or when special conditions mandate this.

4.4 Removable storage medias including security copies must be securely stored under lock and in a way preventing unauthorised access to the Clinical Research Data.

4.5 When transmitting Clinical Research Data via the Internet or other external networks, the PROCESSOR is responsible for ensuring that necessary security measures to prevent access of unauthorised persons apply. As a minimum Clinical Research Data must be encrypted during the transmission. Transmission of sensitive Clinical Research Data requires an encryption algorithm based on at least 128 bit key and complying with the specifications for the encryption standard: AES. When using internal networks, un-authorised access must be prevented.

4.6 The CONTROLLER will instruct the PROCESSOR about storage of Clinical Research Data, after the Clinical Research Data processing task by the PROCESSOR according to the Agreement is completed. Clinical Research Data must be stored in compliance with the current applicable guidelines, if relevant.



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5 Manual Clinical Research Data

5.1 Manual material such as print outs, error- and control lists etc. and other material, which direct or indirectly may refer to specific Clinical Research Data Subjects, must be securely stored, locked away, preventing unauthorised access.

6 Bio-bank and biological material

6.1 Samples with biological samples and biological material in bio-banks must be stored securely locked up, preventing unauthorised access and preventing that the material is lost, deteriorated or accidentally or illegally destroyed.

6.2 Biological material marked with subject identifiers (civil registration number or name) has to be stored under special secure conditions.

6.3 The PROCESSOR must establish internal guidelines for storage of biological material in connection with the individual trial, as well as guidelines for storage of biological material in bio-bank. The guidelines must be updated at least annually and the CONTROLLER shall either be supplied with copy of any applicable and/or updated versions of such guidelines or it should be available for inspection by the CONTROLLER.

7 Information of the Clinical Research Data Subjects

7.1 When collecting and/or monitoring the Clinical Research Data the PROCESSOR is responsible for monitoring that the investigator obtains informed consent including consent for the use of such data from the Clinical Research Data Subjects. As part of this the PROCESSOR must therefore ensure that the Clinical Research Data Subjects are informed about:

7.1.1 The purpose of collecting the Clinical Research Data and that Lundbeck is the CONTROLLER.

7.1.2 That participation in the trial is voluntary, and that consent may be withdrawn at any time

7.1.3 To whom the Clinical Research Data will be disclosed and for what purpose data are disclosed (i.e. to regulatory national and/or international health and/or medicines authorities).

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7.1.4 That the Clinical Trial is notified to the data protection agencies as required in accordance with mandatory regulations regarding Personal Data, and that the Agency has laid down specific terms to be complied with for the purpose of protecting the Data Subject's privacy.

7.1.5 If Clinical Research Data are to be transferred to a Third country, the PROCESSOR is responsible for including such information in the information to the Clinical Research Data Subject.

8 Deletion of Clinical Research Data

8.1 Deletion of Clinical Research Data from electronic media must be done in a way preventing Clinical Research Data recovery.

This Appendix has been made in duplicate and signed by the parties hereto and to the Agreement.

Place and date

CPH. 28. MAR. 2011

For H. Lundbeck A/S

Henrik L. Sønnichsen

Head of Department

Clinical Data Management

Place and date

Gbg 5/4 2011

Department of Pharmacology, Institute of Neuroscience and Physiology

University of Gothenburg

Elias Eriksson, Professor, MD.

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DEFINITIONS:

APPROVED COUNTRIES: shall mean non-EU-member states, which are approved by EU as having at least the same level of data protection measures as a EU member state. Approved countries shall not include Third Countries.

BIOBANK: Shall mean a structured collection of human biological material accessable according to certain criterias, and where the information in the biological material refers to identifiable persons.

CLINICAL DATA SUBJECT´S CONSENT: Any freely given specific and informed indication of his wishes by, which the data subject signifies his agreement to personal data relating to him being processed.

CLINICAL RESEARCH DATA SUBJECTS: Any patient enrolled in Clinical Trials and from whom any clinical research data/personal data are obtained/collected.

CLINICAL RESEARCH DATA: Shall mean Personal Data obtained during Clinical Trials.

CLINICAL TRIALS: Shall mean the testing of pharmaceutical compounds and/or methods on humans.

CONTROLLER: A natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of processing of personal data.

IDENTIFIABLE: Can be identified, directly/indirectly by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

INVESTIGATOR: Shall be defined as in the current applicable guidelines, if relevant.

MEMBER STATE: shall mean member states of EU.

PERSONAL DATA: Any info relating to an identified/identifiable natural subject (data subject)

PROCESSING: Any operation or set of operations, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination etc.

PROCESSOR: A natural or legal person, public authority, agency or any other body, which processes data on behalf of the CONTROLLER.

RECIPIENT: A natural or legal person, public authority, agency or any other body to whom the data are disclosed, whether a third party or not; however authorities which may receive data in the framework of a particular inquiry shall not be regarded as recipient.

SUBJECT IDENTIFICATION CODE: A confidential list of names of all subjects allocated to the trial numbers kept by the investigator.

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SUBJECT IDENTIFICATION CODE LIST: Shall be defined as in the current applicable guidelines, if relevant.

TECHNICAL AND ORGANISATIONAL MEASURES: shall mean the legislation protecting the fundamental rights and freedoms of natural persons and in particular their right to privacy with respect to the processing of personal data applicable to a data CONTROLLER in the Member State, where the Controller is established.

THIRD COUNTRY: Any state which is not a member of the European Community and which has not implemented agreements entered into with the European Community which contain rules corresponding to those laid down in Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

THIRD PARTY: A natural or legal person, public authority, agency or any other body other than the data subject, the processor, the CONTROLLER and the persons who, under the direct authority of the CONTROLLER or the Processor, are authorised to process the data.

TRIAL SITE: Shall be defined as in the current applicable guidelines, if relevant.

UNIVERSITY: Contract Research Organisation, including laboratories, pharmacies, SMOs (Site Management Organisations), TMOs (Trial Management Organisation), Off Storage Archives, contract auditors or any other organisation or person to whom, clinical research work or part of it is contracted.