Standard Operating Procedure (SOP)

Recruitment procedure

Ambulatory Care Setting

Version 2.0

1. Aim

This SOP is intended to provide a minimum set of services in the context of recruiting the ambulatory care settings (including the participants) in Bangladesh, Norway, Pakistan, Poland, the United Kingdom of Great Britain and Northern Ireland (UK), (England, and Northern Ireland). In addition, the regional management teams should take into account the specific cultural and local circumstances in their individual study region.

2. Scope of the SOP

The scope refers to all study regions and ambulatory care facilities involved in the EUthyroid2 ambulatory care setting.

3. Abbreviations

BUHS	Bangladesh University of Health Sciences
GDPR	General Data Protection Regulation
ICP	Islamia College Peshawar, Pakistan
JU	Jagiellonian University, Poland
IMR	Institute of Marine Research, Norway
NDA	Non-Disclosure Agreement
SOP	Standard Operating Procedure
SURREY	University of Surrey, UK
QUB	Queen's University Belfast, UK
UK	United Kingdom of Great Britain and Northern Ireland (England and Northern Ireland)

4. Background

The participating study regions Bangladesh University of Health Sciences (BUHS), Institute of Marine Research, Norway (IMR), Islamia College Peshawar, Pakistan (ICP), Jagiellonian University, Poland (JU), University of Surrey, UK (Surrey) and Queen's University Belfast, UK (QUB) are supposed to recruit a final study population with a complete follow-up data set of 200 participants per region, whereas Surrey and QUB count as one region. Participant recruitment should follow a uniform procedure within each region. This SOP serves as a minimum standard for all settings. Documents are provided in English and should be translated into local languages by the Regional Management of the participating study regions as required. Any changes beyond this basic SOP must be reported to the Steering Committee.

5. Processes

5.1. Flow chart

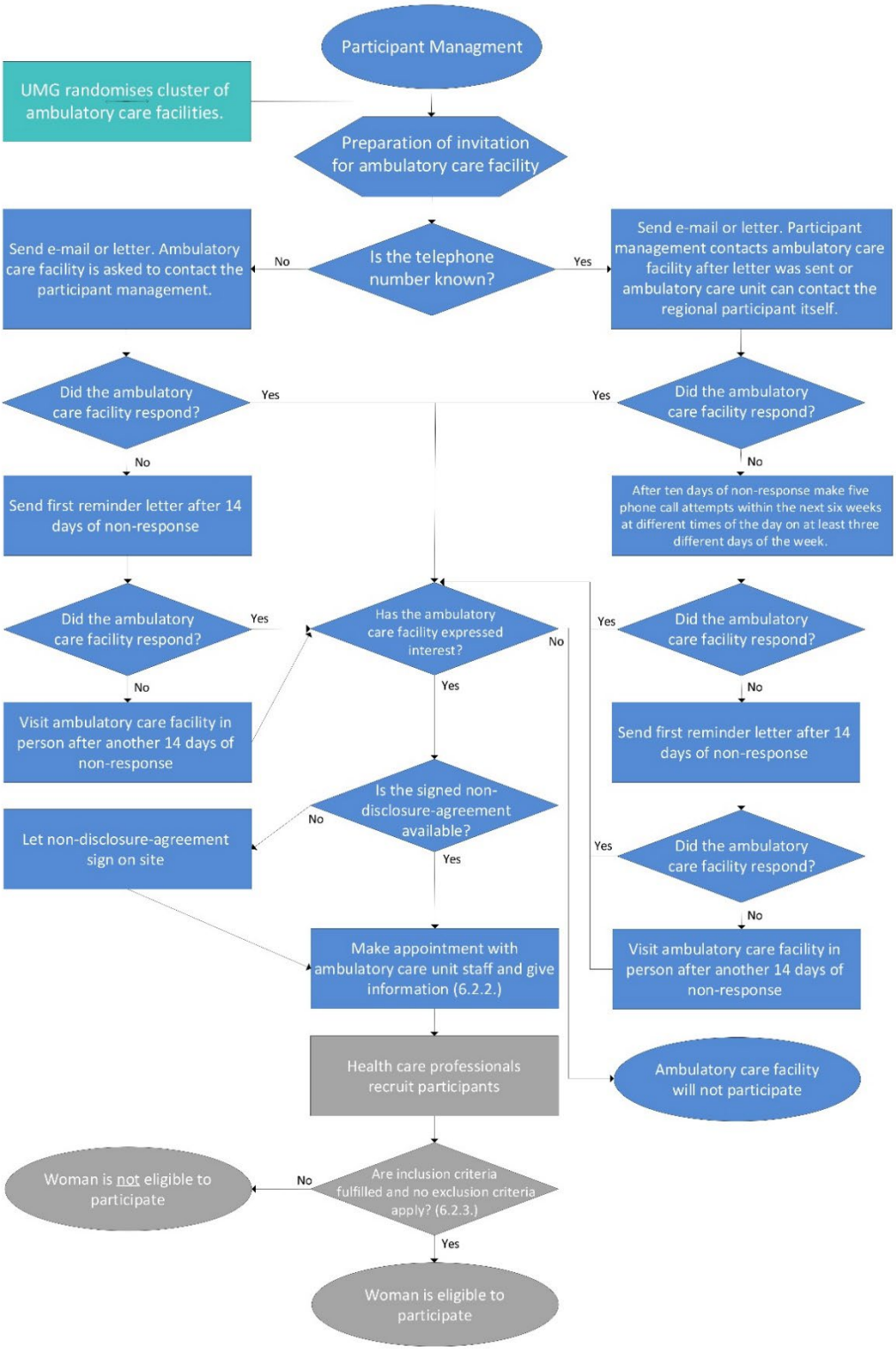

Figure 1. Recruitment process in the ambulatory care setting. Tasks of UMG are marked in turquoise, tasks of the Participant Management are marked in blue, whereas tasks in which the responsibility lies with the health care professionals are marked in grey.

5.2. Recruitment process baseline survey

Each study region operates its own and Participant Management (PM) Regional Management (RM). The participant management is exclusively responsible for the initiation of recruitment (Invitations to participate in the study), administration of address data and consents. A Participant Management employs staff to manage the participants' personal identifying data and ensure that it is processed according to the General Data Protection Regulation (GDPR).

5.2.1. Involvement of ambulatory care facilities

The PM or RM will search for potential ambulatory care facilities and inform them about the study. The PM will manage the contact details of the ambulatory care facilities and the participating healthcare professionals and women with a software of their choice (e.g MS office or something similar).

Potential ambulatory care facilities, who represent clusters, will be randomly allocated into either the intervention or control group. For example, 5 facilities which act as intervention groups and 5 facilities which are control groups. Once the clusters are recruited, the project partner UMG conducts the randomisation. If not all clusters have been known or it turns out that the existing clusters are not sufficient to achieve the target numbers cannot be achieved with the existing clusters, the study can already be started and further clusters can be added in the course of the study. These additional clusters will then also be randomised by the UMG.

5.2.1.1. Invitation

The initial contact to the ambulatory care facilities will be made in writing a letter or an email. The written invitation contains:

- A standardised cover letter
- A standardised response form to make an appointment including non-disclosure agreement
- Prepaid return envelope (if invitation is sent by letter)
- Study information flyer
- Optional: letter of support from local mayor, politicians, ministries, or other important opinion leader

A) Ambulatory care facility with known telephone number

In the cover letter that is send to ambulatory care facilities with a known telephone number, it is announced that a staff member will contact them by telephone in the next few days or they are welcome to contact the staff member themselves either by telephone, email or the enclosed response letter (incl. request for telephone number(s) and availability). If there is no response to the invitation letter within ten days, the study staff will make at least five attempts within the next four weeks at different times of the day and on at least three different days of the week to establish telephone contact. If these attempts are unsuccessful, a reminder letter with reply and prepaid envelope will be sent with the request to actively contact the participant management (see below section: “Reminder procedure”). All contact attempts should be documented in order to be able to demonstrate to the European Commission that the best possible efforts were made to recruit the targeted cluster size per region (see attachment “Documentation of Invitation”).

B) Ambulatory care facility with unknown telephone number

In the cover letter that is sent to ambulatory care facilities for which no telephone number could be researched, those contacted are asked to inform the Participant Management either by telephone, email or the enclosed reply letter with a stamped envelope of the times at which a personal appointment to present the project would be possible. If the institution contacted makes contact by telephone or email and does not provide its telephone number of its own accord, it should be requested. If institutions with an unknown telephone number do not respond to the invitation letter within fourteen days, they will be sent a reminder letter with a reply and prepaid envelope analogous to the procedure described above (see below “Reminder procedure”).

Reminder procedure

If the ambulatory care facilities do not respond to the initial contact attempt (in writing) or if no contact could be made by telephone, a first reminder letter is sent (analogous to the procedure for the initial letter under point B) with a reply and prepaid envelope, etc. This letter should contain wording suitable for both cases (initial telephone contact or written contact attempt) or be adapted to the respective case. If no contact can be made after another waiting period of two weeks, the ambulatory care unit can be visited in person.

5.2.2. Agreements on participation of ambulatory care facilities

After the ambulatory care facility has expressed interest and the Non-disclosure agreement (NDA) is signed, an appointment is made by telephone or in-person.

If an ambulatory care facility has expressed interest without sending back the signed NDA, an appointment can still be made and the signed NDA will be obtained on site.

During the appointment, the following information will be given:

- General project information
- Participant information
- Training plan for the staff performing the study
- Consent forms
- Compliance with data protection regulations
- Viewing materials
- Settlement of the expense allowance (if applicable)

If there is still interest in participating, a second appointment is made to plan and prepare the implementation and to contractually regulate participation.

5.2.3. 6 Recruitment of study participants

The healthcare professionals recruit participants for the study on behalf of the regional management. They will essentially present the contents of the participant information and then issue the informed consents.

Inclusion-and exclusion criteria

Inclusion criteria:

- Female
- Age 18-24 years at the time point of recruitment
- Attending the specified settings

Exclusion criteria:

- Having a thyroid disease
- Existing pregnancy at the time point of recruitment and during the intervention period
- Lactating women

If the participant has insufficient language skills (is not sufficiently proficient in the local language to understand the consent form or the questions in the interview and questionnaires as well as instructions from the healthcare professional), they should be offered to bring along an accompanying person (with the function of an interpreter) who will translate accordingly.

1. Appendix/Referrals

- Attachment 1 Standardised cover letter
- Attachment 2 Study Information Flyer
- Attachment 3 Documentation of Invitation
- Attachment 4 Template Non-Disclosure Agreement

Attachment 1: Standardised cover letter

[Healthcare Professional's Name]
[Healthcare Professional's Department]
[Healthcare Organization's Address]
[City, State, ZIP Code]

Dear [Healthcare Professional's Name],

As part of the ongoing commitment to advancing patient care and promoting evidence-based practices, we are writing to invite you to participate in an upcoming EU-funded intervention study that holds great promise for improving healthcare outcomes in our region and beyond.

At EUthyroid2, we recognise the pivotal role that healthcare professionals play in shaping the quality of care delivered to our community. It is with great excitement that we extend this invitation to you, knowing that your expertise and dedication will significantly contribute to the success of this important research initiative.

This intervention study, entitled EUthyroid2, is the follow-on project of the initial "EUthyroid" that uncovered major limitations in European prevention programmes against iodine deficiency including our country, and it aims to improve the low awareness with respect to iodine deficiency-related risks in young women. Your participation in this study will not only contribute to the growth of scientific knowledge but will also have a direct impact on enhancing the care we provide to our patients.

We have carefully selected a distinguished team of researchers and experts to lead this study, and we are confident that your involvement will enrich the collaborative efforts. Your valuable insights and experience are crucial to the success of this research, and we believe that your participation will benefit the success of this intervention study itself as well as contribute to new evidence in the research of iodine deficiency.

To facilitate your participation, we have attached detailed information about the study, including [...] . We understand that your time is precious. In appreciation of your time and commitment, we are pleased to offer a compensation of [amount of money] for each patient included in the study. Furthermore, we assure you that all efforts will be made to accommodate your schedule and streamline the process to ensure a seamless experience.

Should you have any questions or require further clarification, please do not hesitate to contact us at our EUthyroid2 office.

Thank you for your consideration and your ongoing commitment to advancing healthcare in our region.

Sincerely,
[Name of regional representative]
Head of the Regional Management in [your country]

EUthyroid2 Office
Regional Management of [your country]
[Regional Management's Address]
[City, State, ZIP Code]
[Email Address]
[Phone Number]

Attachment 2: Study Information Flyer- Tri-fold leaflet

Our vision is:

- to find the best ways to inform adolescents and young women on the importance of iodine, increase their knowledge on iodine and improve their iodine status
- to take steps towards the elimination of iodine deficiency in Europe and beyond

Our goals are:

- to raise awareness about the importance of iodine for health, and the risks of iodine deficiency-related disorders
- to have a positive impact on the health of young people, their iodine intake habits, and the health of their future offspring

Join us in the EUthyroid2 project!

Find out more about the project:

https://euthyroid2.eu

Feel free to contact us:

EUthyroid2@qub.ac.uk

Join us in the EUthyroid2 project!

EUthyroid2

- No extra effort needed as all materials needed to take part in the study will be provided
- The study will accommodate your schedule

Photo credits:
© shutterstock.com/Tatjana Baibakova (iodine-sources)
© iStock.com/vreeki: fakes (two women)

Co-funded by the European Union

UK Research and Innovation

Who we are:

A team of researchers, medical experts, and non-profit organisations collaborate in the EUthyroid2 project to improve awareness with respect to the importance of iodine and the risks of iodine deficiency in adolescents and young women.

For this purpose, the EUthyroid2 research team developed interventions for the healthcare and educational settings.

We invite you to participate in the healthcare setting which is designed to educate young women (18-24 years old).

Who is invited to participate?
The healthcare setting intervention will be conducted in 4 European countries (England, Northern Ireland, Norway, and Poland) and 2 non-European countries (Bangladesh and Pakistan).

What are we asking from healthcare settings
If you as a healthcare setting decide to participate, we will accommodate your schedule and **no extra effort will be needed**, we will provide you with all the information you need. You will be allocated to a control or an intervention group.

What does the intervention group do?
In the intervention group, healthcare professionals will be trained to **provide information material** and **educate young women on the importance of iodine**.

To find out if the intervention worked well, healthcare professionals and women will be surveyed on iodine awareness and their experiences with the intervention.

What does the control group do?
The control group will be surveyed as well and will have the possibility to access the intervention material after all surveys are finalised.

Our offer to you:

If you decide to participate in the study as a healthcare setting, this will require no extra effort to take part as **you will receive all the information and materials you need for participation**.

In appreciation of your time and commitment, **we are pleased to off er a small fi nancial incentive** for each participant included in the study.

Be part of increasing young women's awareness about the importance of iodine and improving their iodine status for their own health and that of their future off spring.

[Study region]

Contact the EUthyroid2 team at:
[contact details: study region]

Attachment 3: Documentation of invitation

A) Ambulatory care facilities with known telephone number

If there is **no response** to the invitation letter **within ten days**, the study staff will make at least **five attempts** within the next four weeks at different times of the day and on at least three different days of the week to establish telephone contact. If these **attempts are unsuccessful, a reminder letter** with reply and prepaid envelope will be sent with the request to actively contact the participant management.

Ambulatory care Facility	Dispatch date of invitation letter	Date of 1st telephone contact	Date of 2nd telephone contact	Date of 3rd telephone contact	Date of 4th telephone contact	Date of 5th telephone contact	Dispatch date of reminder letter

B) Ambulatory care facilities with unknown telephone number

Ambulatory care facility	Dispatch date of invitation letter	Date of Response	Dispatch date of reminder letter	Date of visit Ambulatory care facility

Attachment 4: Non-Disclosure Agreement

NON-DISCLOSURE AGREEMENT ON EUthyroid2 (PROJECT 101095643)

This agreement is entered into on this [DD.MM.YY] by and between:

[Insert Name of ambulatory care facility and authorized signatory]

based in [insert address of Ambulatory care facility], hereinafter referred to as the *Discloser* and the EUthyroid2 partner:

[Insert Study Region and Regional Management]

hereinafter referred to as the *Recipient*

WHEREAS:

The Discloser and Recipient hereto desire to collaborate on a European funded project in the field of Public Health, particularly on Iodine Deficiency.

Throughout the aforementioned collaborations, Parties may share between themselves proprietary information or Confidential Information under the terms and covenants set forth below.

NOW IT IS AGREED AS FOLLOWS:

1. Confidential Information

1.1 For the purposes of this Agreement, Confidential Information means any data or proprietary information of the Discloser that is not generally known to the public or has not yet been revealed, whether in tangible or intangible form, whenever and however disclosed, including, but not limited to:

(i) any scientific or technical information, invention, design, process, procedure, formula, improvement, technology or method;

(ii) any concepts, samples, reports, data, know-how, works-in-progress, designs, drawings, photographs, development tools, specifications, software programs, source code, object code, flow charts, and databases;

(iii) any marketing strategies, plans, financial information, or projections, operations, sales estimates, business plans and performance results relating to the

Discloser's past, present or future business activities, or those of its affiliates, subsidiaries and affiliated companies;

(iv) trade secrets; plans for products or services, and customer or supplier lists;

(v) any other information that should reasonably be recognized as Confidential Information by the Discloser.

1.2 The Discloser and the Recipient agree hereby that Confidential Information needs not to be novel, unique, patentable, copyrightable or constitutes a trade secret in order to be designated Confidential Information and therefore protected.

1.3 Confidential Information shall be identified either by marking it, in the case of written materials, or, in the case of information that is disclosed orally or written materials that are not marked, by notifying the Recipient of the confidential nature of the information. Such notification shall be done orally, by e-mail or written correspondence, or via other appropriate means of communication.

1.4 The Recipient hereby acknowledge that the Confidential Information proprietary of the Discloser has been developed and obtained through great efforts and shall be regarded and kept as Confidential Information.

1.5 Notwithstanding the aforementioned Confidential Information shall exclude information that:

(i) is already in the public domain at the time of disclosure by the Discloser to the Recipient or thereafter enters the public domain without any breach of the terms of this Agreement;

(ii) was already known by the Recipient before the moment of disclosure (under evidence of reasonable proof or written record of such disclosure);

(iii) is subsequently communicated to the Recipient without any obligation of confidence from a third party who is in lawful possession thereof and under no obligation of confidence to the Discloser;

(iv) becomes publicly available by other means than a breach of the confidentiality obligations by the Recipient (not through fault or failure to act by the Recipient);

(v) is or has been developed independently by employees, consultants or agents of the Recipient (proved by reasonable means) without violation of the terms of this Agreement or reference or access to any Confidential Information

pertaining to the Discloser.

2. Purpose of the Disclosure of Confidential Information

The Discloser and Recipient will collaborate on a European funded project in the field of Public Health, particularly on Iodine Deficiency.

3. Undertakings of the Recipient

3.1 In the context of discussions, preparations or negotiations, the Discloser may disclose Confidential Information to the Recipient. The Recipient agrees to use the Confidential Information solely in connection with purposes contemplated in this Agreement and not to use it for any other purpose or without the prior written consent of the Discloser.

3.2 The Recipient will not disclose and will keep confidential the information received, except to its employees, representatives or agents who need to have access to the Confidential Information for the purpose of carrying out their duties in connection with the permitted purposes specified in clause 2. The Recipient will inform them about the confidential quality of the information provided and will ensure that their agreement is obtained to keep it confidential on the same terms as set forth in this Agreement. Hence the Recipient will be responsible for ensuring that the obligations of confidentiality and non-use contained herein will be strictly observed and will assume full liability for the acts or omissions made for its personnel representatives or agents.

3.3 The Recipient will use the Confidential Information exclusively for the permitted purpose stated in clause 2 and not use the information for its own purposes or benefit.

3.4 The Recipient will not disclose any Confidential Information received to any third parties, except as otherwise provided for herein.

3.5 The Recipient shall treat all Confidential Information with the same degree of care as it accords to its own Confidential Information.

3.6 All Confidential Information disclosed under this Agreement shall be and remain under the property of the Discloser and nothing contained in this Agreement shall be construed as granting or conferring any rights to such Confidential Information on the Recipient. Principally, nothing in this Agreement shall be deemed to grant to the Recipient a licence expressly or by implication under any patent, copyright or other intellectual property right. The Recipient hereby acknowledges and confirms that all the existing and future intellectual property rights related to the Confidential Information are exclusive titles of the Discloser. For the sake of clarity based in good faith, the Recipient will not apply for or obtain any intellectual property protection in respect of the Confidential

Information received. Likewise any modifications and improvements thereof by the Recipient shall be the sole property of the Discloser.

3.7 The Recipient shall promptly return or destroy all copies (in whatever form reproduced or stored), including all notes and derivatives of the Confidential Information disclosed under this Agreement, upon the earlier of (i) the completion or termination of the dealings contemplated in this Agreement; (ii) or the termination of this Agreement; (iii) or at the time the Discloser may request it to the Recipient.

3.8 Notwithstanding the foregoing, the Recipient may retain such of its documents as required to comply with mandatory law, provided that such Confidentiality Information or copies thereof shall be subject to an indefinite confidentiality obligation.

3.9 In the event that the Recipient is asked to communicate the Confidential Information to any judicial, administrative, regulatory authority or similar or obliged to reveal such information by mandatory law, it shall notify promptly the Discloser of the terms of such disclosure and will collaborate to the extent practicable with the Discloser in order to comply with the order and preserve the confidentiality of the Confidential Information.

3.10 The Recipient agrees that the Discloser will suffer irreparable damage if its Confidential Information is made public, released to a third party, or otherwise disclosed in breach of this Agreement and that the Discloser shall be entitled to obtain injunctive relief against a threatened breach or continuation of any such a breach and, in the event of such breach, an award of actual and exemplary damages from any court of competent jurisdiction.

3.11 The Recipient shall immediately notify upon becoming aware of any breach of confidence by anybody to whom it has disclosed the Confidential Information and give all necessary assistance in connection with any steps which the Discloser may wish to take prevent, stop or obtain compensation for such a breach or threatened breach.

3.12 The Confidential Information subject to this Agreement is made available "as such" and no warranties of any kind are granted or implied with respect to the quality of such information including but not limited to, its applicability for any purpose, non-infringement of third party rights, accuracy, completeness or correctness. Further, the Discloser shall not have any liability to the Recipient resulting from any use of the Confidential Information.

3.13 The Discloser is not under any obligation under this Agreement to disclose any Confidential Information it chooses not to disclose.

3.14 Nothing in this Agreement shall be construed to constitute an agency, partnership, joint venture, or other similar relationship between the Discloser and Recipient.

4. Miscellaneous

4.1 Duration and Termination

4.1.1 This Agreement shall remain in effect from the date of signature until the official end of the project (currently 31.12.2026). Notwithstanding the foregoing, the Recipient's duty to hold in confidence Confidential Information that was disclosed during the term shall remain in effect indefinitely,save otherwise agreed.

4.1.2 If the Discloser and Recipient succeed in the call for proposal referred to in clause 2 and sign the corresponding Grant Agreement (GA) and Consortium Agreement (CA), or entered into partnership under any other kind of collaborative agreement (COA) or association agreement (AA), the non-disclosure provisions of the CA, COA and AA shall supplement this Agreement. In the event that non-disclosure provisions are not provided for the said private agreements in equal terms as stated herein, this Agreement shall remain in force until the end of the collaboration undertaken.

4.2 Applicable Law and Jurisdiction

This Agreement shall be construed and interpreted by the laws of Belgium. The court of Brussels, Belgium shall have jurisdiction.

4.3 Validity

If any provisions of this Agreement are invalid or unenforceable, the validity of the remaining provisions shall not be affected. The invalid or unenforceable provision shall be replaced by a valid and enforceable provision that will meet the purpose of the invalid or unenforceable provision as closely as possible.

4.4 Subsequent Agreements

Ancillary agreements, amendments or additions hereto shall be made in writing.

4.5 Communications

Any notices or communications required may be delivered by hand or e-mail, mailed by registered mail to the address of the Recipient/Discloser as indicated above. Any subsequent modification of addresses should be reasonably communicated in advance to the effect of this Agreement.

IN WITNESS WHEREOF**,** the Parties hereto have caused this Non-Disclosure Agreement to be executed as of the date stated above.

For the discloser

X _____