

PhOSCo General Licence

Guillemot Design Limited

Pharma Open Source Community

PhOSCo General Licence

General Terms and Conditions

<i>Date</i>	<i>Version</i>	<i>Revision History</i>	<i>Author</i>	<i>QA</i>
28/02/00	1.00	Initial Release	MAC-S	CAC
01/03/00	1.01	Amended Credit Card details, Service Provider subscription rates corrected	MAC-S	CAC
19/04/01	2.00	Amended in order to reflect simplified Business Model, updated distribution and subscription rates	MAC-S	CAC
25/03/02	3.00	Updated to reflect new terms.	MAC-S	CAC
20/03/03	4.00	Updated to reflect new terms.	MAC-S	CAC
04/02/04	5.00	Updated for Web Server and new Subscription structure	MAC-S	CAC
24/08/04	6.00	Amended US indemnity	MAC-S	CAC
06/10/04	7.00	Distribution in areas subject to "Software Patents"	MAC-S	CAC

Application Forms

Privacy Policy

Customers applying for PhOSCo Software licences and for PhOSCo Subscription Services are asked to provide certain information, such as name and contact information. Guillemot Design Ltd asks for this information in connection with registrations, credit-checks, research, and marketing programs, and will use this information to personalise its offerings and presentations to you, facilitate your movements throughout the PhOSCo Internet website, provide personalised services, and to communicate separately with you. User application, registration and usage data will only be used by Guillemot Design Ltd for the above purposes and not released to a third party without the users consent unless required by law.

Other information is optional and may be given at your discretion. Information that is optional is clearly identified. Some services may require that you provide personally identifiable information.

Guillemot Design Ltd holds no personal information about any individual person or organisation other than information expressly defined as exempted under United Kingdom Data Protection Acts. Guillemot Design Ltd is no longer registered under the UK Data Protection Acts.

General Information

This document provides you with all necessary information about the PhOSCo contracts as well as the forms for a first time application for a PhOSCo General Licence, for the ordering of additional Usage Packs, and for subscription to the Pharma Open Source Community.

We have tried to be as comprehensive and flexible as we can with these licence terms; if you feel that you don't fit any of the categories we have here, or that your use is special in some way, please contact us and we will be happy to discuss special terms.

Persons or organisations who use PhOSCo software for Non-Profit Research or Personal Use Activities are by the PhOSCo General Licence (the "Licence") granted the use of the software free of any charge provided they accept and adhere to the other terms of the Licence as described below and do not have to complete this application form or contact us. **Use of the software for non-commercial purposes implies your acceptance of these Licence terms.**

Non-Profit Research users who use PhOSCo software for Clinical Trials are requested to notify Guillemot Design Ltd of that use by an email to usage@phosco.com outlining the general nature and phase of the trial and its expected size, scope and duration - no commercially or academically sensitive information need be sent.

All users including Non-Profit Research or Personal Use Activities users may obtain PhOSCo software from the PhOSCo website, or websites of other Licenced users, such as www.phosco.org or the Dusseldorf KKS. The PhOSCo website will not provide all PhOSCo software - Restricted PhOSCo Materials are not available there. It will be possible to create, customise, and run Clinical Trials using PhOSCo materials apart from Restricted PhOSCo materials - see the website for details. To obtain Restricted PhOSCo Materials non-commercial users will either have to complete this document to apply for a PhOSCo licence and send it to Guillemot Design Ltd directly or via a Licenced User, or become a phOSCo Online Subscriber.

Areas subject to "Software Patent" legislation

Following recent legal decisions within the USA, and the decision of some potential licencees not to take up free academic PhOSCo licences due to the potential of third-party intellectual property claims, we have reluctantly come to the conclusion that we can no longer safely distribute or licence PhOSCo to the United States of America, or any other country or area where "software patents" are legally effective.

We wish to make it absolutely clear that so far as we are concerned, PhOSCo is 100% written by us, with no code other than unprotectable elements such as standard constructs and interface definitions taken from other sources, as with any software. We are not aware of any legitimate third-party claim against any element of PhOSCo.

However, recent events in the USA have shown that it is possible for patents to be granted and to appear that cover wide swathes of functionality that it is impossible for any large-ranging software package like PhOSCo to avoid. We (and others) have hitherto taken the view that these patents are or should be largely unenforceable because of their inherent invalidity, either due to prior art or to the fact of their being obvious to any skilled practitioner in the art (two tests for the validity of patents, normally applied in most patent regimes *before* the grant of a patent, but apparently untested by the US Patent Office).

It now appears that juries are finding such patents applicable, and that large companies who should be expected to vigorously defend against such wide-ranging patents are conceding them. These patents are thus acquiring the precedent of being enforceable under law. The known fact of their existence also places us, in the case of US law, under penalty of tripled punitive damages if we know of their existence and continue any so-called "infringement".

Small companies such as ourselves cannot stand against such legal extortion. For us, the lesser evil is not to do business under such a regime.

PhOSCo General Licence

Accordingly, from 9th October, 2004, PhOSCo is no longer licenceable in the United States of America or any other country or region that employs software patents. We will no longer distribute PhOSCo to such countries. While we cannot stop other persons distributing our software to such places, this is henceforth being done without our permission and contrary to the PhOSCo Licence. It is our position that previous versions of the PhOSCo Licence which allowed such distribution allow it only with the person or organisation doing the distribution being responsible for any third-party claims; and we request and strongly recommend to such licencees that they do not perform such distribution.

Personal Use

Note that you only have to complete this document and return it to Guillemot Design Limited if you intend to use the PhOSCo software for commercial gain or to run Clinical trials. If you intend to use the program, or code from it, purely for your personal use and enjoyment, not for commercial gain and not in conjunction with your trade and profession (except for purposes of education and training), you do not need to complete a licence application or communicate with us in any way, though we'd love to hear from you. You are still bound by the personal use terms of the PhOSCo licence and must respect our intellectual property rights.

You will not be given access to all PhOSCo programs or code -there are "restricted materials"; these are only available to licenced users (you may obtain them under "Other Commercial Use" conditions - see below).

Academic or Non-Profit Use

If you intend to use PhOSCo programs or code as part of your trade or profession but you are an academic or work for any other non-profit organisation, you need an Academic Licence.

You or your organisation must either become a PhOSCo subscriber or complete a copy of the PhOSCo General Licence document and send it to us as a paper copy. Until you have been confirmed as a subscriber or we have received that document and indicated to you that you are a licenced organisation (we will send you a licence certificate) you are not licenced to use PhOSCo programs or code.

You will only be given access to "restricted materials" once we have received a licence application from you or you have become a PhOSCo subscriber.

You will not have to pay a fee for any activities you perform unless you or your organisation receive money or "other valuable consideration" (such as shares, promises, patent rights and so on) in payment for the activity directly or indirectly from a commercial non-profit organisation. So:

- Pure research
- Purely Government or charity funded trials
- University or College education, training, and workshops
- Support of or running non-profit trials for other non-profit organisations

are all "non-profit" and will not attract a fee.

If, however, you perform any clinical trial which is even partly funded by any commercial organisation then that is a "for profit" trial and the standard commercial fee for the trial must be paid.

Commercial Use for Clinical Trials

If you are a commercial organisation that runs clinical trials, either as a prime agent or sponsor or on behalf of other organisations, you need a Commercial Licence and must pay a fee for each trial you run or purchase an Enterprise pack covering an unlimited number of trials.

You must complete a copy of the PhOSCo General Licence document and send it to us as a paper copy. Until we have received that document and indicated to you that you are a licenced commercial organisation (we will send you a licence certificate) you are not licenced to run clinical trials with PhOSCo.

PhOSCo General Licence

You will only be given access to "restricted materials" once we have received a licence application from you.

If you use a hosted service provided by a third party organisation you still must obtain a Commercial Licence for PhOSCo software or ensure that the third party obtains one on your behalf.

You can get any third party organisation you choose to perform support or other services you choose using the PhOSCo materials you have licenced; they do not themselves have to be licenced PhOSCo users. However, if they are not licenced users, you must take the responsibility of ensuring that they respect the intellectual property of PhOSCo as a whole and the confidentiality of restricted materials, and you will be responsible for any loss arising out of any breach of trust.

Use of PhOSCo software for commercial purposes without a licence document from Guillemot Design Limited is a violation of international copyright law.

Commercial Use by Service Providers

If you are an organisation that provides services for a fee to other organisations that run clinical trials that necessitates use of or access to PhOSCo Restricted Materials programs or code (this includes but is not limited to such activities as providing software development, maintenance, customisation, hosting services, and so on), you need a Commercial Licence unless your customer is a licenced organisation and you obtain Restricted Materials from them.

To become licenced you must complete a copy of the PhOSCo General Licence document and send it to us as a paper copy. Until we have received that document and indicated to you that you are a licenced Service Provider (we will send you a licence certificate) you are not licenced to perform services based on PhOSCo Restricted Materials, though you may of course offer to perform services on the understanding that you intend to obtain a licence.

You do not need to pay a fee for access to PhOSCo materials; however, you will not be given access by us to Restricted Materials unless you choose to subscribe to PhOSCo as described in Section C below, and your licence does not authorise the use of software for any commercial purpose by you or other parties. Any other commercially licenced PhOSCo user may give you access to Restricted Materials in their possession but only for the purposes of supporting that specific licenced user. If you wish to offer a complete packaged service including commercial licenced use of PhOSCo software you should contact us for a customised licence.

We will not unreasonably refuse a licence under this heading; we only reserve the right to do so in the case of organisations who we believe have in the past violated, are presently violating, or intend in the future to violate, our intellectual property rights.

The PhOSCo Online Subscriber program is not intended for use by Commercial Service Providers and such organisation should not use that process to obtain PhOSCo Restricted Materials. Restricted Materials received via the subscriber program do not provide an organisation with a licence for commercial use as service organisations.

Other Commercial Use

If you are a commercial organisation or user, you will have to obtain a licence from us if you:

- Use the PhOSCo programs or code or significant parts of them,
- Provide services based on the use of PhOSCo programs or code, or
- Create derived works from significant portions of PhOSCo code,

for profit or in direct support of profit-making activities.

You should contact us (email licence@phosco.com preferred) with an indication of the nature and volume of the use you intend. We will charge a fee for the issuing of a licence. If your use is minor or the revenue you make per year from this activity can be reasonably assessed at less than £5000 sterling, you may become a PhOSCo subscriber to obtain Restricted Materials.

PhOSCo General Licence

Provision of restricted materials

We will only provide restricted materials on a continuing basis to any licensee so long as they remain a PhOSCo subscriber.

Currently, restricted materials include the communications code and certain documentation. In future, other PhOSCo modules may be provided as restricted materials.

Completion of this Application

First time applicants should acknowledge that they have read every page of the entire document by marking them with their initials in the field at the bottom of each page. For orders of additional Usage Packs or the Renewal of the subscription only the respective Exhibits including your contract reference number are required.

Please send one duly signed paper copies of the required documents by surface mail to:

Licences&Subscriptions
Guillemot Design Ltd
South Boduel Farm
Moorswater
Liskeard
Cornwall PL14 4JZ
UNITED KINGDOM

We will send you a licence document together with an invoice for commercial users, and where applicable a copy of the PhOSCo software materials which are not available on the PhOSCo website. Allow 1-2 weeks for processing. At certain times of year, a delay of up to 4 weeks may occur; if time is critical, please contact us by email (licences@phosco.com).

Contact Information

* required fields
Company or Organisation *
Department *
First Name *
Last Name *
Position *
Title
Address *
Town or City *
County, State or Province
Postal Code *
Country *
Telephone *
Fax
E-mail *

Business Information

You may tick more than one choice, but must tick at least one	
<input type="checkbox"/>	Pharmaceutical, Biotech or Medical Devices Company
<input type="checkbox"/>	Contract Research Organisation (CRO)
<input type="checkbox"/>	Site Management Organisation (SMO)
<input type="checkbox"/>	Academic Research Centre
<input type="checkbox"/>	Professional Service Provider for IT related services; please specify in what areas you provide services
<input type="checkbox"/>	Packaged Software Company or Software Re-Distributor; please specify your plans concerning 'PhOSCo Clinical Trials'
<input type="checkbox"/>	Other; please specify the type of your business

What will you do with the 'PhOSCo Clinical Trials' software ?

You may tick more than one choice, but at least one. Please explain if you choose more than one area. You may find it useful to consult the ' Definitionsection	
<input type="checkbox"/>	Use 'PhOSCo Clinical Trials ' for Clinical Research
<input type="checkbox"/>	Use 'PhOSCo Clinical Trials ' of non Profit Research, please specify
<input type="checkbox"/>	Use 'PhOSCo Clinical Trials ' for Personal Use Activities, please specify
<input type="checkbox"/>	Provide IT related Services around 'PhOSCo Clinical Trials ' please specify
<input type="checkbox"/>	Use 'PhOSCo Clinical Trials ' for Other Activities, please specify

Billing Information

Please fill in Billing Address if other than Contact Address
Company or Organisation*
Department *
First Name *
Last Name *
Position *
Title
Address *
Town or City *
County, State, or Province
Postal Code *
Country *
Telephone *
Fax
E-Mail *

A. PhOSCo Contracts

The PhOSCo contracts covered in this document (the "Licence" and the "Subscription") are made and entered into by and between Guillemot Design Ltd (hereinafter "Original Developer"), a company engaged in licencing intellectual property, having principal offices at

South Boduel Farm
Moorswater
Liskeard
Cornwall PL14 4JZ
United Kingdom , and

_____ (hereinafter "You"),

having principal offices at

Export Law Assurances.

You may not use or otherwise export or re-export the PhOSCo Software except as authorised by English law and the laws of the jurisdiction in which the PhOSCo Software was obtained. In particular, but without limitation, the PhOSCo Software may not be exported or re-exported into (or to a national or resident of) any European Union embargoed country.

By using the PhOSCo Software, you represent and warrant that you are not located in, under control of, or a national or resident of any such country or on any such list.

USE SUBJECT TO JURISDICTION OF THE UNITED STATES OF AMERICA

Where any party to a contract with Guillemot Design Limited is situated in or is subject to or performs any act under any jurisdiction of the United States of America that party shall indemnify and hold Guillemot Design Limited harmless from any action extra-territorial or otherwise of any third party including but not restricted to government agencies of the United States of America with regard to copyright, copy protection legislation, infringement or other violation of software patent, or other intellectual property restrictions or legislation, and any costs arising from such action.

A.1. Definitions.

1. "**Clinical Research**" means the activity of conducting trials and studies, recording and collecting data for the purpose of establishing evidence about safety and/or efficiency and/or effectiveness and/or economical benefits of pharmaceutical, medical devices or biological products or of a treatment (e.g. Pre-clinical studies, phase I-IV trials, patient registries, pharmaeconomic or outcomes research, disease management studies).
2. "**Non-Profit Research**" means conducting Clinical Research exclusively for non-commercial, educational purposes or use within regulatory authorities or agencies (e.g. Academic or non-profit research educational establishments).
3. "**Personal Use Activities**" means recording medical data or any other data for pure internal or personal professional use other than Clinical or Non-Profit Research, and IT Related Services (e.g. Recording of patient records by a physician). Use of Covered code as a component of a Commercial Service is not Personal Use.
4. "**Other Activities**" means any other usage of the Covered Code for any commercial purpose other than Clinical, Non-Profit Research, Personal Use Activities, and IT Related Services.
5. "**IT Related Services**" means modifying, enhancing, testing, packaging, documenting, distributing, sublicensing, customising, setting up computer and networks, integrating, providing training, providing helpline or helpdesk service or any other value adding or distributing activity performed on, with, or around the Covered Code.
6. "**Contributor**" means each entity that creates or contributes to the creation of Modifications.
7. "**Covered Code**" means the Original Program or Modifications or the combination of the Original Program and Modifications, in each case including portions thereof.
8. "**Executable**" means Covered Code in any form other than Source Code.
9. "**Original Developer**" means Guillemot Design Ltd.
10. "**Larger Work**" means a work which combines Covered Code or portions thereof with code not governed by the terms of this Licence.
11. "**Licence**" means this document, excluding Part C ("Subscription Agreement: Restricted Materials Subscription and Online Subscription.").
12. "**Restricted Materials Subscription**" means this document, excluding Part B ("PhOSCo General Licence Contract").
13. "**Online Subscription**" means this document, excluding Part B ("PhOSCo General Licence Contract") and the application form and fee schedule of Part C ("Subscription Agreement: Restricted Materials Subscription and Online Subscription."), plus the application procedure and fee structure currently applicable on the PhOSCo website (www.phosco.com).

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14. "**Modification**" means any addition, deletion or alteration from the substance or structure of either the Original Program or any previous Modifications. When Covered Code is released as a series of files, a Modification is:
- A. Any addition to or deletion from the contents of a file containing the Original Program or previous Modifications.
 - B. Any new file that contains any part of the Original Program or previous Modifications
14. "**Original Program**" means Source Code of computer software code which is described in the Source Code notice required by Exhibit B-1 as Original Program, and which, at the time of its release under this Licence is not already Covered Code governed by this Licence.
15. "**Source Code**" means the preferred form of the Covered Code for making modifications to it, including all modules it contains, plus any associated interface definition files, scripts used to control compilation and installation of an Executable, or a list of source code differential comparisons against either the Original Program or another well known, available Covered Code of the Contributor' s choice. The Source Code can be in a compressed or archival form, provided the appropriate decompression or de-archiving software is widely available for no charge.
16. "**You**" means an individual or a legal entity exercising rights under, and complying with all of the terms of, this Licence or a future version of this Licence issued under Section B-5.1 or of the Subscription Agreement. For legal entities, "You" includes any entity which controls, is controlled by, or is under common control with You. For purposes of this definition, "control" means (a) the power, direct or indirect, to influence the direction or management of such entity, whether by contract or otherwise, or (b) ownership of fifty percent (50%) or more of the outstanding shares or beneficial ownership of such entity.
17. "**Electronic Distribution Mechanism**" means a mechanism generally accepted in the software development community for the electronic transfer of data.
18. "**General Distribution Copy**" means the packaging of the Covered Code including related documentation distributed under the "PhOSCo General Licence".
19. "**Download Area**" means a Electronic Distribution Mechanism where a Distribution Copy is made available for download.
20. "**Use**" or "**Usage**" means the act of running Covered Code in order to conduct Clinical Research, Non-profit Research, for Personal Use Activities or Other Activities.
21. "**Usage Terms**" means the terms governing the Use of Covered Code.
22. "**Use Type**" or "**Usage Type**" means the area for which You are Using the Covered Code, e.g. Clinical Research, Other Activities.
23. "**Usage Packs**" means acquiring the rights to Use Covered Code for multiple trials in advance for a pre-defined number or trials.

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24. "**Trial**" is used as a general term for trials, studies, recording and collecting data for the purpose of storing, retrieving, cleaning or analysing it.
25. "**Restricted materials**" is used to define source and executable code, documentation, and other materials that are not freely available on an unrestricted area of the PhOSCo website. Restricted PhOSCo materials will be distributed to licencees either directly or via a restricted area of the website.
26. "**Normal Trial**". A "Normal Trial" is a clinical trial or equivalent process in which information is collected from 25 or more Subjects.
27. "**Small Trial**". A "Small Trial" is a clinical trial or equivalent process in which information is collected from fewer than 25 Subjects.
28. "**Software Patent**". Any legal theory whereby the protection of patent law is extended to purely software expressions of ideas, algorithms, or processes.

B. PhOSCo General Licence Contract

B.0. General

1. The terms "PhOSCo" and "Pharma Open Source Community" are registered trade marks of Guillemot Design Ltd. Guillemot Design Ltd makes use of Service Partners' trade marks, service marks, trade names or other identifying information ("Third Party Trade marks"), and those Third Party Trade marks remain the sole and exclusive property of the applicable third parties.

2. The term "PhOSCo Clinical Trials" is a trade mark of Guillemot Design Ltd and must not be used to endorse or promote products derived from Guillemot Design Ltd' sPhOSCo Clinical Trials" software without the prior written and explicit permission of Guillemot Design Ltd. For written permission, please contact info@phosco.com.

3. The "PhOSCo Clinical Trials" software is copyright-protected and all rights are owned by Guillemot Design Ltd. Redistribution of the ' "PhOSCo Clinical Trials" software with or without Modifications or as part of a Larger Work must reproduce Guillemot' s copyright designation and this Licence in the documentation and/or other materials provided with the distribution.

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4. If You transmit Modifications (including feedback, materials, fixes, error corrections enhancements, suggestions and the like) to Guillemot Design Ltd or to the PhOSCo website, you automatically grant Guillemot Design Ltd a world-wide, royalty-free, irrevocable, non-exclusive licence under all intellectual property rights (including copyright) as described under B.1.2 without any obligation from Guillemot Design Ltd to pay a distribution fee. Guillemot Design Ltd will make available such Modifications and improvement suggestions from the PhOSCo website under its own name. Any deviation from this procedure needs to be agreed in writing by both parties.

5. You agree not to publish any part of the materials governed by this Licence without written prior permission of Guillemot Design Ltd. This does not affect your right to publish or communicate with any person any opinion or evaluation you may wish to.

6. GPL Software Extension Licence Notes:

PhOSCo software can use a component, the JCalendarBean GPL library, to handle the input of valid dates into Date widgets. JCalendarBean may be linked to the PhOSCo product through a switchable API such that PhOSCo software is not dependent on the JCalendarBean API. According to GPL conditions, you can find JCalendarBean source code at : <http://www.toedter.com/>

PhOSCo software can use a component, the Mckoi JDBC Database, to handle the storage of data in a local JDBC compliant datastore. Mckoi may be linked to the PhOSCo product through a switchable API such that PhOSCo software is not dependent on the Mckoi database. According to GPL conditions, you can find Mckoi source code at : <http://www.mckoi.com/database>

7. Government End Users. No special terms or privileges shall be assumed by any government users and such users shall be bound by the normal commercial terms of this licence.

PhOSCo General Licence

8. Areas subject to Software Patent Legislation. PhOSCo software is not available for licence and may not be distributed by the Original Developer or any licensee to any country, state, or region where the law at the time of licence or distribution allows the grant of Software Patent or otherwise allows software to fall under the scope of Software Patent, either from within that region or by extra-territorial jurisdiction howsoever caused.

No person from such an area shall request a PhOSCo Licence.

Any person from such an area whether conscious of the fact or not requesting or obtaining a purported licence shall not be validly licenced under this licence, and any such licence howsoever obtained shall not be a valid licence.

Countries known to be so subject include, but are not necessarily restricted to:

The United States of America

B.1. Source Code Licence.

B.1.1. The Original Developer Grant.

The Original Developer hereby grants You a world-wide, non-exclusive licence, subject to third party intellectual property claims:

(a) to reproduce, modify, display, run for activities other than Use, sublicense and distribute the Original Program (or portions thereof) with or without Modifications, or as part of a Larger Work subject to the following obligations:

- (i) only redistributing restricted PhOSCo materials to users intending Clinical Research or IT related Services use (other users may obtain restricted PhOSCo materials directly from the Original Developer or via a PhOSCo subscription);
- (ii) binding any recipient by the exact terms of this Licence;
- (iii) notifying the Original Developer in writing about recipients of the Covered Code to which You have distributed or sublicensed it within thirty (30) days;

(b) to Use the Original Program (or portions thereof) with or without Modifications, or as part of a Larger work for Clinical Research, Non-profit Research, Personal Use Activities or Other Activities subject to following obligations:

- (i) paying the Original Developer a fee for the Use of Covered Code according to the Use Type described in the Usage Terms in Exhibit B-2;

The Original Developer may decide at its sole discretion if and under which Use Type he will grant You the Licence; that decision may be revised at any time and without explanation.

The Original Developer without the obligation for any justification reserves the right not to grant You a Licence.

The Original Developer reserves the rights to contract an approved auditor in order to assess Your compliance with the Licence terms. In case a non-compliance situation is found the audit fees will be borne by You besides any other claims arising from such a situation.

B.1.2. Contributor Grant.

Each Contributor other than the Original Developer hereby grants You and the Original Developer a world-wide, royalty-free, irrevocable, non-exclusive licence under all intellectual property rights (including copyright) to Use, reproduce, modify, display, run for activities other than Use, sublicense and distribute the Modifications created (including any feedback, materials, fixes, error corrections enhancements, suggestions and the like) and distributed by such Contributor (or portions thereof) either on an unmodified basis, with other Modifications, as Covered Code or as part of a Larger Work

Contributor may charge a reasonable fee for the physical act of transferring a copy, and Contributor may at his option offer additional services and/or warranty protection in exchange for a fee.

B.2. Distribution Obligations.

B.2.1. Application of Licence.

The Modifications which You create or to which You contribute are governed by the terms of this Licence, including without limitation Section B.1.2, if said Modifications are made accessible, directly or indirectly, to a third party. The Source Code version of Covered Code may be distributed only under the terms of this Licence or a future version of this Licence released under Section B.5., and You must include a copy of this Licence with every copy of the Source Code You distribute. You may not offer or impose any terms on any Source Code version that alters or restricts the applicable version of this Licence or the recipients' rights hereunder. However, You may include an additional document offering the additional rights described in Section B.2.5.

B.2.2. Availability of Source Code.

Any Modification which You create or to which You contribute must be made available in Source Code form under the terms of this Licence either on the same media as an Executable version or via an accepted Electronic Distribution Mechanism to anyone to whom you made an Executable version available; and if made available via Electronic Distribution Mechanism, must remain available for at least twelve (12) months after the date it initially became available, or at least six (6) months after a subsequent version of that particular Modification has been made available to such recipients. You are responsible for ensuring that the Source Code version remains available even if the Electronic Distribution Mechanism is maintained by a third party.

B.2.3. Description of Modifications.

You must cause all Covered Code to which you contribute to contain a file documenting the changes You made to create that Covered Code and the date of any change. You must include a prominent statement that the Modification is derived, directly or indirectly, from Original Program provided by the Original Developer and including the name of the Original Developer in (a) the Source Code, and (b) in any notice in an Executable version or related documentation in which You describe the origin or ownership of the Covered Code.

B.2.4. Intellectual Property Matters

If You claim or have knowledge that a party claims an intellectual property right in particular functionality or code (or its use under this Licence), you must include a text file with the source code distribution titled "README-LEGAL" which describes the claim and the party making the claim in sufficient detail that a recipient will know whom to contact. If you obtain such knowledge after You make Your Modification available as described in Section B.2.2, You shall promptly modify the README-LEGAL file in all copies You make available thereafter and shall take other steps (such as notifying appropriate mailing lists or newsgroups) reasonably calculated to inform those who received the Covered Code that new knowledge has been obtained.

B.2.5. Required Notices.

You must duplicate the notice in Exhibit B-1 in each file of the Source Code, and this Licence in any documentation for the Source Code, where You describe recipients' rights relating to Covered Code. If You created one or more Modification(s), You may add your name as a Contributor to the notice described in Exhibit B-1. If it is not possible to put such notice in a particular Source Code file due to its structure, then you must include such notice in a location (such as a relevant directory file) where a user would be likely to look for such a notice. You may choose to offer, and to charge a fee for, warranty, support, indemnity or liability obligations to one or more recipients of Covered Code. However, You may do so only on Your own behalf, and not on behalf of the Original Developer or any Contributor. You must make it absolutely clear than any such warranty, support, indemnity or liability obligation is offered by You alone, and You hereby agree to indemnify the Original Developer and every Contributor for any liability incurred by the Original Developer or such Contributor as a result of warranty, support, indemnity or liability terms You offer.

B.2.6. Distribution of Executable Versions.

You may distribute Covered Code in Executable form only if the requirements of Section B.2.1-2.5 have been met for that Covered Code, and if You include a notice stating that the Source Code version of the Covered Code is available under the terms of this Licence, including a description of how and where You have fulfilled the obligations of Section B.2.2. The notice must be conspicuously included in any notice in an Executable version, related documentation or collateral in which You describe recipients' rights relating to the Covered Code. You may distribute the Executable version of Covered Code under a licence of Your choice, which may contain terms different from this Licence, provided that You are in compliance with the terms of this Licence and that the licence for the Executable version does not attempt to limit or alter the recipient' rights in the Source Code version from the rights set forth in this Licence. If You distribute the Executable version under a different licence You must make it absolutely clear that any terms which differ from this Licence are offered by You alone, not by the Original Developer or any Contributor. You hereby agree to indemnify the Original Developer and every Contributor for any liability incurred by the Original Developer or such Contributor as a result of any such terms You offer.

B.2.7. Larger Works.

You may create a Larger Work by combining Covered Code with other code not governed by the terms of this Licence and distribute the Larger Work as a single product. In such a case, You must make sure the requirements of this Licence are fulfilled for the Covered Code.

You may distribute the Larger Work in Executable or Source form only if the requirements of Section B.2.1-2.5 have been met for the Covered Code, and if You include a notice stating that the Source Code version of the Covered Code is available under the terms of this Licence, including a description of how and where You have fulfilled the obligations of Section B.2.2.

B.3. Inability to Comply Due to Statute or Regulation.

If it is impossible for You to comply with any of the terms of this Licence with respect to some or all of the Covered Code due to statute or regulation then You must:

- (a) comply with the terms of this Licence to the maximum extent possible; and
- (b) describe the limitations and the code they affect.

Such description must be included in the README-LEGAL file described in Section B.2.4 and must be included with all distributions of the Source Code. Except to the extent prohibited by statute or regulation, such description must be sufficiently detailed for a recipient of ordinary skill to be able to understand it.

B.4. Application of this Licence.

This Licence applies to code to which the Original Developer has attached the notice in Exhibit B-1, and to related Covered Code.

B.5. Versions of the Licence.

B.5.1. New Versions.

The Original Developer may publish revised and/or new versions of the Licence from time to time. Each version will be given a distinguishing version number.

B.5.2. Effect of New Versions.

Once Covered Code has been provided to You under a particular version of the Licence, You may always continue to use it under the terms of that version. You may also choose to use such Covered Code under the terms of any subsequent version of the Licence published by the Original Developer. No one other than the Original Developer has the right to modify the terms applicable to Covered Code created under this Licence.

B.5.3. Derivative Works.

If you create or use a modified version of this Licence (which you may only do in order to apply it to code which is not already Covered Code governed by this Licence), you must

- (a) rename Your licence so that the phrases "PhOSCo", " PhOSCo Clinical Trials' ", or any confusingly similar phrase do not appear anywhere in your licence and
- (b) otherwise make it clear that your version of the licence contains terms which differ from the PhOSCo General Licence.

(Filling in the name of the Original Developer, Original Program or Contributor in the notice described in Exhibit B-1 shall not of themselves be deemed to be modifications of this Licence.)

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This Licence and the rights granted hereunder will terminate automatically if You fail to comply with terms herein and fail to cure such breach within 30 days of becoming aware of the breach. All sublicences to the Covered Code which are properly granted shall survive any termination of this Licence. Provisions which, by their nature, must remain in effect beyond the termination of this Licence shall survive.

B.8. LIMITATION OF LIABILITY.

UNDER NO CIRCUMSTANCES AND UNDER NO LEGAL THEORY, WHETHER TORT (INCLUDING NEGLIGENCE), CONTRACT, OR OTHERWISE, SHALL THE ORIGINAL DEVELOPER OR ITS DIRECTORS, OFFICERS, EMPLOYEES, OR AFFILIATES, ANY OTHER CONTRIBUTOR, OR ANY DISTRIBUTOR OF COVERED CODE, OR ANY SUPPLIER OF ANY OF SUCH PARTIES, BE LIABLE TO YOU OR ANY OTHER PERSON FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY CHARACTER INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF GOODWILL, WORK STOPPAGE, COMPUTER FAILURE OR MALFUNCTION, OR ANY AND ALL OTHER COMMERCIAL DAMAGES OR LOSSES, EVEN IF SUCH PARTY SHALL HAVE BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGES. THIS LIMITATION OF LIABILITY SHALL NOT APPLY TO LIABILITY FOR DEATH OR PERSONAL INJURY RESULTING FROM SUCH PARTY'S NEGLIGENCE TO THE EXTENT APPLICABLE LAW PROHIBITS SUCH LIMITATION. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THAT EXCLUSION AND LIMITATION MAY NOT APPLY TO YOU. IN NO EVENT SHALL GUILLEMOT'S TOTAL LIABILITY TO YOU FOR ALL DAMAGES EXCEED THE AMOUNT OF FIFTY POUNDS STERLING (£50.00).

B.9. Applicable Law and Jurisdiction.

This Licence shall be governed by English law.

All disputes arising under this Licence shall be subject to the exclusive jurisdiction of the courts at the registered office of the Original Developer in England. The Original Developer, however, shall remain entitled to bring legal action against You at any other place where jurisdiction is permissible.

B.10. MISCELLANEOUS.

This Licence represents the complete agreement concerning subject matter hereof. If any provision of this Licence is held to be unenforceable, such provision shall be reformed only to the extent necessary to make it enforceable.

Company/Date/Location

Signature(s)

PhOSCo General Licence

EXHIBIT B-1.

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The Original Developer of the Original Program is Guillemot Design Ltd.

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Contributor(s): _____."

Company/Date/Location

Signature(s)

EXHIBIT B-2.

Usage Terms: Client/Server

The terms in this section are for Client/Server PhOSCo (Trial Builder, Trial recorder, Trial Monitor, Trial Server, Trial Autocoder, and associated utilities).

The Licence terms for the Use of the Covered Code are governed by the Use Type. Based on the Use Type that You belong to different Usage Fees will be due to the Original Developer.

Use Type: Clinical Research

The Usage Fee is due to the Original Developer on a per Trial basis. This includes use for "pilot trials" - collecting data from real patients is considered as Use. The fee paid per trial may vary depending on the number of Subjects per trial; if you run "Small Trials" (trials with fewer than 25 Subjects) you may opt to licence at the lower rate. However, you must pay a Normal Trial rate for any trial with 25 or more Subjects. The Usage Fee is to be paid in advance. You have the option to select between different Usage Packs covering one (1), five (5), ten (10), fifty (50) and an Enterprise Pack covering an unlimited number of Trials. You are required to keep track of the amount of Trials You are conducting and to check the compliance with the Usage Terms. If You are in a non-compliance situation You are required to order additional Usage Packs within thirty (30) days.

Usage Packs	Normal Trials	Small Trials
1 Trial	<input type="checkbox"/> UK pounds 5000	<input type="checkbox"/> UK pounds 4000
5 Trials	<input type="checkbox"/> UK pounds 22,000	<input type="checkbox"/> UK pounds 15,000
10 Trials	<input type="checkbox"/> UK pounds 40,000	<input type="checkbox"/> UK pounds 20,000
50 Trials	<input type="checkbox"/> UK pounds 150,000	<input type="checkbox"/> UK pounds 75,000
Enterprise Pack	<input type="checkbox"/> UK pounds 350,000	<input type="checkbox"/> UK pounds 350,000

The payment of the Usage fee entitles You to distribute free of charge and for an unlimited period of time read-only components of Covered Code to Regulatory Authorities and to Investigators for reviewing and archiving purposes of the respective Trial(s).

Use Types: Non Profit Research and Personal Use Activities

No fees will be charged for the Use of Covered Code. For Non-Profit Research and Personal Use Activities.

Use Type: IT related Services

You are not entitled to Use the software for productive purposes.

Use Type: Other Activities

You should contact us (email licence@phosco.com preferred) with an indication of the nature and volume of the use you intend. We will charge a fee for the issuing of a licence. If your use is minor or the revenue you make per year from this activity can be reasonably assessed at less than £5000 sterling, you should become an online subscriber and not use this licence.

Flat fee	<input type="checkbox"/> UK pounds
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All prices in this Exhibit are excluding VAT and other taxes. Subscribers within the European Community will be charged VAT at the rate then current.

Company/Date/Location

Signature(s)

Usage Terms: Web Server

The terms in this section are for Web Server PhOSCo (PhOSCo PhWebServlet, PhWeb JApplets, and associated utilities).

The Licence terms for the Use of the Covered Code are governed by the Use Type. Based on the Use Type that You belong to different Usage Fees will be due to the Original Developer.

Use Type: Clinical Research

The Usage Fee is due to the Original Developer on a tiered yearly basis. This includes use for "pilot trials" - collecting data from real patients is considered as Use. The Usage Fee is to be paid in advance. You have the option to select between different Volume Tiers covering up to five (5), five or over but less than ten (10), ten or over but less than fifty (50), fifty or over but less than one hundred (100) and over 100 trials per year. You are required to keep track of the amount of Trials You are conducting and to check the compliance with the Usage Terms. If You are in a non-compliance situation You are required to upgrade to a higher Volume Tier within thirty (30) days.

Volume Tier	Yearly Subscription
Up to 5 trials	<input type="checkbox"/> UK pounds 3000
5 Trials up to 10	<input type="checkbox"/> UK pounds 5,000
10Trials up to 50	<input type="checkbox"/> UK pounds 10,000
50 Trials up to 100	<input type="checkbox"/> UK pounds 15,000
Over 100 Trials	<input type="checkbox"/> UK pounds 20,000

Use Types: Non Profit Research and Personal Use Activities

No fees will be charged for the Use of Covered Code. For Non-Profit Research and Personal Use Activities.

Use Type: IT related Services

You are not entitled to Use the software for productive purposes.

Use Type: Other Activities

You should contact us (email licence@phosco.com preferred) with an indication of the nature and volume of the use you intend. We will charge a fee for the issuing of a licence. If your use is minor or the revenue you make per year from this activity can be reasonably assessed at less than £5000 sterling, you should become an online subscriber and not use this licence.

Flat fee	<input type="checkbox"/> UK pounds
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C. Subscription Agreement: Restricted Materials Subscription and Online Subscription.

C.0. General.

1. The purpose of PhOSCo Subscription is to support the ongoing development and maintenance of the PhOSCo software and to provide access to Restricted PhOSCo Materials and is not a fee for access to the PhOSCo website. Most PhOSCo software will be freely available to the general public on the PhOSCo website, but we may from time to time provide some materials (Restricted PhOSCo Materials) which are accessible only to subscribers or direct from the Original Developer. All users of PhOSCo will only be entitled to receive updates to and new versions of Restricted PhOSCo Materials if they have a current subscription. Subscriptions may be of two types: "Restricted Materials Subscription" for commercial users, and "Online Subscription" for non-profit and minor use users. This section details the terms of both types and the application form and fee schedule for the Restricted Materials Subscription. The Application form and fee schedule for the Online Subscription are on the website.
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7. The Original Developer makes no representation that materials on this Internet site are appropriate for any purpose.

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We may from time to time offer subscription services that allow subscribers to post information on part of the PhOSCo website. It is a condition of providing such a service that we reserve the right without any restriction to remove any such information that any person posts to any facility we provide for any or no reason. It is further a condition of providing such a service that users of it agree that they will not post information that is obscene, defamatory, confidential or personal to any third party, unprofessional, or unrelated to the business of PhOSCo and that subscribers will be liable to Guillemot Design Ltd for any financial loss caused by improper use.

C.2. Termination.

The Original Developer may terminate this Agreement and your subscription at any time without any obligation to refund any prior fees if You violate any provision of this Agreement or if he is unable to verify or authenticate the information You provide.

C.3. Non-Transferable.

This Agreement is personal to You, and You may not transfer your rights or obligations to anyone.

C.4. Links

Links on the Site are provided for your convenience and the Original Developer does not necessarily endorse or support them. Please direct your concerns regarding any external link to the relevant website administrator or webmaster.

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All disputes arising under this Subscription shall be subject to the exclusive jurisdiction of the courts at the registered office of the Original Developer in England. The Original Developer, however, shall remain entitled to bring legal action against You at any other place where jurisdiction is permissible.

Company/Date/Location

Signature(s)

EXHIBIT C-1.

Restricted Materials Subscription Fee to the Pharma Open Source Community

In order to continue your subscription you will have to pay a yearly fee. The subscription fee is based on the Use Type and on a tiered model dependant on the potential value You will be able to derive from the use of the Covered Code. The fee is due for calendar years following the year of the initial signature date.

Use Type: Clinical Research

Subscription period: year <input type="text"/>	
Yearly subscription	<input type="checkbox"/> UK pounds 10,000

Use Type: IT Related Services and Other Activities

The tiered subscription and pricing model is based on the yearly revenue that You make in the area of IT Related Services in the area of Clinical Research or commercial use in Other Areas that is dependent on or influenced by the use of PhOSCo materials.

Subscription period: year <input type="text"/>	
Planned IT Related Services Revenue during the Subscription period	
< 1m US Dollars	<input type="checkbox"/> UK pounds 5,000
1- 2m US Dollars	<input type="checkbox"/> UK pounds 10,000
2 - 3m US Dollars	<input type="checkbox"/> UK pounds 20,000
> 3m US Dollars	<input type="checkbox"/> UK pounds 50,000

All other Use Types

Subscription period: year <input type="text"/>	
Flat fee	<input type="checkbox"/> UK pounds 500

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