

REQUEST FOR PROPOSALS (US)

Revision of a Course

Introduction

The Association of Clinical Research Professionals (ACRP) is a not-for-profit voluntary organization for clinical researchers in the pharmaceutical, biotechnology, and medical device industry. ACRP contributes to the training of professionals in hospitals, academic and non-academic centers. ACRP was founded in 1976 and comprises a diverse network of clinical research professionals including clinical research coordinators, principal investigators (PIs), clinical research associates, pharmaceutical physicians, research and development project managers, regulatory affairs and compliance professionals. ACRP's mission is to provide global leadership for the clinical research profession by promoting and advancing the highest ethical standards and practices.

Project Objectives

ACRP has for many years been a key provider of clinical research education to diverse audiences worldwide. In order to retain the currency of both the content and the suitability of the training methodology, the courses are reviewed and updated periodically.

ACRP hereby invites suitable qualified trainers whether individuals, institutions or training organizations experienced in content development and updated (called Reviewers or Proposers in this document) to review and update one course.

REVIEWERS MUST BE FAMILIAR WITH THE COURSE THAT THEY APPLY. IN THIS RESPECT 'FAMILIAR' MEANS HAVING TAUGHT THE ACRP COURSE AT LEAST ONCE IN THE LAST 3 YEARS.

The Reviewers will need to satisfy the minimum requirements for the task.

Course to be reviewed:

GOOD CLINICAL PRACTICE FOR CLINICAL RESEARCH PROFESSIONALS – 2 DAY COURSE

Proposals should be made using the Proposal Questionnaire for Reviewer (Appendix 2) emailed to Blanche Selby by COB on Monday, March 30, 2009.

ACRP regrets that incomplete proposals may not be considered.

Proposer must not offer to substitute ACRP's courses with other alternatives. ACRP will choose the most suitable Reviewer based on the qualifications and experienced stated. ACRP's decision will be final.

Whether relevant ad possible, proposers should provide supporting statements and evidence especially where directly asked. Where the information requested is inadequate or not received by the stated deadline, ACRP reserves the right to reject the proposal.

Submission Date:

The deadline for receipt of submissions by ACRP is COB March 30th, 2009

Confirmation of selection date:

The successful proposer will be informed at latest April 9th, 2009

Contract

The contract between the successful Reviewer and ACRP will be written by ACRP according to the generic terms in Appendix 3.

Nature of course materials to be reviewed

The course materials to be reviewed will generally include PowerPoint presentations, MCQs, workshop exercises and guidelines. These are specifically stated in Appendix 1.

Confidentiality

All training documents provided to the Reviewer are confidential. The reviewer will be asked to sign a confidentiality agreement, as well as a financial disclosure declaration form prior to receiving any course materials.

Enquiries

Please contact Blanche Selby, Administrator for any enquiries regarding this RFP at blanche@acrpn.net; telephone +44 1753 831 900 between 9:00-17:30 GMT.

Withdrawal of this Request for Proposals

ACRP reserves the right to withdraw this request for proposal in whole or in part or not award it altogether or in part without having to provide any justification to proposers.

Conditions of Award

ACRP reserves the right to determine which proposers have met the base requirements of this RFP. In addition, ACRP may reject, in whole or in part, any and all proposals, waive minor irregularities in proposals, allow the proposer to correct minor irregularities and negotiate with all responsible parties in any manner deemed necessary to serve the best interests of ACRP, its affiliates, members and its clients, collaborators and partners.

ACRP reserves the right, to award the contract in accordance with its best interests and its members and its clients, collaborators and partners

APPENDIX 1: COURSE TO REVIEWED AND UPDATED

Good Clinical Practices – Two Day Course

Course Description:

This is an intensive training course designed to boost knowledge and understanding of GCP and locally applicable regulations and guidelines such as the FDA Code of Federal Regulations (CFR), the European Directives and the International Conference on Harmonisation (ICH). It is intended for clinical research physicians, investigators, study coordinators or other members of the study team. It contains interactive exercises, lectures and question-and-answer forums that will suit attendees of any level of experience. It is strongly encouraged that both the investigator and study coordinator from a research site attend the program together. This GCP course is currently offered as a blended learning program with both classroom and e-learning components. Course attendees are required to complete the online GCP course modules including a test prior to attending the classroom portion of this course. The online component is not expected to be updated at this point in time.

A listing of the course contents is available on the ACRP website at www.acrpnnet.org under the Classroom Learning section.

This program provides 13.25 continuing education hours including the online component.

Currently the Learning Objectives are:

Upon completion of this course, participants should be able to:

- Describe the evolution of Good Clinical Practice, from its origins to currently acceptable standards and the imperative of keeping abreast of changing practices and regulations.
- Define the major steps and phases of the drug development process.
- Describe the main regulations governing the practice of clinical research and other applicable guidelines, including the EU Directive, FDA CFR, Data Privacy/HIPAA, and ICH.
- Cite the legal, professional and ethical constraints on various clinical research processes, such as the management of informed consents, IRB/IECs, disclosures of financial interests and electronic signatures.
- Identify the tools and techniques for successfully managing and executing trials.
- Cite the international principles of ethical conduct and subject protection together with examples of acceptable and non-acceptable norms.

Target Audience:

Clinical Research physicians, investigators, study coordinators, or other member of the study team that would like to improve trials and ensure compliance with Good Clinical Practices, FDA regulations, EU Directives and ICH Guidelines will benefit from this course.

Qualifications of the Reviewer :

- Experience in course development and course update (essential)
- At least 7 years practical clinical research experience (essential)



- At least 5 years of training clinical research professionals including physicians
- Excellent writing skills (essential)
- Has taught this course for ACRP at least once in the last 3 years (essential)
- ACRP certified (preferred)
- ACRP credentialed trainer (preferred)

APPENDIX 3: AGREEMENT FOR REVISION OF A COURSE

This agreement (this "Agreement") is effective as of <DATE> and is made and entered into by and between The Association of Clinical Research Professionals {"ACRP"} having its principal place of business at 500 Montgomery Street, Suite 800, Alexandria, VA and <FULL NAME> ("Course Developer" or "Developer" or "You") having <HIS/HER> registered office at <FULL ADDRESS>.

When signed by ACRP and countersigned by You (collectively the "Parties"), the following will reflect the terms and conditions of this Agreement;

Whereas ACRP desires that its training materials are maintained and updated so as to remain compliant with all laws and regulations governing the practice of clinical research;

Whereas ACRP as a professional association aims that its training materials are developed and taught to the highest standards and remain credible to the profession that it represents;

Whereas ACRP desires that the Developer revise and update existing ACRP training materials ("Services");

Whereas Developer desires to perform the Services upon the terms and conditions stated herein below;

Therefore ACRP and Developer agree as follows:

SCOPE OF THE SERVICES

The scope of the Services is the update of ACRP's existing <duration> -day course <course title> (the "Course") and its training materials, as further described herein below.

The existing training materials for the Course were previously developed by <COMPANY NAME or ACRP>, a training organization based in <CITY, STATE>. The training materials will remain focused on the < FDA regulations and will be assumed to be for use for the training of North American Participants >. Course participants earn 13.25 continuous education hours for the full course.

The updated Course and training materials will include, among other things, the following:

1. Restatement of the overall course objectives and the individual session objectives as appropriate.
2. Statement of the overall course objectives and the individual session objectives in both the PowerPoint presentations and the course manual.
3. Assurance that the contents satisfy the objectives, both as set generally and as set for the individual sessions.
4. Compilation of a curriculum outline (syllabus) which will be included in the course manual and also used for marketing such curriculum being the comprehensive listing of the course contents and including topics introduced by Developer.
5. Production of a revised and updated participant *course manual* from the electronic word template supplied to You by ACRP, including all training exercises excluding copies of any regulations. The updated manual will be sent to ACRP electronically on a CD using Microsoft Word.
6. Production of a revised and updated *PowerPoint training* presentation matching the training manual using the current ACRP PowerPoint template including the current ACRP logo to be supplied to You by ACRP.
7. Production of *validation questions* which will be set to participants at the appropriate juncture during training to test the participants' understanding. These questions will

- appear in both the participant's manual and in the PowerPoint presentations.
8. Updated interactive techniques including but not limited to exercises, case studies, role plays, simulations, discussions and which involve participants in the learning process.
 9. Copies of any videos and exercises needed to best achieve the learning objectives together with instructions to ACRP as to their origins and indications of ACRP's usage rights and obligations.
 10. An annotated detailed "Leader's Guide", intended for use by trainers submitted on a CD using XP Professional which sets in greater detail the contents of the participant's manual, any and all exercises and PowerPoint presentations and explains the objectives of each session. The Leader's guide should be developed in parallel with the revision of the text of the participant's manual and the PowerPoint presentations as this will provide an additional test of the validity of the objectives and the contents. The

Leader's Guide will also give the following:

- a. The training design, I.e. when to use the lectures, discussions and exercises or other activities;
- b. A set of model questions and answers and suitable discussion topics and activities; and
- c. c. References and suggested reading for each session.

In providing the Services listed hereinabove, Developer agrees to exercise due diligence and to perform the services in a professional manner and provide the highest quality materials by presenting relevant accurate and current information. Developer will assure that the training materials have a professional appearance.

TIMELINES FOR THE WORK

In order to ensure that the revised and updated Course and training materials are delivered at <EVENT NAME> in <TOWN> in <MONTH> <DAY>, the following timelines will be adhered to:

Discussion and agreement on objectives, terms and conditions.	
Issue of contracts for execution.	
Contracts executed.	
Circulation of early drafts and first status review teleconference. In order ensure that Developer and ACRP are fully agreed on the revisions from the beginning, Developer will send a sample of the initial work (or the extent of revisions achieved) to ACRP for review discussions.	
Circulation of current drafts and second status review teleconference.	
1st full submission to ACRP from You of PowerPoint presentations and student manual for review. This submission will ideally include but may not include the <YEAR> Leader's Guide.	
ACRP's comments circulated to Developer	
Developer discusses ACRP's comments with ACRP	
Submission of first draft of Leader's Guide to ACRP unless submitted earlier.	
ACRP's comments on Leader's Guide circulated to Developer.	
2nd draft of Manual incorporating discussions circulated by Developer to ACRP.	
Second draft of leader's guide submitted by Developer to ACRP	
Review completed by Education Committee of ACRP	
ACRP's Education Committee's comments reviewed and implemented	

by Developer.	
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<i>The following timelines are listed for information only and do not fall within the scope of Services</i>	
Submission of Manual, Presentations and Leaders Guide to ACRP's Education Committee	
Texts sent to printers for design	
Production of initial design	
Final proofs approved	
Workbook ready for packing and shipping to the <Course venue>	
<NAME OF COURSE> course is scheduled for <DATE>	

OWNERSHIP OF THE COPYRIGHTS AND OTHER INTELLECTUAL PROPERTY

You hereby assign and agree to assign in the future to ACRP all of your right, title and interest to any and all Inventions (as defined herein below) and any and all related patent rights, copyrights and applications and registrations therefore. You also agree to assign all your right, title and interest in and to any particular Inventions to a third party as directed by ACRP. During and after the performance of the Services, you shall cooperate with ACRP, at ACRP's expense, in obtaining proprietary protection for the Inventions and you shall execute all documents which ACRP shall reasonably request in order to perfect ACRP's rights in the Inventions. You hereby appoint ACRP your attorney to execute and deliver any such documents on your behalf in the event that you should fail or refuse to do so within a reasonable period following the ACRP's request. You understand that, to the extent this Agreement shall be construed in accordance with the laws of any country or state which limits the assign ability to ACRP of certain contractor inventions, this Agreement shall be interpreted not to apply to any such invention which a court rules or ACRP agrees is subject to such limitation.

For the purposes of this Agreement, "Inventions" means all ideas, concepts, discoveries, inventions, developments, improvements, formulations, products, processes, know-how, designs, formulas, methods, materials, information, developmental or experimental work, clinical data, original works of authorship, software programs, software and systems documentation, trade secrets, technical data, or licenses to use (whether or not patentable or registrable under any copyright statute or similar statutes), that are or were made, conceived, devised, invented, developed or reduced to practice or tangible medium by the Developer, either alone or jointly with others (a) during any period that the Developer was rendering Services, whether or not during normal working hours or on the premises of ACRP, which relate, directly to the scope of the Services or (b) which arise out of, or are incidental to the Services.

All original works of authorship made by You (solely or jointly with others) within the scope of the Services, including but not limited to the revised Course and its training materials, which are protectible by copyright are intended to be "works made for hire", as that term is defined in Section 101 of the United States Copyright Act of 1976 (the "Act"), and shall be the property of ACRP and ACRP shall be the sole author thereof within the meaning of the Act. If the copyright to any such copyrightable work shall not be the property of ACRP by operation of law, You will, without further consideration, assign to ACRP all of your right, title and interest in such copyrightable work and will cooperate with ACRP and its designees, at ACRP's expense, to secure, maintain and defend for ACRP's benefit copyrights and any extensions and renewals thereof on any and all such work. You hereby waive all claims to moral rights in any works of authorship made by you within the scope of the Services.

Upon completion of this Agreement, Developer shall retain one copy of all course materials on file and promptly return to ACRP all other printed electronic, audio-visual and other tangible manifestations of the work product including all originals.

ACRP agrees for Developer to state itself on the front cover of the manual as having revised and updated the training materials.

The provisions of this section shall survive the termination of this Agreement.

WARRANTY AND COVENANT OF DEVELOPER

The Developer hereby warrants to and covenants ACRP that any and all materials, Inventions, works of authorship and other work products made, developed, created or produced by the Developer within the scope of, as part of or incidental to the Services shall not infringe on the copyright or other intellectual property right of any other party.

The Developer shall indemnify and hold ACRP harmless against any claims by third parties to any and all materials, Inventions, works of authorship and other work products made, developed, created or produced by the Developer within the scope of, as part of or incidental to the Services.

The provisions of this section shall survive the termination of this Agreement.

COMPENSATION TO DEVELOPER FOR PROVIDING THE SERVICES

The expected breakdown of Developer's activities is as follows:

Session Identification Number and Title	Time Developer will spend on revising and updating sessions
<COMPLETE AS PER PRODUCT>	<NO> hours
Total:	<total> hours

As compensation for providing the Services, Developer will be paid by ACRP a fee of <RATE> per hour. The total sum payable is USD <TOTAL>.

Payment will be made by ACRP upon receipt of an invoice stating the extent of work completed at the time that the invoice is made. Developer will send invoices monthly at the end of the month starting from January 09. ACRP will settle all undisputed invoices within 30 days of receiving an invoice. The Parties agree that the time specified above is a reasonable and accurate estimate of the time the Developer will actually spend and any material deviations from the above stated time will need prior approval of ACRP.

EXPENSES:

All reasonable expenses incurred in sourcing interactive materials in relation to the Services will be refunded provided that Developer has taken reasonable care to secure the most cost effective materials and also that the expense is pre-approved by ACRP.

TERMINATION OF THE AGREEMENT:

ACRP may terminate this Agreement upon serving written notice to Developer provided that ACRP will compensate Developer for work already performed and for all out of pocket expenses relating to the provision of the Services.

Either Party may terminate this Agreement in the event of a material breach by the other Party. Upon the termination of this Agreement, Developer shall retain one copy of all course materials on file and promptly return to ACRP all other printed, electronic, audio-visual and other tangible manifestations of the work product including all originals.

GENERAL PROVISIONS

This Agreement sets forth the entire understanding between the Parties on the subject matter thereof. The Agreement shall not be amended or modified except in writing and signed by both Parties.

The Parties agree that time is of essence for the purposes of this Agreement.

All communication pursuant to this Agreement shall be sent to the Parties at their respective addresses first mentioned above.

The relationship between the Parties is that of independent contractors. Nothing herein creates any association, joint venture, partnership or agency relationship of any kind between the Parties. Each Party agrees not to obligate the other Party, incur any liability or expense on behalf of the other Party, or act in the name of the other Party except as expressly provided in this Agreement or as provided in writing between the Parties.

This Agreement shall be governed and construed under the laws of The Commonwealth of Virginia.

If any provision of this Agreement is held to be invalid or unenforceable, such provision shall be discussed in good faith and revised to the satisfaction of the Parties.

Agreed to and accepted, intending to be legally bound hereby

<Name or Company>	ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS
By: _____ Course Developer Date: _____	By: _____ James Thomasell Acting CEO and President Date: _____