

- to provide **coop opportunities** in our *CRO/SMO Access Clinical Research* as *pro-bono Clinical Research Assistant* and **individually adapted** programs in consultancy roles to GCP qualified professionals, if so agreed.
- to support the title of CTA/CRA-I, announced on the CRTC web site, Student's CV, LinkedIn and other profiles after beginning of the Internship program and till hire, or until the **internship** continues, which comes first.
- to honor the **Satisfaction Guaranteed Program** obligations as exposed at the company's web site

3. Obligations of the Student

- to keep **confidential** all information and training content and **not divulge** it to third parties, as specified in the enclosed **Confidentiality Agreement**, which is integral part of this Contract.
- to make in timely fashion the **homework tasks and tests** after each chapter and email the HW tasks in **Word format** for verification and comments in order to get access to the next chapter.
- to effect regularly the **internship tasks** and assigned **administrative tasks**, if applicable, and remit them in time for verification, or to inform CRTC about delays, if such happen to occur
- to **consult CRTC before** sending any **CV or pre-selection questionnaire** anywhere in order to discuss the JD with our consultants, **adapt CV** to the specific job requirements and **prepare** for the interview (highly recommended)
- to **record** the answers given during telephone interviews (optional) on a MP3, cellphone, dictaphone, or on the computer in order to **discuss** them with our consultants in order to prepare better for the next interview.
- to work regularly on transforming the new **terminology** and industry **slang** into **active vocabulary** to use it in interviews and professional communications, and on the improvement of the level of **English**, if necessary
- to try **contacting** by email at least **4-5 persons** per week in different target companies & create an organization to **maintain** the relation with them in order to get timely information about **hidden jobs**
- to verify regularly (daily) incoming emails and Skype communications and try to respond within 24 hours
- to report the **progress** on assigned **CTA tasks**, if any, by *email* or *Skype* at least once per week , or as required
- to assist with **suggestions** in improving the overall quality of the CRA/CRC training program
- to pay for the **CRA/CRC Certification & Job Placement Assistance Program** in 1, 2, 3, 6 (in words: _____) **monthly installments** (circle what applies) of \$ _____ (in words: _____) by cash, by debit/credit card (PayPal/e-Interac), direct transfer, money order or certified check (*circle what applies*)
- in the case of **deferred payments** to effect the monthly installments according to the following approximate **payment schedule** (indicate the preferred **week** of the month):

<i>Installment</i>	<i>1 month</i>	<i>2 month</i>	<i>3 month</i>	<i>4 month</i>	<i>5 month</i>	<i>6 month</i>	<i>7 month</i>	<i>8 month</i>	<i>9 month</i>
<i>Week of month</i>									

- to **compensate payment delays** of more than 3 weeks by effecting some administrative work in the field of his/her competence if these delays have not been *coordinated* in advance with the Company.

4. Other conditions:

In general, all tasks should be performed **remotely** from a home computer, when convenient for the Student and **without** a fixed working time and frequency. In most of the cases there should be no need to go out to perform any of the above mentioned tasks. The program is **unlimited** in time and the support continues till hire.

5. Validity of the agreement:

This is a preliminary agreement and can be detailed with additional clauses if both parties accept them in writing.

(signature)

(signature)

Svetomir Krastev, Director CRTC

Student: _____
(first name, family name)

Montreal, _____
(date)

_____/_____
(city) / (date)

Clinical Research Training Center, CRA/CRC Certification Program

Course outline

Module I

- 1) The pharmaceutical industry, Glossary
- 2) History of the clinical trials regulations
- 3) Ethical principles in clinical research, Medical terminology
- 4) Phases of clinical trials
- 5) Role and tasks of the Sponsor, PI, CRC and CRA

Module II

- 6) Overview of drug regulatory process, 21 CFR
- 7) Canadian Clinical Trials Regulations & ICH GCP
- 8) Institutional Review Board, IRB/IEC/REB
- 9) Informed Consent Process, ICD design
- 10) Safety monitoring and AE/SAE reporting

Module III

- 11) Study Preparation and Design
- 12) Fundamentals of clinical trials conduct
- 13) Design of Clinical Trial Protocols
- 14) Design of Case Report Forms (CRF)
- 15) Site management, Recruitment and Retention

Module IV

- 16) Site Evaluation and Site Selection Visit
- 17) Investigator Meeting & Site Initiation Visit
- 18) Site Monitoring Visit
- 19) Study Termination, Site Close-Out Visit
- 20) Preventing Errors, Fraud and Misconduct

Module V

- 21) Clinical Trial Data Management
- 22) HIPAA Compliance Requirements
- 23) Data Safety Monitoring Board
- 24) EDC and Clinical Trial Management Systems
- 25) Audits and Inspections

Module VI

- 26) Essential documents in clinical trials
- 27) Medical devices in USA and Canada
- 28) Pre-market notification, FDA 510(k) PMN
- 29) Investigational Device Exemption, IDE
- 30) Medical Devices Pre-market Approval, PMA

Module VII

- 31) Monitoring Efficiency, Time management for CR Professionals
- 32) CV adaptation, Job descriptions and Interviews' preparation for CR
- 33) E-CRO Internship with a remote Clinical Trial Management System
- 34) Networking 2.0 – coaching on the use of professional social media
- 35) CV adaptation, Interview preparation and analysis till hire