SOP : BHS Clinical Research Assistant

(version 1, July 7, 2012)

A. GENERAL SETTING

BHS clinical trials

- The BHS may initiate academic clinical research trials in the field of Hematology.
- The sponsor of these trials must be a Belgian University or a Belgian Hospital that has a department of Hematology with a registered Specialist in Internal Medicine with a special competence in Hematology.
- These trials must abide by all applicable rules and laws of Belgium and be conducted according to international Good Clinical Practice (GCP) guidelines. Among other requirements, this implies that all such trials are approved by Ethics Committees and the National Competent Authority (for Belgium : the AFMPS/FAGG), and benefit from a trial insurance.
- To facilitate such clinical trials, the BHS may proceed to the recruitment of one or more Clinical Research Assistants (CRA).

Recruitment of a BHS CRA

- CRA working for the BHS will not be directly employed by the BHS, but shall be employed by a Belgian Hospital that has a department of Hematology with a registered Specialist in Internal Medicine with a special competence in Hematology.
- A request for hiring a BHS CRA can only be made by an official BHS committee. The chair of this committee must provide in writing to the BHS board all required documentation supporting this request.
- The BHS board shall determine when a CRA should be hired, for which time equivalent (partial of full TE) and for which duration (limited or unlimited in time).
- The BHS board shall determine in which hospital the CRA shall be located, based on the location of the CRA supervisor. The choice of the CRA supervisor shall be mostly based on his/her leading role in the specific (current and projected) portfolio of BHS clinical trials on which the CRA will work. The BHS board will make sure that the BHS-CRA is integrated in a team of local CRA in the Department of Hematology.
- Once this choice has been made, the BHS board shall contact the Department of Human Resources in order to jointly determine the process for publishing the call for candidates, the selection procedure and the type of contract.
- The BHS board shall designate at least 3 board members to be part of the selection jury. If necessary, the board may also designate committee members.
- The selection process shall at least include :
  - A pre-selection based on CV and motivation letters
  - A written test evaluating the capacity of the candidates to understand a protocol, and to write in English a summary, documents and mails relating to this protocol.
  - A written and oral test of the language skills of the candidates in Dutch and French.
  - An interview conducted in English before the selection jury.
- At each of these steps, candidates may be eliminated from the group selected for the next step.
- If hired to work only part-time for the BHS, the CRA may also be hired for the remaining time by the Department of Hematology of the employing hospital.

Contract and financial matters

- A written contract shall be signed between the employing hospital and the BHS-CRA. The initial contract will usually be for 1 year with an appropriate probation period. After this (1

year) period, the BHS-CRA may receive a permanent contract that shall include a provision ensuring that the part of the contract working for the BHS will be terminated after appropriate notice if the BHS decides to stop this program. This contract must be approved by the BHS board.

- A written contract shall be signed between the employing hospital and the BHS President and Treasurer, notably to define payment modalities of the CRA salary by the BHS to the employing hospital. This contract must be approved by the BHS board.
- The BHS shall pay for the salary (including all legal taxes, social security fees and other benefits) of the BHS-CRA.
  - A first pre-payment corresponding to the probation period (usually 6 months) shall be paid by the BHS treasurer to the employing hospital.
  - After the probation period, a second pre-payment corresponding to the remaining duration of the initial contract shall be paid by the BHS treasurer to the employing hospital.
  - From then on, an annual prepayment covering the full salary charges of a 1-year period (or shorter if the duration of the contract is shorter) shall be paid by the BHS treasurer to the employing hospital. This amount shall be adapted to the (indexed) real cost of the CRA for the employing hospital.
- The-BHS-CRA shall be entitled to the standard rules of promotion in place at the employing institution. Such promotions must be approved by the BHS board.
- The employing hospital will also send twice a year an invoice covering working expenses of the CRA. This may include : (1) computer equipment; (2) travel expenses to Belgian BHS centers or to BHS meetings. This may not include office supplies, tel or fax costs. Other exceptional expenses may be paid by the BHS if approved in advance by the BHS board.

B. CRA WORKING CONDITIONS

Role of the BHS CRA

- The BHS-CRA will help to set up, monitor and complete BHS clinical trials in accordance with the GCP guidelines. Typical work activities include :
  - writing of protocol and related documents
  - submission to competent authorities and Ethics committees,
  - protocol presentation, briefing investigators, conducting initiation visits
  - data collection from local data managers, conducting monitoring visits
  - pharmacovigilance, AE management
  - document management, preparing reports…
- The BHS-CRA must commit to make certain that the scientific integrity and the confidentiality of the data collected is protected and verified.
- The BHS-CRA shall not work on non-BHS protocols or other duties during her working hours for the BHS. Working schedules may however be flexible.
- The BHS-CRA shall work under the direct authority of the CRA supervisor, but after the BHS board has defined his/her general role and the protocol portfolio under his/her responsibility.
- The BHS-CRA shall not be used as a substitute to perform routine work of local CRA, especially regarding data collection in patient files.
- The BHS-CRA should report any difficulties to his/her supervisor. In case there are serious difficulties in his/her working relationship with his/her supervisor, the BHS-CRA should report directly to the BHS board.

Role of the BHS CRA supervisor

- A local (working in the same hospital) BHS investigator selected by the BHS board shall directly supervise the BHS-CRA.
- The CRA supervisor shall report yearly to the BHS board on the work of the BHS-CRA.
- The CRA supervisor is responsible for providing a desk and appropriate working environment for the BHS-CRA.

- The CRA supervisor shall ensure that the BHS-CRA works in compliance with the International Conference on Harmonization-Good Clinical Practice (GCP) process for clinical studies.
- If the CRA supervisor wishes to change significantly the responsibilities of the BHS-CRA with regards to a specific BHS protocol, this will have to be approved by the BHS board.
- The CRA supervisor shall also make sure that the BHS-CRA may benefit from training sessions (JACIE, GCP…) and/or may attend (international) meetings. This will have to be agreed by the BHS board and could be financed through a BHS travel or training grant or other sources.

Role of BHS committees and principal investigators

- Belgian academic protocols are discussed within the BHS committees.
- The BHS committees have the responsibility to approve and label protocols as « BHS protocols », and to designate a principal investigator (PI) who will be in charge of the study.
- The BHS committees can submit to the BHS board a request to have administrative support from the BHS-CRA. This request shall be done by sending to the board and to the CRA supervisor :
    - A request form (« Request for BHS-CRA support for a BHS study »), which details information such as : name of the committee, committee chair, study title, PI name, financing sources of the protocol and if there is money planned to pay for the data monitoring, and a list of requested tasks for the BHS-CRA.
    - A synopsis of the study, using the « BHS protocol summary template ».
- Support can only be requested for academic trials as defined under “General setting”. Support cannot be requested for commercial protocols or for protocols sponsored and/or organized by international organizations such as the EORTC, LYSA, HOVON, IFM…
- BHS committees and investigators are strongly encouraged to find financing sources to support the data monitoring of their studies. This effort will be part of the decision to approve the CRA support. If such co-financing is not feasible, this should be clearly justified.
- The requesting PI must be a member of the BHS, but can be from any hematology clinical center (does not need to be from the hospital to which the BHS-CRA is attached).
- The PI of a study shall be responsible for resolving any issue concerning regulatory or clinical aspects of the BHS protocol, and for providing the BHS-CRA with answers to any questions relevant to his/her tasks.

Role of the BHS board

- The BHS board has the responsibility to prepare the selection process among the requests for BHS-CRA support for BHS studies, and to select which protocol(s) can benefit from this support.
- It shall be the responsibility of the BHS board that all requests from committees are discussed and that support by the BHS-CRA is evenly distributed among BHS protocols requesting his/her help, depending on BHS protocol priority.
- The BHS board shall obtain the opinion of the CRA supervisor on the request before taking a decision.
- The BHS board shall define the responsibilities of the BHS-CRA with regards to a selected BHS protocol. This means that the BHS board can decide that the BHS-CRA tasks could be limited to specific aspects or several of these aspects. The decision of the BHS board shall take into account :
  - the request of the BHS committee.
  - the funding sources available to contribute to the payment of the BHS-CRA salary and costs.
  - the workload of the BHS-CRA (number and complexity of BHS protocols managed by him/her), and the opinion of the CRA supervisor.
- The BHS board shall communicate its decision to the BHS committee chair on the request form (« Request for BHS-CRA support for a BHS study »).

BHS-CRA support for a BHS study
Request to the BHS board

(Version 1, July 7, 2012)

Name of BHS committee	
Chair of BHS committee	
Title of clinical trial	
EUDRACT	
Funding sources	
Amount (€) scheduled for BHS-CRA	
If no such funding, justify :	

List of requested tasks for the BHS-CRA

Task	Requested by BHS committee		Approved by BHS board	
Writing of protocol	☐ Yes	☐ No	☐ Yes	☐ No
Writing of ICF	☐ Yes	☐ No	☐ Yes	☐ No
Writing of other documents	☐ Yes	☐ No	☐ Yes	☐ No
Certificate of insurance	☐ Yes	☐ No	☐ Yes	☐ No
Submission to EC	☐ Yes	☐ No	☐ Yes	☐ No
Submission to FAGG/AFMPS	☐ Yes	☐ No	☐ Yes	☐ No
Distribution of protocol documents	☐ Yes	☐ No	☐ Yes	☐ No
Initiation visits	☐ Yes	☐ No	☐ Yes	☐ No
Patient inclusion	☐ Yes	☐ No	☐ Yes	☐ No
Patient randomization	☐ Yes	☐ No	☐ Yes	☐ No
CRF collection	☐ Yes	☐ No	☐ Yes	☐ No
Data verification	☐ Yes	☐ No	☐ Yes	☐ No
Monitoring visits	☐ Yes	☐ No	☐ Yes	☐ No
Pharmacovigilance	☐ Yes	☐ No	☐ Yes	☐ No
Management of AE	☐ Yes	☐ No	☐ Yes	☐ No
Preparation of database for statistical analysis	☐ Yes	☐ No	☐ Yes	☐ No
Other : …….	☐ Yes	☐ No	☐ Yes	☐ No
Other : …….	☐ Yes	☐ No	☐ Yes	☐ No

Name of committee chair		[redacted]
Date		
Signature		
Name of BHS President	[redacted]	
Date		
Signature		

BHS protocol summary template

(to be also posted on BHS website)

<table>
<tr><td>Title</td><td colspan="4"></td></tr>
<tr><td>Summary</td><td colspan="4"><u>Objective :</u>

<u>Primary outcome :</u>

<u>Disease :</u>

<u>Treatment :</u></td></tr>
<tr><td>Principal inclusion criteria</td><td colspan="4">• …</td></tr>
<tr><td rowspan="4">Type of trial</td><td>Phase</td><td colspan="3"></td></tr>
<tr><td>Number of patients</td><td colspan="3"></td></tr>
<tr><td>Patient allocation</td><td colspan="3"></td></tr>
<tr><td>Blinding to treatment</td><td colspan="3"></td></tr>
<tr><td rowspan="2">Protocol N°</td><td>BHS number *</td><td>EC number</td><td>EUDRACT</td><td>ClinicalTrial.org</td></tr>
<tr><td>… - ..</td><td></td><td>xxxx-xxxxxx-xx</td><td>NCTxxxxxxxx</td></tr>
<tr><td rowspan="3">Principal investigator and sponsor</td><td colspan="2">Principal investigator</td><td colspan="2">Sponsor</td></tr>
<tr><td>Name</td><td>Institution</td><td colspan="2" rowspan="2">xxx</td></tr>
<tr><td>xxx</td><td>xxx</td></tr>
<tr><td>Participating centres</td><td colspan="4">• …</td></tr>
<tr><td rowspan="2">Status</td><td colspan="2">Start of study</td><td colspan="2">xxx</td></tr>
<tr><td colspan="2">Approximate duration</td><td colspan="2">xxx</td></tr>
</table>

* BHS number structure : “2-3 letter abbreviated committee name” - “Consecutive number of protocol”
Example : 8th protocol of Transplant Commmittee : “TC-08”
Example : 24th protocol of MDS Commmittee : “MDS-24”