

No: 08/2014/TT-BYT

Hanoi, 26 February 2014

CIRCULAR

Regulating On Research Support Activities For Clinical Trials In Vietnam

Pursuant to Decree 63/2012/NĐ-CP of the Government dated the 31st of August, 2012 defining Functions, Tasks and Organization Structure of the Ministry of Health;

Minister of Health hereby issues the Circular on the Research Support Activities for Clinical Trials in Vietnam.

Chapter I.

GENERAL PROVISIONS

Article 1. Governing Scope, Applicable Entities

This circular provides regulations on conditions, registration, scope of activities, rights and responsibilities of the organizations undertaking research support activities for clinical trials in Vietnam (hereinafter referred to as Research Support Organizations).

Article 2. Terminology Interpretation

1. *Research support activities for clinical trials* include monitoring, quality control activities, data management and statistical analysis, laboratory testing and administrative support in clinical trials.

2. *Clinical Research Associate* – CRA is a professional-graduated person with experience suitable for the field of research support for clinical trials that require monitoring. Those personnel need to master and administer the research's documents, and master the requirements of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) and other applicable laws and regulations.

3. *Clinical Research Coordinator* – CRC is a person working for a Research Support Organization whose main duty is to assist the Principal Investigator during the clinical trial, manage documentation, data files and data relevant to the trial; and to support research sites in working with sponsors, CRAs (or monitors) and Regulatory Inspectors.

Chapter II.

CONDITIONS FOR RESEARCH SUPPORT ACTIVITIES FOR CLINICAL TRIALS IN VIETNAM

Article 3. General Conditions for Research Support Organizations

1. Conditions on Organization:

Any organization having legal entity in operating in the field of research support for clinical trials, established under decision of state authorizations (for state-run organizations) or owning business license granted by Vietnamese competent authorizations (for private organizations and non-governmental organizations).

2. Conditions on Personnel:

a) The professional person in charge must have technical college degree or above on health science, suitable to professional activities of Research Support Organizations, having at least 03 years experience in at least one of the field relevant to clinical research support.

b) The Research Support Organization must have sufficient personnel satisfying regulations in this Circular, suitable to professional activities registered by the research organization.

3. Conditions on Facilities:

Having offices with adequate facilities and equipments in accordance to Appendix 1 of this Circular, ensuring registered clinical research support activities.

4. Condition on Quality Control

a) Having Standard Operation Procedures (SOPs) applied for clinical research support activities.

b) Having a data storage system capable of giving evidence on SOP compliance.

c) Having a Quality Control System following ISO or other equivalent standards.

5. Beside the general conditions, Research Support Organizations registered for one or more than one activities supporting clinical research (monitoring, inspection/audit, statistical data analysis, data management, laboratory testing service, administration support service) need to meet requirement in Article 4, 5, 6, 7, 8 in this Circular.

Article 4. Conditions for organizations registered to provide clinical research monitoring service

1. Fully qualified conditions stipulated at Article 3 of this Circular.
2. Having at least 01 Clinical Research Associate (CRA) satisfying following conditions:
 - a) Having been employed legally by the Research Support Organization. As for expats, it's necessary to have working permit granted by competent authority in order to perform their profession in Vietnam.
 - b) Holding at least a university degree in fields relating to support activities for the clinical researches and trials.
 - c) Having certificates or endorsements of training in clinical research monitoring and in Good Clinical Practice (GCP) granted by the Ministry Of Health (MOH) or organizations recognized by the MOH.
 - d) Having certificates or endorsements of annually training theory and practical skills of clinical research monitoring.

Article 5. Conditions for organizations registered to provide Clinical Research Inspection service

1. Fully comply with conditions stated at Article 3 this Circular.
2. Having at least 01 qualified inspector who meets following requirements:
 - a) Having been employed legally or in contract by the Research Support Organization. As for expats, it's necessary to have working permit granted by competent authority in order to perform their profession in Vietnam.
 - b) Holding at least a university degree in fields relating to clinical research inspection.
 - c) Having certificates or endorsements of training theory and practical skills of clinical research inspection and periodically training in clinical research.

Article 6. Conditions for organizations registered to provide data analysis and data management services

1. Fully comply with qualified conditions stated at Article 3 of this Circular.
2. Having at least 01 statistician who meets following requirements:

a) Having been employed legally by the Clinical Research Organization. As for expats, it's necessary to have working permit granted by competent authority in order to perform their profession in Vietnam.

b) Owning training certificate on biomedical statistics granted by authorized Vietnamese or foreign training establishments.

c) Being trained in statistics profession on an annual basis.

3. Having at least 01 data management staff who meets following requirements: owning certificates or endorsements of training in data management system or data management software complying with GCP.

4. Having equipments and IT systems capable of data security assurance for data analysis and data management. Quality testing methods for data analysis and data management software must be available.

Article 7. Conditions for organizations registered to provide laboratory services for Clinical Research

1. Fully comply with conditions stipulated at Article 3 of this Circular.

2. Having test labs in accordance with following requirements:

a) Qualified for ISO 15189 or equivalent standards adequate for carrying test works in the research. The organization(s) running tests for clinical research & trials must show qualified standard certificates of oversea labs to which they send sample for test.

b) Having adequate facilities, equipments and personnel complied to professional operations and having been certified as qualified to such tests in accordance to the MOH's regulations.

Article 8. Conditions for organizations registered to provide administration support service for Clinical Research.

1. Fully comply with conditions stipulated at Article 3 of this Circular.

2. Having at least 01 Clinical Research Coordinator who meets the following requirements:

a) Having been employed legally by the Clinical Research Organization. As for expats, it's necessary to have working permit granted by competent authority in order to perform their profession in Vietnam.

b) Holding at least a technical college degree in the fields relating to registered support activities.

c) Holding a GCP training certificate granted by the MOH or other organizations recognized by the MOH.

d) Holding certificates on protocol and procedure training prior to support activities.

Chapter III.

REGISTRATION FOR SUPPORT ACTIVITIES FOR CLINICAL RESEARCH IN VIETNAM

Article 9. Registry Agencies

Before operating in the research support activities in clinical trials, the Research Support Organizations are responsible to perform the initial registration or notification/registration for amendment or additional services to the Administration of Science, Technology and Training, Ministry of Health, as per requirements in Article 10 below. **Article**

10. Types of Registration for Clinical research support activities in Vietnam

1. Registration for clinical research support activities.
2. Registrations for amendment or addition of organization - leader, person in charge of professional and scope of service or registration for change of office location and/or contact address

Article 11. Registration Documents

The Research Support Organizations submit the initial (first) registration documents which consist of:

1. Application form given at Appendix 01 of this Circular.
2. Certified copies of one of the following papers: Decision for Establishment, License, Investment license, Business Registration Certificate of the organization(s).
3. List of personnel following the Form given at Appendix 02 of this Circular.
4. Requirements on Documents Submittal for Clinical Research monitoring Activities:
 - a) Certified copies of university graduate degree in the field suitable for supporting activities.
 - b) Copies of certificates in GCP training and clinical research monitoring training granted by the MOH or organizations recognized by the MOH.
 - c) Copies of certificates or endorsements of annually training in theory and practical skills.
5. Requirements on Documents Submittal for inspection activities.
 - a) Certified copies of university graduate degree or above in the field related to clinical research inspection..

b) Copies of certificates or endorsements of training in initial training in theory and practical skills, and annual training in clinical research.

6. Requirements on Documents Submittal for data management and data analysis of Clinical Research:

a) Copies of certificate of training in biomedical statistics granted by authorized Vietnamese or oversea training establishments.

b) Copies of certificates on annually training in statistics of data analysts

c) Copies of certificates or endorsements of training in usage and management of data management softwares or data management systems complied to GCP.

d) List of equipments, statistics softwares and information security systems suitable to each type of research, used for data collection, data analysis and data management.

7. Requirements for Documents for laboratory testing for Clinical Research

a) Certified copies of documents which are evidence of having internal quality assurance system or participating in external quality assurance or participating in inter-labs quality comparison with ISO 15189 labs.

b) Certified copies of documents of operating permit or document certified laboratory meets standard on biological security.

8. Requirements for Documents for administration support service of Clinical Research:

a) Certified copies of college graduate certificates or above in fields suitable for supporting activities.

b) Copies of certificates of GCP training granted by the MOH or organizations recognized by the MOH.

c) Copies of certificate or endorsement of fully training in protocols and Procedures of clinical trial before undertaking supporting work.

Article 12. Documents submitted for amendment or addition of legal representative/ technical managers in charge; name, address of headquarters or information administrative of Research Support Organization

Research Support Organizations send documents which include;

1. Application for amendment following Forms given at Appendix 03 of this Circular.

2. Certified copies of relevant certificates, degrees of the legal representative(s)/technical managers.

Article 13. General Conditions on Language, Form and Legislation Property of Registration Documents.

1. Language to be used in the Documents:

The language to be used in registration documents of Research Support Organizations must be in Vietnamese. Professional documents in foreign languages must be translated into Vietnamese.

2. Form of Registration Documents:

Registration Documents for Clinical Research support service in Vietnam must be prepared in A4 papers, firmly bound, with table of content. Materials in the documents must be arranged by order of content with separators and separated parts must be indexed in order to make it easy for reference.

3. Legislation Property of Registration Documents:

Registration Application and content of Registration Documents must be signed and endorsed by the representative in law or legally authorized person. Legal documents originated from oversea must be verified in signatures by Vietnamese authorities and legalized by consulates as regulated.

Article 14. Procedures of Registration, Amendment with Research Support Organizations.

1. Procedure of registration with Research Support Organization:

a) Research Support Organizations send directly 01 set of original documents and 01 copy of initial registration, amendment registration to MOH.

b).Administration of Science, Technology and Training is sole office to receive registration documents, issuing receipt following Forms given at Form 04 of this Circular. This office is also responsible for guiding for correction of unconfirmed registration documents.

c) Within a limit of 20 working days from the date of receiving conforming registration documents, Administration of Science, Technology and Training /MOH is responsible for processing and issue approval letter, using Forms given in Form 05 of this Circular. In case of rejection, Administration of Science Technology and Training/MOH must inform the rejection by written document following Forms given at Form 06 of this Circular, declaring the reason(s) for rejection.

2. The procedure of notice amendment:

a) Research Support Organizations send directly 01 set of notice documents to MOH in 7 working days, from the date of amendment.

b) Administration of Science, Technology and Training is sole office to receive notice documents from Research Support Organizations.

Chapter IV

SCOPE, RIGHTS AND OBLIGATIONS OF RESEARCH SUPPORT ORGANIZATIONS

Article 15. Scope of Operation of clinical research support activities

1. Clinical research support activities include:

- a) Developing the research proposal and research documents.
- b) Labeling investigational products in compliance with current standards and regulations.
- c) Site qualification and selection, investigator quantification and selection.
- d) Preparing documents for submission to authorities for assessing the research
- đ) Selection of qualified CRAs.
- e) Implementing and maintaining quality control systems.
- g) Feasibility Assessment and Site qualification before study initiation, planned site monitoring and close out monitoring.
- h) Providing and updating adequate information to investigators.
- i) Supervision and management of investigational product at site.
- k) Fully attending research inspections
- l) Safety assessment and Adverse Event (AE) reporting
- m) Data analysis, data management and study document archive.
- n) Reporting progress and study results.
- o) Fulfill financial obligations.
- p) Carrying out Sponsors' missions in clinical research & trials following GCP requirements.

2. Administrative support activities in clinical research & trials include:

- a) Support establishing and operating offices for clinical trials.
- b) Support preparing Standardized Operation Procedures (SOP).
- c) Support managing research products.
- d) Support screening and selecting subjects.
- đ) Support of taking informed consent forms.

e) Support for entering data into Case Report Form (CRF) and electronic Case Report Form (eCRF).

g) Support for storage and management of source documents, essential documents and relevant documents. .

h) Support of conducting researches in compliance with the proposal, SOPs and GCP (on track of procedures, guidelines as to ensure proper implementations)

i) Support in checking and updating requested documents.

k) Support following-up patients (to make and remind visit schedule)

l) Support reporting Adverse Events (AE)/Serious Adverse Events (SAE).

m) Support logging in, activating and updating the online research system (if any)

n) Support in preparation for Sponsors' audit

o) Support in preparation for inspections from authorities and the Ethics Committee

p) Other supports requested by principal investigators

3. Clinical research monitoring

a) Assigned Clinical Researches Associates conduct monitoring on approved schedule as to monitor progress of clinical trials and ensure researches are conducted, recorded and reported in compliance with research proposal, SOPs, GCP principles as well as relevant legal requirements.

b) Clinical research monitoring activities is conducted during the research, including: pre-study monitoring, periodically and planned monitoring, occasional monitoring on request of Research Support Organization(s)/Sponsors and Authorities, and study close out monitoring.

c) Clinical research monitoring at site include: subject recruitment location, at relevant laboratory, imaging units...

d) Clinical research monitoring must be reported to sites by written documents, before and after monitoring visits. Concrete actions of CRAs include:

- Verifying professional level and workmanship of investigators, the availability of resources before and during research.

- Monitoring the availability and sufficiency of investigational product storage facilities.

- Monitoring the dispense of study products to subjects including dosage, duration and instruction of use.

- Ensuring the delivery and storage of essential documents.
- Ensuring sufficient training for investigator.
- Monitoring protocol compliance and reporting deviations and violations to Sponsors.
- Observing and reporting recruitment rate to the Sponsors.
- Ensuring the study's case-records being written-down properly, clearly and appropriately.
- Submitting post-monitoring written reports to Sponsors after every visit.
- Monitoring and making documentation for storing, treatment, delivery and taking back of study products following the study protocol and SOPs.

Article 16. Entitlement of Research Support Organizations

1. Entitle to run support activities following registered operations scope as defined by the law.
2. Entitle to negotiate and sign contracts on support activities with organizations sponsors or sites following applicable laws.
3. Capable of being on behalf of sponsors or sites to work with Ethics Committee or Relevant State Administrative Authorities following signed contracts between the parties.
4. Entitle of others right as agreed in signed contracts of support activity.

Article 17. Obligations of Organizations Supporting Clinical Researches & Trials

1. Act strictly conforming to Vietnamese Law and regulations on clinical research support activities, to GCP's regulations and ethical code for bio-medical research.
2. Be responsible to the Law for their support activities carried out in Vietnam.
3. Prepare training plan and conduct training and continuous training for their staff.
4. Annually report to Administration of Science, Technology and Training/MOH on their support activities occasional report at the Authorizations' requests following Form 7 given with this Circular.
5. Report to the Administration of Science, Technology and Training/MOH and conduct required procedures when there are changes in the following cases:
 - a) Termination of support activities in Vietnam.
 - b) Merger or split of the Research Supporting Organization in Vietnam.

Chapter V.

IMPLEMENTATION PROVISIONS

Article 18. Inspections and audit of Research Support Organizations

1. The MOH organizes periodical or occasional inspections/audit Research Support Organizations in Vietnam.

2. Procedures of inspections and audit of **Research Support Organizations**:

a) The MOH sends notice of inspection/audit to **Research Support Organizations** 10 working days in advance the date of inspection, following Form 08 given with this Circular.

b) **Research Support Organizations** is responsible to prepare personnel and prepare for work as informed by the MOH.

c) In 20 working days since the inspection/audit, the MOH send the inspection's results in written documents to the **Research Support Organizations**.

3. Research Support Organizations has responsible for implement according to inspection's results.

Article 19. Effective of Implement

This Circular takes effect from the 1st of May 2014.

Article 20. Transition Provision

Organizations has been conducting support activities in Vietnam before the effective date of this Circular must complete all procedures as to register operations following requirements of this Circular before the 1 November 2014.

Article 21. Implementation Responsibilities

1. The MOH assigns Administration of Science, Technology and Training hosting the implementation of this circular.

2. Heads of relevant agencies, organizations and units are responsible for announcing, populating and implementing this Circular

Any matters or problems arising during the course of implementation of this Circular must be reported timely to Administration of Science, Technology and Training - MOH for consideration, amendments and supplements.

Receivers:

- Minister Nguyễn Thị Kim Tiến(for notification) .
- GO (Official Journal, Government Portal);
- Ministries and equivalences;
- Ministry of Justice (...);
- Ministry Science and Technology (...);
- MOH's Deputy Ministers;
- Provincial People Committees;
- Provincial DOH (Department of Health);
- Hospitals under MOH and Other Ministries;
- Bureaus, Departments, General Departments, Ministry Office under MOH;
- MOH Portal ;
- Filed: VT, PC, K2ĐT

On behalf of the Minister

Deputy minister

Lê Quang Cường

NAME OF ORGANIZATION

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.
*About : Registration of Clinical research
support activities in Vietnam*

.... ,*day month year*

Form No.1

**APPLICATION FOR REGISTRATION OF CLINICAL RESEARCH SUPPORT
ACTIVITIES IN VIETNAM**

To: Department of Science, Technology and Training, Ministry of Health

Name of registered organization:

The legal representative:

Position:

Office address:

Phone:

Fax:

Email:

the application for registration of clinical research support activities in Vietnam includes the following specific activities:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

The other documents enclosed with this application according to the regulations of Ministry of Health include

- 1.
- 2.
- 3.

We hereby commit to implement our registered activities with the Ministry of Health in compliance with all regulations of Vietnamese laws, guidelines and current regulations related to research, clinical trials in Vietnam, subjected to inspection and audit by the competent management agencies of Vietnam.

**Legal Representative of Registered
Organization**
(Sign, specify full name, title and sea)

NAME OF ORGANIZATION

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.

.... *Day month year*

About: Declaring personnel of clinical research organization in Vietnam

Form No. 2

**DECLARATION OF PERSONNEL FOR CLINICAL RESEARCH SUPPORT
ACTIVITIES IN VIETNAM**

To: Department of Science, Technology and Training, Ministry of Health

Name of registered organization:

The staffs registering research support activities for clinical trials (*with resumes, professional Degrees, training certificates attached*) include:

No.	Full name	Role, functions and tasks in the organization
1		
2		
3		
4		
5		

Legal Representative of registered organization
(Sign,specify full name, title and seal)

**NAME OF
ORGANIZATION**

**SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness**

No. About :
*Changing supplementing personnel or
information of clinical research organization
Vietnam*

...., day month yearr

Form No.3

ANNOUNCEMENT OF AMENDMENTS AND SUPPLEMENTS

To: Department of Science, Technology and Training, Ministry of Health

Name of organization:

The legal representative:

Position:

Office address:

Phone: .

Fax:

Email:

Notification of amendments , / supplementation of personnel and information for clinical research support activities in Vietnam, described as follows:

I. Content of Amendment, Supplement

1.1. Old Information

1.2. New information

**Legal Representative of registered organization
(Sign, specify full name, title and seal)**

MINISTRY OF HEALTH
DEPARTMENT OF
SCIENCE, TECHNOLOGY
AND TRAINING

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Code: / K2DT-TNLS

Ha Noi , day month year

About:tomake notification for receiving
registered records

Form No. 4

ANNOUNCEMENT

About

Receipt for receiving registered record on clinical research support activities

The Department of Science, Technology and Training, Ministry of Health would like to inform to the organization that we has received the application No.. dated and the other enclosed documents

In comparison with the current regulations on registration of clinical research support activities in Vietnam, we are pleased to announce to the organization:

- All records should be registerd completely according to current regulations.
- Records registered incompletely, It is needed to be supplemented with the following documents:

- 1.
- 2.
- 3.

Recipients:

- As above;
- Director (for b / c);
- Archives, TNLS (02)

**REPRESENTATIVE OF OFFICE
LEADER**

MINISTRY OF HEALTH
DEPARTMENT OF
SCIENCE, TECHNOLOGY
AND TRAINING

Code: / K2DT-TNLS

*About acceptance of activities of Clinical
Research Support Organization*

Form No. 5

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Ha Noi , day month year

To:

The Department of Science, Technology and Training has received the record –for registration of clinical research support activities of the organization.

After reviewing the record, the Department of Science, Technology and Training approved and allowed the organization to implement the clinical research support activities in Vietnam.

All clinical research support activities of the organization must be in accordance with the organization's application for registration with the Ministry of Health, in full compliance with the provisions of Vietnamese laws, guidelines and current regulations related to research, clinical trials in Vietnam, subjected to inspection and examination of the competent management agencies of Vietnam.

This is to let organizations know and implement. /.

**REPRESENTATIVE OF OFFICE
LEADER**

Recipients:

- As above;
- Director (for b / c);
- Archives, TNLS (02).

MINISTRY OF HEALTH
DEPARTMENT OF
SCIENCE AND
TECHNOLOGY AND
TRAINING

Code: / K2DT-TNLS

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Ha Noi , day month year

*About : disapproval of activities of clinical
Research Organization*

Form No. 6

To:

The Department of Science, Technology and Training has received the records for registration on clinical research support activities of the organization.

After reviewing the records, the Department of Science, Technology and Training disapprove of the implementation of clinical research support activities in Vietnam with the following reasons:

1.

2.

.....

This is to let organizations know and implement. /.

**REPRESENTATIVE OF OFFICE
LEADER**

Recipients:

- As above;
- Director (for b / c);
- Archives, TNLS (02).

**AGENCY NAME,
ORGANIZATION**

**SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness**

Code:

..... , day month year

*About: Report on Clinical Research Support
Activities in Vietnam*

Form No. 7

**REPORT ON RESEARCH SUPPORT ACTIVITIES FOR CLINICAL TRIALS
IN VIETNAM**

To: Department of Science, Technology and Training, Ministry of Health

Name of organization:

The legal representative:

Position:

Office address:

Phone:

Fax:

Email:

Clinical research support activities of the organization over time are reported as follows:

1. Describe the clinical research support activities which has been carried out in comparison with registered content.
2. Describe the research that the organization has supported (*with specific contents including: 1 Study title , study period, Study rationale , area of treatment, patient enrollment status,, summary of the safe and effective data if available, summary of the cases incompliant with protocol, mistake with protocol reasons for early termination of the study if any*).
3. Results of the inspection, examination (if applicable) (*attached with the and conclusions of inspection, examination*).

**Legal Representative of registered organization
(Sign, specify full name, title and seal)**

MINISTRY OF HEALTH
DEPARTMENT OF
SCIENCE, TECHNOLOGY
AND TRAINING

Code: / K2DT-TNLS
About: checking activities of clinical

research organization s t

Form No. 8

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Ha Noi , day month year

To:

The Department of Science, Technology and Training in company with Standing Committee h evaluate ethical issues in biomedical research, Ministry of Health has plan to inspect the research support acitivies for clinical trials of the organization by the following contents:

1.Content:

2. Time:

3.Components:

Sincerely notice to the organization to know and implement. /.

**REPRESENTATIVE OF OFFICE
LEADER**

Recipients:

- As above;
- Director (for b / c);
- Archives, TNLS (02).