MINISTRY OF HEALTH **SOCIALIST REPUBLIC OF VIETNAM**

Independence - Freedom - Happiness

No. 6586/BYT-K2ĐT

*About***:** *guiding report, recognition SAE in clinical trials* Hanoi, date October 02, 2012

To:

Organizations receive clinical trial/chaired units of clinical trial

Sponsors in clinical trial research

Organizations in clinical research contract

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To ensure research quality and safety for participants in clinical trial research conducted in Vietnam, based on the contents of the Circular 0s3/2012/TT-BYT dated 02/02/2012 about guiding clinical drug trial, Ministry of Health issues the official letter **"guiding on recognizing, handling and reporting serious adverse events in clinical trials conducted in Vietnam"** and form for reporting serious adverse events attached to this official letter.

Ministry of Health suggests Organizations receive clinical trial/chaired units, Sponsors and Organizations in clinical research contract perform and compliance this guideline.

This guide replaces the guidance in official letter No. 558/BYT-K2ĐT dated February 13, 2012

Thank for the collaboration of units./.

Deputy Director of Administration of science technology and training

NGUYEN NGO QUANG

MINISTRY OF HEALTH **SOCIALIST REPUBLIC OF VIETNAM**

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GUIDELINE

About recognizing, handling and reporting serious adverse events in clinical trials conducted in Vietnam

(*Enclosed to the official letter 6586/BYT-K2ĐT October 2, 2012)*

1. General principles:

The recognition, handling and reporting serious adverse events (SAE) in the clinical trials should comply with the international and Vietnam guidelines on Good Clinical Practice (GCP).

This guideline applied to SAE that occurs at the clinical trial research locations conducted in Vietnam.

2. Definition and classification

a. *Adverse event (AE)* is any untoward medical occurrence in clinical investigation subject whether or not related to the trial products. An adverse event can be any signs, symptoms, illness conditions or testing values in the worse direction occurs in subjects participating clinical trials, whether or not related to the trial product.

b. *Serious Adverse Event (SAE)* is any untoward medical occurrence that at any dose that could lead to one of the following circumstances: results in death or life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, a congenital anomaly/birth defect.

c. *Adverse Drug Reaction (ADR)* is unintended harm response in the worse direction occurs in subjects participating clinical trials and is considered having causative relationship with trial product at any dose. For products already circulating in the market: adverse drug reaction is harmful and unexpected reactions, occurring at normal dose used for the purposes of prevention, diagnosis or treatment.

d. *Unexpected Adverse Drug Reaction* is an adverse reaction to a drug in which the nature or severity has never been recorded in previous studies or in the current product information.

3. The responsibilities of the parties in the recognition, management and reporting of SAE in clinical trials conducted in Vietnam

a. *Principal Investigator, principal investigator at the study site* is responsible for the detection and management of SAE timely, safe for the study subjects; monitor and record adequately information; SAE report sent to donors, grassroots level ethnic board, committee of evaluation of ethical issues in biomedical research Ministry of Health. In case of the level and frequency of SAE exceed permissible limits, Investigator can propose to the donors and ethics boards halted trials.

b. *Organizations receive clinical trial*, organizations deploying clinical trials responsible for managing and supervising the implementation, handling, tracking SAE reported in the study site to ensure safety for the study subjects.

c. *Ethical/Science Board grassroots level* of organization receive clinical trials consider and give the expert opinions of SAE occurred in the study site, ensuring absolute safety for research subjects.

d. *Donors and the organizations authorized by sponsors* (organizations and individuals with drug for clinical trials, organizations in clinical research contract, organize monitoring research sites) responsible for:

Coordinating with Principal Investigator report SAE occurred in the study site in Vietnam sent to the office of committee of evaluation of ethical issues in biomedical research Ministry of Health, grassroots level ethnic board of organizations receive clinical trial/chaired units of clinical trial

Update on the unexpected ADR information of the trial product at the study sites to inform researchers and add to the research profile;

Update on the unexpected ADR information by the researchers in the study point to inform researchers and additions to the research profile;

Synthesis data of adverse events, serious adverse events put into annual periodic progress reports and summarized report on research results.

e. Committee of evaluation of ethical issues in biomedical research, Ministry of Health: Responsible for considering and evaluating the SAE reports, organize supervision and inspection the research sites in necessary cases and give advice to management agencies to have timely guidance for investigators, organizations receive clinical trial/deployment research units, donors to ensure absolute security for research subjects.

f. *The National Center of Drug Information and Adverse Drug Reactions Monitoring*: responsible for coordinating with Committee of evaluation of ethical issues in biomedical research, Ministry of Health to analysis, statistical data of reports SAE in clinical trials.

4. Procedure, deadlines and forms for reporting SAE

For all SAEs: principal investigator is responsible for reporting urgent to Donor and grassroots level ethnic board of organizations receive clinical trial within 24 hours after being given the information. Depending on the type of SAE, the report to Committee of evaluation of ethical issues in biomedical research, Ministry of Health and related organizations as follows:

a. *For fatal or life-threatening SAEs*: Principal Investigator coordinating with Donor to complete information and send report to the office of Committee of evaluation of ethical issues in biomedical research, Ministry of Health. **Initial report** in writing and sent as soon as possible but no later than 7 days after being given SAE information. Contents of initial report under the reporting form (Appendix 1) but not necessarily enough information at the time of reporting. **The next monitoring report** should be sufficiently detailed all part of the report form (Appendix 1) was completed and sent within 15 days from the time having SAE information.

b. *For SAEs do not belong to fatal or life- threatening type*: Principal Investigator coordinating with Donor to complete information and send the detailed report of SAE (Appendix 1) to Committee of evaluation of ethical issues in biomedical research, Ministry of Health as soon as possible but no later than 15 days after being given SAE information.

FORM FOR SEVERE ADVERSE EVENTS REPORT

Code of protocol: **Principal Investigator:**

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Name of research:

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Research Donor:

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Organization receives clinical trial:

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Serious adverse events report (SAE):

REPORT NUMBER: ……

- ☐ **The initial report**
- ☐ **Updated tracking reports (times…)**
- ☐ **Final report**

I. Information on the subject of SAE:

1. Research Subject Code	2. Abbreviation name	3. Gender	4. Age

II. Information about product in research:

1. Name of research product (generic name, trade name, Manufacturer)
2. The batch number: .....Manufacturing date: ..... Expiry date: ……
3. Indications:
4. The dosage, route of administration:
5. The date and time start using:
6. Date and time end of using (or period for using product):
7. How many doses be used? (for vaccines):

III. SAE information:

1. Name of SAE: …….
2. Place recorded SAE (the study site?):

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3. Description of SAE *(SAE detailed):*

Time (date and time) appears SAE

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Evolution of signs, clinical symptoms: ……..

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Para-clinical tests:

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Why investigator identified this is the SAE:

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The relevance level of SAE to research product (as identified by investigator):

- ☐ *Certainly related:*
- ☐ *More likely related*
- ☐ *Possibly related*
- ☐ *Less likely related*
- ☐ *Extraneous*

4. This SAE is:

- ☐ Have known/expected with product (expected)
- ☐ Unexpected

(*Nature, frequency and severity of adverse events in the literature on the research product/medical literature or have ever observed or not?)*

Yes: Expected *No: Unexpected*

5. Severity level of SAE:

- ☐ Death:
- ☐ Life-threatening:
- ☐ No fatal or life-threatening (specify): .....

6. How many similar SAEs occurred in the study site (in this study up to date of report).....

IV. Information about treatment/handling of SAE

1. The simultaneous medication before appearing SAE:

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   ……

2. Drugs, medical interventions for study subject with SAE (specify details).

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3. Condition of subject with SAE in the current reporting time:

☐ Not yet recovery ☐ Sequelae recovery ☐ Death

☐ is recovering ☐ Recovery without sequelae ☐ Unclear

V. Professional opinion of the Council of ethical/Scientific Council of organization receives clinical trial/chaired unit

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Proposal:

For subject with SAE ☐ Continuing the study ☐ Pause ☐ Withdrawal from the study

For the study ☐ Continuing deployment ☐ Pause ☐ Stop

VI. Proposal of principal investigators:

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Report date: ……..

Reporter (signature, full name, qualifications):

Chaired unit leader (signature and full name):