

ICH Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance

Part 7. INVESTIGATOR'S BROCHURE Part 8. ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL

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GUIDELINE FOR GOOD CLINICAL PRACTICE

INTRODUCTION

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involves the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

7. INVESTIGATOR'S BROCHURE

7.1 Introduction

The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration, and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in a concise, simple, objective, balanced, and non-promotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial. For this reason, a medically qualified person should generally participate in the editing of an IB, but the contents of the IB should be approved by the disciplines that generated the described data.

This guideline delineates the minimum information that should be included in an IB and provides suggestions for its layout. It is expected that the type and extent of information available will vary with the stage of development

of the investigational product. If the investigational product is marketed and its pharmacology is widely understood by medical practitioners, an extensive IB may not be necessary. Where permitted by regulatory authorities, a basic product information brochure, package leaflet, or labelling may be an appropriate alternative, provided that it includes current, comprehensive, and detailed information on all aspects of the investigational product that might be of importance to the investigator. If a marketed product is being studied for a new use (i.e., a new indication), an IB specific to that new use should be prepared. The IB should be reviewed at least annually and revised as necessary in compliance with a sponsor's written procedures. More frequent revision may be appropriate depending on the stage of development and the generation of relevant new information. However, in accordance with Good Clinical Practice, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Boards (IRBs)/ Independent Ethics Committees (IECs) and/or regulatory authorities before it is included in a revised IB.

Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator(s) and the investigators are responsible for providing the up-to-date IB to the

responsible IRBs/IECs. In the case of an investigator sponsored trial, the sponsor-investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor-investigator, then he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol that contains the minimum current information described in this guideline.

7.2 General Considerations

The IB should include:

7.2.1 Title Page

This should provide the sponsor's name, the identity of each investigational product (i.e., research number, chemical or approved generic name, and trade name(s) where legally permissible and desired by the sponsor), and the release date. It is also suggested that an edition number, and a reference to the number and date of the edition it supersedes, be provided. An example is given in Appendix 1.

7.2.2 Confidentiality Statement

The sponsor may wish to include a statement instructing the investigator/recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and the IRB/IEC.

7.3 Contents of the Investigator's Brochure

The IB should contain the following sections, each with literature references where appropriate:

7.3.1 Table of Contents

An example of the Table of Contents is given in Appendix 2

7.3.2 Summary

A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic, and clinical information available that is relevant to the stage of clinical development of the investigational product.

7.3.3 Introduction

A brief introductory statement should be provided that contains the chemical name (and generic and trade name(s) when approved) of the investigational product(s), all active ingredients, the investigational product(s) pharmacological class and its expected position within this class (e.g. advantages), the rationale for performing research with the investigational product(s), and the anticipated prophylactic, therapeutic, or diagnostic indication(s). Finally, the introductory statement should provide the general approach to be followed in evaluating the investigational product.

7.3.4 Physical, Chemical, and Pharmaceutical Properties and Formulation

A description should be provided of the investigational product substance(s) (including the chemical and/or structural formula(e)), and a brief summary should be given of the relevant physical, chemical, and pharmaceutical properties.

To permit appropriate safety measures to be taken in the course of the trial, a description of the formulation(s) to be used, including excipients, should be provided and justified if clinically relevant. Instructions for the storage and handling of the dosage form(s) should also be given.

Any structural similarities to other known compounds should be mentioned.

7.3.5 Nonclinical Studies

Introduction:

The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavourable and unintended effects in humans.

The information provided may include the following, as appropriate, if known/available:

- Species tested
- Number and sex of animals in each group
- Unit dose (e.g., milligram/kilogram (mg/kg))
- Dose interval
- Route of administration
- Duration of dosing
- Information on systemic distribution
- Duration of post-exposure follow-up
- Results, including the following aspects:
 - .Nature and frequency of pharmacological or toxic effects
 - .Severity or intensity of pharmacological or toxic effects
 - .Time to onset of effects
 - .Reversibility of effects
 - .Duration of effects
 - .Dose response

Tabular format/listings should be used whenever possible to enhance the clarity of the presentation.

The following sections should discuss the most important findings from the studies, including the dose response of observed effects, the relevance to humans, and any aspects to be studied in humans. If applicable, the effective and nontoxic dose findings in the same animal species should be compared (i.e., the therapeutic index should be discussed). The relevance of this information to the proposed human dosing should be addressed. Whenever possible, comparisons should be made in terms of blood/tissue levels rather than on a mg/kg basis.

(a) Nonclinical Pharmacology

A summary of the pharmacological aspects of the investigational product and, where appropriate, its significant metabolites studied in animals, should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g. efficacy models, receptor binding, and specificity) as well

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as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect(s)).

(b) Pharmacokinetics and Product Metabolism in Animals

A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied should be given. The discussion of the findings should address the absorption and the local and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species.

(c) Toxicology

A summary of the toxicological effects found in relevant studies conducted in different animal species should be described under the following headings where appropriate:

- .Single dose
- .Repeated dose
- .Carcinogenicity
- .Special studies (e.g. irritancy and sensitisation)
- .Reproductive toxicity
- .Genotoxicity (mutagenicity)

7.3.6 Effects in Humans

Introduction:

A thorough discussion of the known effects of the investigational product(s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacodynamics, dose response, safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should also be provided regarding results of any use of the investigational product(s) other than from in clinical trials, such as from experience during marketing.

(a) Pharmacokinetics and Product Metabolism in Humans

A summary of information on the pharmacokinetics of the investigational product(s) should

be presented, including the following, if available:

- .Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).
- .Bioavailability of the investigational product (absolute, where possible, and/or relative) using a reference dosage form.
- .Population subgroups (e.g., gender, age, and impaired organ function).
- .Interactions (e.g., product-product interactions and effects of food).
- .Other pharmacokinetic data (e.g., results of population studies performed within clinical trial(s)).

(b) Safety and Efficacy

A summary of information should be provided about the investigational product's/products' (including metabolites, where appropriate) safety, pharmacodynamics, efficacy, and dose response that were obtained from preceding trials in humans (healthy volunteers and/or patients). The implications of this information should be discussed. In cases where a number of clinical trials have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data. Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications) would be useful. Important differences in adverse drug reaction patterns/incidences across indications or subgroups should be discussed.

The IB should provide a description of the possible risks and adverse drug reactions to be anticipated on the basis of prior experiences with the product under investigation and with related products. A description should also be provided of the precautions or special monitoring to be done as part of the investigational

use of the product(s).

(c) Marketing Experience

The IB should identify countries where the investigational product has been marketed or approved. Any significant information arising from the marketed use should be summarised (e.g., formulations, dosages, routes of administration, and adverse product reactions). The IB should also identify all the countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.

7.3.7 Summary of Data and Guidance for the Investigator

This section should provide an overall discussion of the nonclinical and clinical data, and should summarise the information from various sources on different aspects of the investigational product(s), wherever possible. In this way, the investigator can be provided with the most informative interpretation of the available data and with an assessment of the implications of the information for future clinical trials. Where appropriate, the published reports on related products should be discussed. This could help the investigator to anticipate adverse drug reactions or other problems in clinical trials.

The overall aim of this section is to provide the investigator with a clear understanding of the possible risks and adverse reactions, and of the specific tests, observations, and precautions that may be needed for a clinical trial. This understanding should be based on the available physical, chemical, pharmaceutical, pharmacological, toxicological, and clinical information on the investigational product(s). Guidance should also be provided to the clinical investigator on the recognition and treatment of possible overdose and adverse drug reactions that is based on previous human experience and on the pharmacology of the investigational product.

7.4 Appendix 1

TITLE PAGE OF INVESTIGATOR'S BROCHURE (Example)

Sponsor's Name:
Product:
Research Number:
Name(s): Chemical, Generic (if approved)
Trade Name(s) (if legally permissible and desired by the sponsor)
Edition Number:
Release Date:
Replaces Previous Edition Number:
Date:

7.5 Appendix 2

TABLE OF CONTENTS OF INVESTIGATOR'S BROCHURE (Example)

- Confidentiality Statement (optional)
- Signature Page (optional)
- 1. Table of Contents
- 2. Summary
- 3. Introduction
- 4. Physical, Chemical, and Pharmaceutical Properties and Formulation
- 5. Nonclinical Studies
 - 5.1 Nonclinical Pharmacology
 - 5.2 Pharmacokinetics and Product Metabolism in Animals
 - 5.3 Toxicology
- 6. Effects in Humans
 - 6.1 Pharmacokinetics and Product Metabolism in Humans
 - 6.2 Safety and Efficacy
 - 6.3 Marketing Experience
- 7. Summary of Data and Guidance for the Investigator
- NB: References on
 - 1. Publications
 - 2. Reports

8. ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL

8.1 Introduction

Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements.

Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor, and monitor. These documents are also the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

The minimum list of essential documents that has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated (1) before the clinical phase of the trial commences, (2) during the clinical conduct of the trial, and (3) after completion or termination of the trial. A description is given of the purpose of each document, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable. Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files. Any or all of the documents addressed in this guidance may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

8.2 Before the Clinical Phase of the Trial Commences

During this planning stage the following documents should be generated and should be on file before the trial formally starts.

	Title of Document	Purpose	Located in Files of Investigator/ Institution Sponsor	
	Investigator's brochure	To document that relevant and current scientific information about the investigational product has been provided to the investigator		
	Signed protocol and amendments, if any, and sample case report form (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF		
	Information given to trial subject - Informed consent form (Including all applicable translations) - Any other written information -Advertisement for subject recruitment (if used)	To document the informed consent To document that subjects will be given appropriate written information (content and wording) to support their ability to X give fully informed consent To document that recruitment measures are appropriate and not coercive		
8.2.4	Financial aspects of the trial	To document the financial agreement between the investigator/institution and the sponsor for the trial		
8.2.5	Insurance statement (where required)	To document that compensation to subject(s) for trial-related injury will be available		
8.2.6	Signed agreement between involved parties, e.g.: - Investigator/institution and sponsor - Investigator/institution and CRO - Sponsor and CRO required) - Investigator/institution and authority(ies (where required)	To document agreements,		x x x x(Where required)
8.2.7	Dated, documented approval/favorable\ opinion of IRB/IEC of the following: - Protocol and any amendments - CRF (if applicable) - Informed consent form(s) - Any other written information to be provided to the subject(s) - Advertisement for subject recruitment (if used) - Subject compensation (if any) - Any other documents given approval/favorable opinion approval/favorable opinion.	To document that the trial has been subject to IRB/IEC review and given approval/ favorable opinion. To identify the version number and date of the document(s).		
8.2.8	Institutional review board/independent ethics committee composition	To document that the IRB/IEC is constituted in agreement with GCP		x (where required)

	Title of Document	Purpose	Located in Files of Investigator/ Institution Sponsor	
8.2.9	Regulatory authority(ies) authorization/approval/ notification of protocol (where required)	To document appropriate authorization/ approval/ notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	x (where required)	x (where required)
8.2.10	Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and subinvestigators	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects		
8.2.11	Normal value(s)/range(s) for medical/ laboratory/technical procedure(s) and/or test(s) included in the protocol	To document normal values and/or ranges of the tests		
8.2.12	Medical/laboratory/technical procedures/tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	To document competence of facility to perform required test(s), and support reliability of results		
8.2.13	Sample of label(s) attached to investigational product container(s)	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects		
8.2.14	Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational products and trial-related materials		
8.2.15	Shipping records for investigational product(s) and trial-related materials	To document shipment dates, batch numbers, and method of shipment of investigational product(s) and trial related materials. Allows tracking of product batch, review of shipping conditions, and accountability.		
8.2.16	Certificate(s) of analysis of investigational product(s) shipped	To document identity, purity, and strength of investigational products to be used in the trial.		
8.2.17	Decoding procedures for blinded trials	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment		x (third party if applicable)
8.2.18	Master randomization list	To document method for randomization of trial population		x (third party if applicable)

	Title of Document	Purpose	Located in Files of Investigator/ Institution Sponsor	
8.2.19	Pretrial monitoring report	To document that the site is suitable for the trial (may be combined with 8.2.20)		
8.2.20	Trial initiation monitoring report	To document that trial procedures were reviewed with the investigator and investigator's trial staff (may be combined with 8.2.19)		
8.3	During the Clinical Conduct of the Trial - In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.			
8.3.1	Investigator's Brochure updates	To document that investigator is informed in a timely manner of relevant information as it becomes available		
8.3.2	Any revisions to: - Protocol/amendment(s) and CRF - Informed consent form - Any other written information provided to subjects - Advertisement for subject recruitment (if used)	To document revisions of these trial- related documents that take effect during trial		
8.3.3	Dated, documented approval/ favorable opinion of institutional review board (IRB)/independent ethics committee(IEC) of the following: - Protocol amendment(s)- Revision(s) of: - Informed consent form - Any other written information to be provided to the subject - Advertisement for subject recruitment (if used) -Any other documents given approval/favorable opinion - Continuing review of trial (see section 3.1.4)	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion. To identify the version number and date of the document(s)		
8.3.4	Regulatory authority(ies) authorizations/ approvals/notifications where required for: - Protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	x (where required)	
8.3.5	Curriculum vitae for new investigator(s) (and/or subinvestigators)	See section 8.2.10)		
8.3.6	Updates to normal value(s)/range(s) for medical laboratory/technical procedure(s)/test(s) included in the protocol	To document normal values and ranges that are revised during the trial (see section 8.2.11)		

	Title of Document	Purpose	Located in Files of Investigator/ Institution Sponsor	
8.3.7	Updates of medical/ laboratory/technical procedures/tests - Certification or - Accreditation or - Established quality control and/or external quality assessment or - Other validation (where required)	To document that tests remain adequate throughout the trial period (see section 8.2.12)	x (where required)	
8.3.8	Documentation of investigational product(s) and trial-related materials shipment	(See section 8.2.15)	x	x
8.3.9	Certificate(s) of analysis for new batches of investigational products	(See section 8.2.16)		x
8.3.10	Monitoring visit reports	To document site visits by, and findings of, the monitor		x
8.3.11	Relevant communications other than site - Letters conduct, adverse event (AE) reporting - Meeting notes - Notes of telephone calls	To document any agreements or visits significant discussions regarding trial administration, protocol violations, trial	x	x
8.3.12	Signed informed consent forms	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission (see section 8.2.3)	x	
8.3.13	Source documents	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	x	
8.3.14	Signed, dated, and completed case report forms (CRFs)	To document that the investigator or authorized member of the investigator's staff confirms the observations recorded	x (copy)	x (original)
8.3.15	Documentation of CRF corrections	To document all changes/ additions or corrections made to CRF after initial data were recorded	x (copy)	x (original)
8.3.16	Notification by originating investigator to sponsor of serious adverse events and related reports	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11	x	x
8.3.17	Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s)/ IEC(s) of unexpected adverse drug reactions and of other safety information	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with 4.11.2 and 5.16.2	x (where required)	x

	Title of Document	Purpose	Located in Files of Investigator/ Institution Sponsor	
8.3.18	Notification by sponsor to investigators of safety information	Notification by sponsor to investigators of safety information in accordance with 5.16.2	x	x
8.3.19	Interim or annual reports to IRB/IEC and authority(ies)	Interim or annual reports provided to IRB/IEC in accordance with 4.10 and to authority(ies) in accordance with 5.17.3	x	x (where required)
8.3.20	Subject screening log	To document identification of subjects who entered pretrial screening		x (where required)
8.3.21	Subject identification code list	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	x	
8.3.22	Subject enrollment log	To document chronological enrollment of subjects by trial number	x	
8.3.23	Investigational product(s) accountability at the site	To document that investigational product(s) have been used according to the protocol	x	x
8.3.24	Signature sheet	To document signatures and initials of all persons authorized to make entries and/or corrections on CRFs	x	x
8.3.25	Record of retained body fluids/tissue samples (if any)	To document location and identification of retained samples if assays need to be repeated	x	x
8.4	After Completion or Termination of the Trial After completion or termination of the trial, all of the documents identified in sections 8.2 and 8.3 should be in the file together with the following:			
8.4.1	Investigational product(s) accountability at site	To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor	x	x
8.4.2	Documentation of investigational product(s) destruction	To document destruction of unused investigational product(s) by sponsor or (if destroyed at site at site)	x (if destroyed at site)	x
8.4.3	Completed subject identification code list	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time	x	

	Title of Document	Purpose	Located in Files of Investigator/ Institution Sponsor	
8.4.4	Audit certificate (if required)	To document that audit was performed (if required) (see section 5.19.3(e))		x
8.4.5	Final trial close-out monitoring report	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		x
8.4.6	Treatment allocation and decoding documentation	Returned to sponsor to document any decoding that may have occurred		x
8.4.7	Final report by investigator/institution to IRB/IEC where required, and where applicable, to the regulatory authority(ies) (see section 4.13)	To document completion of the trial	x	
8.4.8	Clinical study report (see section 5.22)	To document results and interpretation of trial	x (if applicable)	x

NURSES - BIOTERRORISM and DISASTER RESPONSE NATIONAL NURSE RESPONSE TEAM (U.S. Public Health Service)

see <http://nursingworld.org/news/disaster/response.htm> call 800-872-6367

About The Team

The American Nurse Association (ANA) is working with the Office of Emergency Response, U.S. Department of Health & Human Services, in the establishment of the National Nurses Response Team (NNRT). September 11, 2001, and the Anthrax incidents that followed, were a wake up call with regard to the overall preparedness of the U.S. health system to adequately respond to a terrorist attack. ANA knows that U.S. registered nurses stand ready to respond. The NNRT now creates an excellent opportunity for registered nurses who on September 11 were asking themselves, "What can I do to help my country?"

The NNRT will comprise ten (10) regionally based teams of 200 registered nurses who could be called upon to assist in chemoprophylaxis or vaccination of hundreds of thousands or millions of Americans, or in another scenario requiring hundreds of nurses. Team members will be enrolled in the National Disaster Medical System.

Join The Team

Access the application form on the National Disaster Medical System website at www.oep-ndms.dhhs.gov/NDMS/Downloads/downloads.html. Choose either the Application package for non-federal individuals or the Application package for Federal Employees.

Mail the completed forms to the administrative officer for the team in your region of the country. You will also need to send a digital photo of yourself, with a white background, in jpeg format.

NNRT members are to complete web-based training programs, stay current in treatment recommendations for diseases compatible with weapons of mass destruction, participate in a yearly training exercise, and be available to deploy when needed.

Volunteer Opportunities for Registered Nurses

ANA strongly recommends that if you want to respond to a disaster, do so as part of a team. This helps to ensure that you have the proper specialized training, are credentialed, and that the appropriate protective equipment and coordination are in place to make the best use of your skill and expertise.

Additional information on other organized response efforts

In addition, contact your state nurses association and ask about state-level opportunities that may exist for a strong state and local level response of registered nurses.

More Information From ANA

It is also important that you work with your employer as part of your preparation to participate in this type of response effort. ANA's Commission on Workplace Advocacy (CWPA) developed two position statements to help guide you in your discussions with your employer. The first position statement, Registered Nurses Rights and Responsibilities Related to Work Release During a Disaster, which is posted in PDF format, speaks to the rights and responsibilities of registered nurses who desire release from their workplaces for the purpose of participating in a disaster relief effort. The second position statement, Policy for Work Release During a Disaster PDF, is a policy for use by employers to govern the release of registered nurses from their workplaces for the purpose of participating in a disaster relief effort.

Self Study Program Guidelines

If you are interested in writing an article for SoCRA's self study program, please do so by following these guidelines.

Instructions for Contributors:

1. Electronically submit a minimum of four double spaced pages to the editorial staff, SoCRA.
2. Provide a brief and specific title.
3. List at least three objectives and three to ten key words.
4. Obtain written permission to publish any materials that have been published previously.
5. Number any references in the order in which they appear in your article.
6. Determine the number of contact hours you recommend for reading and testing. A minimum of ten questions is required for one contact hour.
7. Provide one correct answer for each question.

The Editorial Staff will review each submission for content, grammar, and punctuation. The Editorial Staff reserves the right to publish, reject, condense, and edit all contributed materials.

Self Study Questions

Self Study Questions ICH E6 Guideline - Parts 7 and 8 The following ten questions were developed from the Guideline for Good Clinical Practice

1. _____ are those documents which individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced.
 - a. Essential documents
 - b. Case report forms
 - c. Monitoring report
 - d. all of the above
2. A compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects is known as the _____.
 - a. monitoring report
 - b. investigator's brochure (IB)
 - c. investigator's summary
 - d. none of the above
3. Generally, the _____ is/are responsible for providing the up-to-date IB to the responsible institutional review boards (IRBs)/independent ethics committees (IECs).
 - a. sponsor
 - b. investigator(s)
 - c. monitor
 - d. both a & b
4. The pretrial monitoring report should be found in the files of the _____.
 - a. sponsor
 - b. investigator/institution
 - c. both a and b
 - d. none of the above
5. The signed informed consent forms should be found in the files of the _____.
 - a. sponsor
 - b. investigator/institution
 - c. both a and b
 - d. none of the above
6. The signature sheet documents the signatures and initials of all persons authorized to make entries and/or corrections to the case report forms should be found in the files of the _____.
 - a. sponsor
 - b. investigator/institution
 - c. both a and b
 - d. none of the above
7. The subject enrollment log is used to document the chronological enrollment of subjects by trial number.
 - a. true
 - b. false
8. If a marketed product is being studied for a new use, an IB specific to the new use does not need to be prepared?
 - a. true
 - b. false
9. The marketing experience section of the IB should include _____.
 - a. countries where the investigational product has been approved or marketed
 - b. countries where the investigational product did not receive approval/ registration for marketing
 - c. both a and b
 - d. none of the above
10. A final close-out of a trial can only be done when the _____ has reviewed both investigator/institution and sponsor files and confirmed that all of the necessary documents are in the appropriate files.
 - a. sponsor
 - b. sponsor and monitor
 - c. monitor
 - d. IRB/IEC

This self study qualifies for one hour of SoCRA CE (Continuing Education).
See answer key on page 31. Please retain this document for your CE record.

Name _____ Date _____

Ready, Set, Go!

You are now ready to begin initiating clinical trials in the community hospital setting. Review your process, dot all your i's and cross all your t's and let your community know the resources you have for them. You are on your way to offering the cutting edge medical care to your patients right in their own neighborhood!

Sample of Policy and Procedure Categories

General Administration	Protocol Management	Human Subject Management	Data Management	Quality Management
Policy Management	Study Initiation	Screening and Recruitment	Data Collection	Internal Audits
Job Descriptions	IRB Submissions and Communications	Entering patients on protocol	Data Submission	External Audits
Orientation and Education	Sponsor Communications	Monitoring patients on protocol	Data Maintenance	Misconduct in Science
Budgets	Regulatory Documents	Follow up of patients on protocol		Notification of Patients
Contracts	Patient Records Management	Communications with Patients		Conflict of Interest
	Drug Accountability	Special Procedures		
	Site Visits			
	Study Close Out			

Self Study Quiz - Answer Key

(See Pg. 16)

1. a. Essential documents (Section 8.1)
2. b. investigator's brochure (Section 7.1)
3. b. investigator (Section 7.1)
4. a. sponsor (Section 8.3.10)
5. b. investigator/institution (Section 8.3.12)
6. c. both a and b (Section 8.3.24)
7. a. true (Section 8.3.22)
8. b. false (Section 7.1)
9. c. both a and b (Section 7.3.6.c)
10. c. monitor (Section 8.1)