1. PURPOSE AND SCOPE

Within the scope of Regulation on Clinical Trials, this guideline is prepared for determining rules and conditions required to be followed if the principal investigator assigned in clinical trials being conducted in our country desires to include, under his/her responsibility and supervision, a qualified subject as the site coordinator from a commercial or academic contracted research institution, which operates in conformity with scientific principles and good clinical practices, in order to perform Site Organization Management (COM) services in the study site.

For data entry service in order to record the data for required media, participant physicians in observational drug studies may request to include a qualified person as a data entry support staff from a commercial or an academic contract research organization that works in accordance with scientific principles and good clinical practices, to study team under supervision of him/her. This guidance has been also prepared to determine the terms and conditions that are related to data entry support and required to be followed. Data entry support staff is assigned for the studies which are defined in the current guideline for observational drug studies.

2. GENERAL CONDITIONS

2.1. It should be preferred that the subject to be added to the study team as the site coordinator is selected from personnel of the site / institution where the study is conducted.

2.2. If the subject to be assigned as site coordinator is not personnel of the site / institution where the study is conducted, the principal investigator may have such request, independently from the sponsor, from Contract Research organization (CRO) in order to fulfill site organization management services. This request should be documented using “Site Coordinator Request Form for Site Organization Management Service”.

2.3. Subjects to be assigned as site coordinator should be graduated from healthcare / physical sciences.

2.4. A site coordinator, who is the employee of CRO, should not simultaneously undertake any task in studies with different sponsors. However, if Turkey Pharmaceuticals and Medical Device Agency deems suitable and justifications are submitted by the applicant, site coordinator can be simultaneously assigned to more than one study with different sponsors and the issue should be notified to the sponsor.

2.5. The personnel working as site coordinator should be necessarily authorized by the CRO which assigned the concerning site coordinator.

2.6. The person to be authorized by CRO should work as a site coordinator with up to 5 different principal investigators. CRO should ensure the control of circumstance. CRO should notify this circumstance to Turkey Pharmaceuticals and Medical Device Agency with using "updated report of site coordinator projects" which is in the attachment of this guidance.

2.7. Site coordinators should have trainings about basic good clinical practices and clinical trials which they will be participated in.

2.8. Within the scope of this guideline, site coordinators can be only participate in the clinical trials which are conducted in accordance with Regulation on Clinical Trials.

2.9. Data entry support staff can be authorized by the coordinator participant physicians at the sites where kind of studies, defined in the guideline for observational studies conducted on drugs, are conducted. The respective authorization of each participant physicians is not required.

2.10. Independently of the sponsor, the coordinator physician may request contract research organization to fulfill the data entry support services. This request should be documented with “Data Entry Support Staff Request Form for Data Entry Support Service”.

2.11. The person who works as data entry support staff should be certainly authorized by the CRO where he/she works.

2.12. Data entry support staff should have trainings about basic good clinical practices and clinical trials which they will be participated in.

3. RESPONSIBILITIES

3.1. Responsibilities of Principal Investigator

3.1.1. The principal investigator of the study site, where site coordinator will be assigned, should document that sponsor of the study is notified.

3.1.2. Site coordinator shall be instructed only by principal investigator. Principal investigator should offer the site coordinator to be assigned to the approval of the study sponsor.

3.1.3. The person assigned as site coordinator should commit that he/she works independently from the sponsor and he/she follows the terms of references specified in the authorization list and he/she has no means the right to change the clinical study data.

3.1.4. The principal investigator is responsible for administrative notifications mandated by the concerning institution in relation with the site coordinator assigned.

3.2. Responsibilities of Coordinator/Participant Physician

3.2.1. The participant physician of the study site, where data entry support staff will be assigned, should document that sponsor of the study is notified.

3.2.2. The person assigned as data entry support staff should commit that he/she works independently from the sponsor and he/she follows the terms of references specified in the authorization list and he/she has no means the right to change the observational drug study data.

3.2.3. Participant physician or coordinator physician is responsible for administrative notifications mandated by the concerning institution in relation with the site coordinator assigned.

3.3. Responsibilities of Sponsor

3.3.1. In case site organization management services are fulfilled by the site coordinator assigned by a commercial or academic organization, which operates in conformity with scientific principles and good clinical practices, commercial agreements required for financing such services should be made.

3.3.2. In case data entry support services are fulfilled by the data entry support staff assigned by a commercial or academic organization, which operates in conformity with scientific principles and good clinical practices, commercial agreements required for financing such services should be made.

3.3.3. The sponsor, other than the financial support, may train the site coordinators or data entry support staff in study specific trainings and basic good clinical practices training provided to the study team and it may not get involved in any other way.

3.3.4. The sponsor should previously inform the CRO or submit the training records to the CRO regarding the trainings to be performed for site coordinator or data entry support staff.

3.4. Responsibilities of Contracted Research Organization (CRO)

3.4.1. When a commercial or academic organization, which operates in conformity with scientific principles and good clinical practices, ensures meeting the site organization management service via site coordinator, the organization may not assign the same personnel in clinical drug studies conducted by different investigators under support of different sponsors. However, if Turkey Pharmaceuticals and Medical Device Agency deems suitable and justifications are submitted by the applicant, site coordinator can be simultaneously assigned to more than one study with different sponsors and the issue should be notified to the sponsor.

3.4.2. Assignment or task cancellation notifications of the site coordinators to be assigned to site organization management service are under responsibility of CRO.

3.4.3. Records of trainings which site coordinators and data entry support staff have about basic good clinical practices and clinical trials in which they will be participated should be kept.

3.4.4. CRO should assure that required training is provided for fulfilling the responsibilities of site coordinators and data entry support staff properly.
3.4.5. CRO should perform the notifications related to the site coordinator and data entry support staff in accordance with the related regulation.
3.4.6. Assignment or task cancellation notifications of the data entry support staff to be assigned for data entry support service are under responsibility of CRO.
3.4.7. CRO should regularly report to the sponsor and the coordinator/participant physician regarding the data entry.

4. NOTIFICATION

4.1. Applications should be made in accordance with the forms published at the web site of Turkey Pharmaceuticals and Medical Device Agency.
4.2. The site coordinator to be assigned by CRO for fulfilling site organization management services should be notified by CRO to Turkey Pharmaceuticals and Medical Device Agency and Ethics Committee. These notifications should be done simultaneously. The site coordinator may begin his/her duty at the investigational site as of notification date of Turkey Pharmaceuticals and Medical Device Agency. Notification of site coordinator for Ethics Committee and Turkey Pharmaceuticals and Medical Device Agency should be done after permission letter of Turkey Pharmaceuticals and Medical Device Agency for the clinical trial. However, they may attend the investigator meeting to be performed prior to clinical trial, on the condition that they have CRO intra-company authorization documents. If this person is a staff of the site/institution where the clinical trial is conducted, he/she can be also included in the study staff in the status of sub-investigator.
4.3. The data entry support staff to be assigned by CRO for fulfilling data entry support services should be notified by CRO to Turkey Pharmaceuticals and Medical Device Agency and Ethics Committee. These notifications should be done simultaneously. The data entry support staff may begin his/her duty at the investigational site as of notification date of Turkey Pharmaceuticals and Medical Device Agency. Notification of data entry support staff for Ethics Committee and Turkey Pharmaceuticals and Medical Device Agency should be done after permission letter of Turkey Pharmaceuticals and Medical Device Agency for observational drug study. However, they may attend the coordinator/participant physician meeting to be performed prior to observational drug study, on the condition that they have CRO intra-company authorization documents. If this person is a staff of the site/institution where the clinical trial is conducted, he/she can be also included in the study staff in the status of sub-investigator.

5. TASKS AND RESPONSIBILITIES OF SITE COORDINATOR WITHIN SCOPE OF SITE ORGANIZATION MANAGEMENT SERVICE

5.1. Some of tasks and responsibilities of the site coordinator, within scope of COM, are listed below:
5.1.1. Visiting reference centers, if there are reference centers which ensure referral of patients meeting study criteria to the study site, visiting physicians of the site and reminding voluntary screening conditions,
5.1.2. If required, reviewing hospital files under supervision of principal investigator in order to help preliminary volunteer screening procedures in the recruitment period, should all necessary permits are obtained, and making efforts to find eligible volunteers,
5.1.3. Providing help to the study personnel who is assigned in the trial in screening volunteers who are deemed eligible to the trial protocol by the principal investigator (appointment organization of volunteers, helping the study personnel assigned in the trial in non-invasive procedures which are authorized by the principal investigator)

5.1.4. Filing the informed consent forms obtained from volunteers, reminding the principal investigator give one copy of the form to the volunteer,
5.1.5. Organizing and monitoring appointments in order to make volunteer visits are performed in timely manner,
5.1.6. Making necessary preparations in order to help the principal investigator perform procedures in accordance with the trial protocol during visits (for example, making list of procedures to be performed and reminding them to the principal investigator or other investigators),
5.1.7. Sending blood samples drawn from volunteers to central or local laboratory as per the trial protocol, organization, tracking of courier procedures, , monitoring laboratory reports, making the investigator who is principal investigator or physician or dentist examine reports, filing reports, informing those concerned for taking immediate measure if there is a remarkable or labeled abnormal finding in the report,
5.1.8. Assisting the investigator who is principal investigator or physician or dentist in recording all procedures in a complete manner and in filing the documents,
5.1.9. Providing help in recording information of volunteers completely to reference documents (patient file, study file) of the hospital,
5.1.10. Within the authorization of the coordinator/participant physician, to help entering data obtained from volunteers completely and truly to printed or electronic case report forms (e-CRF), volunteer file and screening cards.
5.1.11. Making the investigator who is principal investigator or physician or dentist evaluate and undersign documents such as laboratory results, ECG examinations, IVRS confirmation faxes and scales, which are amended specifically for the study, in a complete and timely manner and if required, making them filed.
5.1.12. Taking necessary measures in order to ensure adequate amount of study materials, patient diaries, laboratory kits, patient identification cards and is available throughout the study,
5.1.13. Relevant form for safety notifications which fulfill definition of serious adverse event reported by the volunteers is filled in by the investigator who is principal investigator or physician or dentist and it is immediately notified to the sponsor and monitoring such events (for example, discharge reports of patients, hospitalization records or supplying death reports),
5.1.14. Making all documents, such as investigator's brochure amendment, protocol amendment and investigator's notification received during the study, required to be notified in relation with the study to the ethics committee and Turkey Pharmaceuticals and Medical Device Agency are notified and monitoring the decisions on those notifications,
5.1.15. Filing all correspondences received from the sponsor and the ethics committee to the principal investigator's file,
5.1.16. Ensuring that principal investigator answers, in a timely manner, the questions set forth about issues requiring clarification in relation with information of volunteer,
5.1.17. Supplying necessary volunteer information requested by the department performing the data analysis or by other assessment committees in interim analysis periods while the study is in progress,
5.1.18. Ensuring that the letter indicating completion of the study is notified to the ethics committee,
5.1.19. Providing help in establishing a place where study files will be retained,

6. TASK AND RESPONSIBILITIES OF DATA ENTRY STAFF WITHIN THE SCOPE OF DATA ENTRY SUPPORT SERVICE

6.1. The task and responsibilities of the data entry staff within the scope of data entry support service are given below:

6.1.1. If required, reviewing hospital files under supervision of participant investigator in order to help preliminary volunteer screening procedures in the recruitment period, should all necessary permits are obtained, and making efforts to find eligible volunteers,

6.1.2. Filing the informed consent forms obtained from volunteers, controlling the availability of informed consent forms/data release forms of the patients whose data will be entered.

6.1.3. Controlling the data of the patients, entered during the visits, in accordance with study protocol and transferring under the supervision of the participant physician.

6.1.4. Within the authorization of the coordinator/participant physician, to help entering data obtained from volunteers completely and truly to printed or electronic case report forms (e-CRF), volunteer file and screening cards.

6.1.5. Supplying necessary volunteer information requested by the department performing the data analysis or by other assessment committees in interim analysis periods while the study is in progress, answering correction forms related to the study data and sending them to the related data processing units. Superseded

7. SUPERSEDED REGULATIONS

"The Guideline on Site Organization Management in Clinical Drug Trials", which has been put into force based on the Authority Consent Numbered 7481 dated 23.08.2011, has been superseded.

8. EFFECTIVE DATE

This guideline will be put into force at approval date.

ANNEX -1: SITE COORDINATOR REQUEST FORM OF PRINCIPAL INVESTIGATOR FOR SITE ORGANIZATION MANAGEMENT SERVICE

__/__/20__

Within scope of the clinical drug study titled “INSERT NAME OF CLINICAL DRUG TRIAL” with protocol numbered “INSERT PROTOCOL NUMBER”, of which “INSERT NAME OF THE SPONSOR” is the sponsor and I undertook the task of coordinator / principal Investigator, We hereby request that “INSERT NAME OF THE SITE COORDINATOR”, whom we have an agreement with “INSERT NAME OF ORGANIZATION”, participates to our study team in order to provide help in performing study procedures in our study site in compliance with given authorization by virtue of related regulation.

I, hereby, commit that the site coordinator assigned for site organization management service works independent from the sponsor and they follow terms of reference specified in the authorization list which is prepared in accordance with related regulation and they have no means the right to change clinical study data.

I agree that sponsor of the study is informed about the participation and I will perform administrative notifications in our study site, if required.

Name and Surname of Principal Investigator:

Institution:

Date / Signature:

The request of the investigator for site organization management service is to the best of our knowledge.

Name and Surname of Authorized Person of the Sponsor:

Date / Signature:

ANNEX -2: CONTRACTED RESEARCH ORGANIZATION, INTRA-COMPANY AUTHORIZATION DOCUMENT

__/__/20__

Within scope of the clinical study titled “INSERT NAME OF CLINICAL TRIAL” with protocol numbered “INSERT PROTOCOL NUMBER”, of which “INSERT NAME OF THE SPONSOR” is the sponsor, “INSERT NAME OF THE SITE COORDINATOR” is assigned as site coordinator by “INSERT NAME OF THE ORGANIZATION” in order to assist in performing study procedures in compliance with given authorization by virtue of related regulation for the “INSERT NAME OF THE STUDY SITE, WHERE SITE COORDINATOR WILL BE ASSIGNED” study site.

On behalf of the Contracted Research Organization,

Name / Surname of Authorized Person:

Date / Signature:

Note: This document should be printed on letterhead of the organization.

ANNEX – 3: CONTRACTED RESEARCH ORGANIZATION, INTRA-ORGANIZATION TASK ACCEPTANCE DOCUMENT

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Within scope of the clinical study titled “INSERT NAME OF CLINICAL TRIAL” with protocol numbered “INSERT PROTOCOL NUMBER”, of which “INSERT NAME OF THE SPONSOR” is the sponsor, I, “INSERT NAME OF THE SITE COORDINATOR”, am assigned as site coordinator by “INSERT NAME OF THE ORGANIZATION” in order to assist in performing study procedures in compliance with given authorization by virtue of related regulation, in the “INSERT NAME OF THE STUDY SITE, WHERE SITE COORDINATOR WILL BE ASSIGNED” study site. I state that I accept the task assigned for performing specified works throughout the clinical trial period.

Name / Surname of the Site coordinator:

Signature / Date:

Note: This document should be printed on letterhead of the organization.

ANNEX – 4: TABLE OF UPDATED STATUS FOR SITE COORDINATOR PROJECTS

1	**Name and Surname of Principal Investigator**	
Clinical Trial Code		**Site/Name of Institution**
2	**Name and Surname of Principal Investigator**	
Clinical Trial Code		**Site/Name of Institution**
3	**Name and Surname of Principal Investigator**	
Clinical Trial Code		**Site/Name of Institution**
4	**Name and Surname of Principal Investigator**	
Clinical Trial Code		**Site/Name of Institution**
5	**Name and Surname of Principal Investigator**	
Clinical Trial Code		**Site/Name of Institution**

On behalf of the Contracted Research Organization;

Signature/Date: **Name/Surname (CRO Authorized Person):**	**Signature/Date:** **Name/Surname (Site Coordinator):**

ANNEX -5: DATA ENTRY SUPPORT STAFF REQUEST FORM OF COORDINATOR / PARTICIPANT PHYSICIAN FOR DATA ENTRY SUPPORT SERVICE

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Within scope of the study titled “INSERT NAME OF STUDY” with protocol numbered (if any) “INSERT PROTOCOL NUMBER”, of which “INSERT NAME OF THE SPONSOR” is the sponsor and I undertook the task of coordinator physician, We hereby request that “INSERT NAME OF THE DATA ENTRY SUPPORT STAFF”, whom we have an agreement with “INSERT NAME OF ORGANIZATION”, participates to our study team in order to assist in our study site in accordance with related regulation.

I, hereby, commit that the data entry support staff assigned for data entry support service works independent from the sponsor and he/she follows terms of reference specified, and he/she has no means the right to change clinical study data.

I agree that sponsor of the study is informed about the participation and I will perform administrative notifications in our study site, if required.

Name and Surname of Coordinator Participant Physician:

Institution:

Date / Signature:

The request of the investigator for data entry support service is to the best of our knowledge.

Name and Surname of Authorized Person of the Sponsor:

Date / Signature:

ANNEX -6: CONTRACTED RESEARCH ORGANIZATION, INTRA-COMPANY AUTHORIZATION DOCUMENT

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Within scope of the study titled “INSERT NAME OF STUDY” with protocol numbered (if any) “INSERT PROTOCOL NUMBER”, of which “INSERT NAME OF THE SPONSOR” is the sponsor, “INSERT NAME OF DATA ENTRY SUPPORT STAFF” is assigned as data entry support staff in order to assist in compliance with related regulation.

On behalf of the Contracted Research Organization,

Name / Surname of Authorized Person:

Date / Signature:

Note: This document should be printed on letterhead of the organization.

ANNEX – 7: CONTRACTED RESEARCH ORGANIZATION, INTRA-ORGANIZATION TASK ACCEPTANCE DOCUMENT

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Within scope of study titled “INSERT NAME OF STUDY” with protocol numbered (if any) “INSERT PROTOCOL NUMBER”, of which “INSERT NAME OF THE SPONSOR” is the sponsor, I, “INSERT NAME OF THE DATA ENTRY SUPPORT STAFF”, am assigned as data entry support staff by “INSERT NAME OF THE ORGANIZATION” in order to assist in compliance with related regulation and under supervision of coordinator/participant physician. I state that I accept the task assigned for performing specified works throughout the study period.

Name / Surname of the Data Entry Support Staff:

Signature / Date:

Note: This document should be printed on letterhead of the organization.