《ICH-GCP》E6（R2）中英文版
INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE ICH E6(R2)

临床试验管理规范指导原则

INTRODUCTION

前言

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve 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.

临床试验管理规范(GCP)是设计、实施、记录和报告涉及人类对象参加的试验的国际性伦理和科学质量标准。遵循这一标准为保护受试者的权利、安全性和健康，为与源于赫尔辛基宣言的原则保持一致以及临床试验数据的可信性提供了公众保证。

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.

ICH GCP 指导原则的目的是为欧盟、日本和美国提供统一的标准，以促进这些管理当局在其权限内相互接受临床数据。

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).

本指导原则的发展考虑了欧盟、日本、美国，以及澳大利亚、加拿大、北欧国家和世界卫生组织(WHO)的现行 GCP。

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

在有意向提交给药政管理当局临床数据时应当遵循本指导原则。

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.

本指导原则中确立的原则也可应用于可能影响人类对象安全和健康的其他临床研究。

Since the development of the ICH GCP Guideline, the scale, complexity, and cost of clinical trials have increased. Evolutions in technology and risk management processes offer new opportunities to increase efficiency and focus on relevant activities. When the original ICH E6(R1) text was prepared, clinical trials were performed in a largely paper-based process. Advances in use of electronic data recording and reporting facilitate implementation of other approaches. For example, centralized monitoring can now offer a greater advantage, to a broader range of trials than is suggested in the original text. Therefore, this guideline has been amended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure human subject protection and reliability of trial results. Standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated.

自从 ICH GCP 发展以来，临床试验的规模、复杂性和成本在不断增加。技术和风险管理程序的

创新，为提高临床试验效率和相关活动带来了新的发展机遇。当 ICH E6（R1）指南在制定时，大部分临床试验还是在用纸质流程进行操作。电子数据记录和报告的发展与进步促进了新的临床试验方法的产生。例如，如今大规模的临床试验，中心化监察比传统模式更有优势。因此，对本指南进行了修订，以鼓励在临床试验设计、实施、监督、记录和报告中使用更先进、有效的方法。同时，继续确保受试者得到保护，试验结果可靠。更新了电子记录标准和必要文件，旨在提高临床试验的质量和效率。

This guideline should be read in conjunction with other ICH guidelines relevant to the conduct of clinical trials (e.g., E2A (clinical safety data management), E3 (clinical study reporting), E7 (geriatric populations), E8 (general considerations for clinical trials), E9 (statistical principles), and E11 (pediatric populations)).

本指南应当结合其他临床试验实施相关的 ICH 指南一起阅读，如 E2A（临床安全性数据管理）、E3（临床研究报告）、E7（老年人）、E8（临床试验总则）、E9（统计原则）和 E11（儿科）。

This ICH GCP Guideline Integrated Addendum provides a unified standard for the European Union, Japan, the United States, Canada, and Switzerland to facilitate the mutual acceptance of data from clinical trials by the regulatory authorities in these jurisdictions. In the event of any conflict between the E6(R1) text and the E6(R2) addendum text, the E6(R2) addendum text should take priority.

本 ICH GCP 完整增补版指南为欧盟、日本、美国、加拿大和瑞士提供了统一标准，以促进这些管理当局在其权限内相互认可彼此提供的临床数据。当 E6（R1）内容和 E6（R2）增补内容出现冲突时，以 E6（R2）内容为准。

1.GLOSSARY

1.术语

1.1 Adverse Drug Reaction (ADR)

1.1 药品不良反应(ADR)

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

在一个新的药品或药品的新用途在批准之前的临床实践，尤其是治疗剂量尚未确定前，ADR 是指与药物任何剂量有关的所有有害的和非预想的反应都应被考虑为药品不良反应。该术语用于药品是指在药品与不良反应之间的因果关系至少有一个合理的可能性，即不能排除这种关系。

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

对已上市药品，ADR 指人对用于预防、诊断或治疗疾病或改善生理功能的药物在常用剂量出现的有害和非预想的反应(参见 ICH 临床安全性数据管理指导原则：快速报告的定义和标准)。

1.2 Adverse Event (AE)

1.2 不良事件(AE)

Any untoward medical occurrence in a patient or clinical investigation subject

administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

正在用药病人或临床研究受试者中发生的任何不良医学事件，但不一定与治疗有因果关系。因此，一个不良事件(AE)可以是与使用(研究)药物在时间上相关的任何不利的和非预想的征兆(包括异常的实验室发现)、症状或疾病，而不管其是否与药物有关(参见 ICH 临床安全性数据管理指导原则：快速报告的定义和标准)。

1.3 Amendment (to the protocol)

1.3 修改(试验方案)

See Protocol Amendment.

见试验方案修改。

1.4 Applicable Regulatory Requirement(s)

1.4 适用的管理要求

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

有关实施试验用药品临床试验的任何法律和法规。

1.5 Approval (in relation to Institutional Review Boards)

1.5 批准(关于机构审评委员会)

The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

IRB 表示赞成的决定：指对一项临床试验已经进行审评，并可在 IRB、研究机构、GCP 和适用管理要求的前提下由研究机构方实施。

1.6 Audit

1.6 稽查

A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol,sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

对试验相关活动和文件进行系统和独立的检查，以判定试验的实施和数据的记录、分析与报告是否符合试验方案、申办者的标准操作程序(SOP)、临床试验管理规范(GCP)以及适用的管理要求。

1.7 Audit Certificate

1.7 稽查证书

A declaration of confirmation by the auditor that an audit has taken place.

稽查员确认已进行过稽查的声明。

1.8 Audit Report

1.8 稽查报告

A written evaluation by the sponsor's auditor of the results of the audit.

由申办者方稽查员出具的关于稽查结果的书面评价。

1.9 Audit Trail

1.9 稽查轨迹

Documentation that allows reconstruction of the course of events.

可重现整个稽查事件过程的对应文件。

1.10 Blinding/Masking

1.10 设盲

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigators), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

临床试验过程中使一方或多方人员不知道受试者治疗分配的程序。单盲指受试者不知；双盲指受试者、研究者、监查员以及在某些情况下数据分析者均不知治疗分配。

1.11 Case Report Form (CRF)

1.11 病例报告表(CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

按试验方案所规定设计的一种印刷的、光学的或电子的文件，用来记录每一名受试者在研究过程中的全部信息报告给申办者。

1.12 Clinical Trial/Study

1.12 临床试验研究

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

在人类对象进行的任何意在发现或证实一种试验用药品的临床、药理学和/或其他药效学作用；和/或确定一种试验用药品的任何不良反应；和/或研究一种试验用药品的吸收、分布、代谢和排泄，以确定药物的安全性和/或有效性的研究。术语临床试验和临床研究同义。

1.13 Clinical Trial/Study Report

1.13 临床试验/研究报告

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).

在人类对象进行的任何治疗、预防或诊断剂的试验研究的书面描述。临床和统计描述、陈述和分析全部列入该单份报告（见 ICH 临床研究报告的结构和内容指导原则）。

1.14 Comparator (Product)

1.14 对照（药物）

An investigational or marketed product (i.e. active control), or placebo, used as a reference in a clinical trial.

临床试验中用做对照的试验用药品或市售药物(即活性对照)或安慰剂。

1.15 Compliance (in relation to trials)

1.15 依从性(关于试验的)

Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.

遵循与试验有关的所有要求、临床试验管理规范(GCP)要求和相应的药政管理要求。

1.16 Confidentiality

1.16 保密性

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

不得向未经授权的个人泄露申办者所有的资料或受试者的身份。

1.17 Contract

1.17 合同

A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

在两方或多方之间的一份书面的、有日期和签字的协议，其中陈述了关于工作和责任的委托和分派的安排，以及相关财务问题的安排。试验方案可以作为合同的基础。

1.18 Coordinating Committee

1.18 协调委员会

A committee that a sponsor may organize to coordinate the conduct of a multicentre trial.

由申办者组织的协调实施多中心试验的委员会。

1.19 Coordinating Investigator

1.19 协调研究者

An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial.

在多中心临床试验中负责协调参加各中心研究者工作的一名研究者。

1.20 Contract Research Organization (CRO)

1.20 合同研究组织(CRO)

A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

与申办者订立契约，受委托完成其执行临床试验中的某些任务和工作的个人或组织(商业性的，学术的或其他)。

1.21 Direct Access

1.21 直接访问

Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

允许检查、分析、核对和复制任何对于评价临床试验有重要意义的记录与报告。直接访问的任何一方(如国内和国外的管理当局，申办者方的监查员和稽查员)应当受适用管理要求约束，采取一切合理的预防措施维护受试者身份和申办者资料的保密性。

1.22 Documentation

1.22 文件

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

用于描述或记录试验的方法、实施和/或结果，影响试验的因素，以及采取的措施等的任何形式的记录(包括但不限于书面、电子、磁性和光学的记录，以及扫描、X 射线和心电图)。

1.23 Essential Documents

1.23 必需文件

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see 8. Essential Documents for the Conduct of a Clinical Trial).

指各自和合在一起允许评价一个研究的执行情况和所得数据的质量文件(见 8.实施临床试验的必需文件)。

1.24 Good Clinical Practice (GCP)

1.24 临床试验管理规范(GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

是临床试验设计、实施、执行、监查、稽查、记录、分析和报告的标准，目的确保数据和所报告结果的可信性和准确性，并确保受试者的权利、完整性和机密性得到保护。

1.25 Independent Data-Monitoring Committee (IDMC) (Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee)

1.25 独立的数据监查委员会(IDMC)(数据和安全监查委员会，监查委员会，数据监查委员会)

An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

由申办者方设立一个独立的数据监查委员会，它定期对研究进展、安全性数据和有效性终点进行评估，向申办者建议是否继续、调整或停止试验。

1.26 Impartial Witness

1.26 公正见证人

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

如果受试者或其法定代理人不能阅读，公正见证人将参与知情同意过程，并向受试者阅读提供给他们的知情同意书和其他书面资料，作为独立于临床试验的个人，其不受与试验有关人员的不公正影响。

1.27 Independent Ethics Committee (IEC)

1.27 独立的伦理委员会(IEC)

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

一个由医学专业人员和非医学专业人员组成的独立机构(研究机构的、地区的、国家的或超国家的审评机构或委员会)，其职责是确保受试者的权益、安全性和健康得到保护；并通过对试验方案、研究人员、设施以及用于获得和记录试验对象知情同意的方法和材料的合理性进行审评和批准/提供起促进作用的意见以对这种保护提供公众保证。

The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

在不同的国家，独立的伦理委员会的法律地位、组成、职责、操作和适用的管理要求可能不同，但是应当如本指导原则所述，允许独立的伦理委员会按 GCP 进行工作。

1.28 Informed Consent

1.28 知情同意

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

指向受试者告知一项试验的各方面情况后，受试者自愿确认其同意参加该项临床试验的过程。该过程须以书面的、签名和注明日期的知情同意书作为文件证明。

1.29 Inspection

1.29 视察

The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities,or at other establishments deemed appropriate by the regulatory authority(ies).

药政管理部门对一项临床试验的有关文件、设备、记录和其他方面进行官方审阅，视察可以在试验单位、申办者和/或合同研究组织或管理当局认为合适的其他机构进行。

1.30 Institution (medical)

1.30(医学)研究单位

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

实施临床试验的任何公共或私人的实体、代理机构、医学或牙科设施。

1.31 Institutional Review Board (IRB)

1.31 机构审评委员会（IRB）

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

由医学、科学和非科学成员组成的一个独立机构，其职责是通过对试验方案及其修订本，获得受试者知情同意所用的方法和资料进行审评、批准和继续审评，确保一项试验的受试者的权利、安全和健康得到保护。

1.32 Interim Clinical Trial/Study Report

1.32 临床试验/研究中期报告

A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

根据试验进行过程中所作的分析写出的中期结果和评价的报告。

1.33 Investigational Product

1.33 试验用药品

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

一种在临床试验中供试验的或作为对照的活性成分或安慰剂的药物制剂。包括一个已上市药品以不同于所批准的方式使用或组合(制剂或包装)，或用于一个未经批准的适应症，或用于收集一个已批准用法的更多资料。

1.34 Investigator

1.34 研究者

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Sub-investigator.

负责在一个试验单位实施临床试验的人。如果在一个试验单位是由一组人员实施试验，研究者指这个组的负责人，也称为主要研究者。见次级研究人员。

1.35 Investigator/Institution

1.35 研究者/研究机构

An expression meaning "the investigator and/or institution, where required by the applicable regulatory requirements".

表示“符合适用药政管理要求的研究者和/或研究机构”。

1.36 Investigator's Brochure

1.36 研究者手册

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (see 7. Investigator's Brochure).

是有关试验药品在进行人体试验室已有的该药品的临床和非临床资料的汇编（见 7.研究者手册）。

1.37 Legally Acceptable Representative

1.37 法定监护人

An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

在适用法律下，被授权可代表受试者同意参加临床试验的个人，或司法人员或其他主体。

1.38 Monitoring

1.38 监查

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted,

recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

监督一个临床试验的进展，保证临床试验按照试验方案、标准操作程序(SOP)、临床试验管理规范(GCP)和相应的药政管理要求实施、记录和报告的活动。

1.39 Monitoring Report

1.39 监查报告

A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

监查员在结束每一次现场访问和/或完成其他与试验有关的交流后，根据申办者的 SOP 完成的一份提交给申办者的书面报告。

1.40 Multicentre Trial

1.40 多中心试验

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

按照同一个试验方案，在一个以上试验单位实施，由多名以上研究者共同完成的临床试验。

1.41 Nonclinical Study

1.41 非临床试验

Biomedical studies not performed on human subjects.

在人体之外进行的生物医学研究。

1.42 Opinion (in relation to Independent Ethics Committee)

1.42 意见(与独立的伦理委员会相关)

The judgement and/or the advice provided by an Independent Ethics Committee (IEC).

由独立的伦理委员会(IEC)给出的评价和/或建议。

1.43 Original Medical Record

1.43 原始医学记录

See Source Documents.

见源文件。

1.44 Protocol

1.44 试验方案

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

一个阐明试验目的、设计、方法学、统计学考虑和组织的文件。试验方案通常包括试验的背景和理论基础，但这也可以写在与方案有关的其他参考文件中。在 ICH 指导原则中，试验方案这一术语指试验方案和方案的修改。

1.45 Protocol Amendment

1.45 试验方案的修改

A written description of a change(s) to or formal clarification of a protocol.

对试验方案的改变或正式澄清的书面描述。

1.46 Quality Assurance (QA)

1.46 质量保证(QA)

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

为保证试验的进行和数据产生、记录以及报告都符合临床试验管理规范(GCP)和适用管理要求所建立的有计划的系统活动。

1.47 Quality Control (QC)

1.47 质量控制(QC)

The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

在质量保证系统内所采取的操作技术和活动，以查证与试验有关的活动都符合质量要求。

1.48 Randomization

1.48 随机化

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

为了减少偏倚，采用机遇决定分配的原理将受试者分配到治疗组或对照组的过程。

1.49 Regulatory Authorities

1.49 管理当局

Bodies having the power to regulate. In the ICH GCP Guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections (see 1.29). These bodies are sometimes referred to as competent authorities.

有权进行管理的机构。在 ICH GCP 指导原则中，管理当局一词包括审评所提交的临床数据和实施视察的机构(见 1.29)。这些机构有时指主管当局。

1.50 Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)

1.50 严重不良事件(SAE)或严重药品不良反应

Any untoward medical occurrence that at any dose:

在任何剂量下发生的任何不利医学事件:

-results in death,

导致死亡

-is life-threatening,

危及生命

-requires inpatient hospitalization or prolongation of existing hospitalization,

需要住院治疗或延长住院时间

-results in persistent or significant disability/incapacity, or

导致永久或严重的残疾/能力丧失，或

-is a congenital anomaly/birth defect

先天性异常/出生缺陷。

(see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

(见 ICH 临床安全性数据管理指导原则：快速报告的定义和标准)

1.51 Source Data

1.51 源数据

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

临床试验中的临床发现、观察或其他活动的原始记录及其可靠副本中的全部资料，它们对于重建和评价试验是必要的。源数据包含在源文件中(原始记录或可靠副本)。

1.52 Source Documents

1.52 源文件

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

原始文件、数据和记录(如医院记录，临床和办公室图表，实验室笔记，备忘录，受试者日记卡或评价表，药房发药记录，自动仪器的记录数据，在核对后作为准确副本的可靠复印件或抄件，显微胶片，摄影负片，缩微胶卷或磁介质，X 线，受试者文件，以及保存在药房、实验室和与参与临床试验的医学技术科室中的记录)。

1.53 Sponsor

1.53 申办者

An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

发起一项临床试验的，并对该试验的管理和财务负责的个人、公司、机构或组织。

1.54 Sponsor-Investigator

1.54 申办者-研究者

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

单独或与其他人一起，发起并实施一个临床试验的个人。在他(们)的直接指示下，给对象服用、发给对象或由对象使用试验用药品。该术语并不包括除了个人以外的任何人(如不包括一个公司和一个机构)。一个申办者-研究者的义务包括一个申办者和一个研究者两者的义务。

1.55 Standard Operating Procedures (SOPs)

1.55 标准操作程序（SOP）

Detailed, written instructions to achieve uniformity of the performance of a specific function.

为达到均一性完成一个特定职责制订的详细书面说明。

1.56 Sub-investigator

1.56 次级研究人员

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

在一个试验单位，在主要研究者指定和监督下的临床试验组中完成与试验有关的重要程序和/或作出与有关试验的重大决定的成员(如同事，住院医生，特别是研究生)。见研究者。

1.57 Subject/Trial Subject

1.57 对象/试验对象

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

参加一个临床试验作为试验药品的接受者或作为对照的个人。

1.58 Subject Identification Code

1.58 对象识别编码

A unique identifier assigned by the investigator to each trial subject to protect the subjects identity and used in lieu of the subject's name when the investigator reports

adverse events and/or other trial related data.

研究者为每一名受试者分配的一个独特识别号码，以保护对象的身份并在研究者报告不良事件和其他与试验有关数据时用来代替受试者的姓名。

1.59 Trial Site

1.59 试验单位

The location(s) where trial-related activities are actually conducted.

进行与临床试验有关活动的场所。

1.60 Unexpected Adverse Drug Reaction

1.60 非预期的药品不良反应

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

一种不良反应，其性质或严重程度与现有的产品资料(如一种未批准的试验用药品的研究者手册，或包装插入页/一个已经批准药物的产品性能摘要)不符的不良反应(见 ICH 临床安全性数据管理指导原则：快速报告的定义和标准)。

1.61 Vulnerable Subjects

1.61 弱势对象

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

指受到不正当的影响而成为临床试验志愿者的人，他们可能由于期望（无论正当与否）参加试验而伴随的利益，或者拒绝参加会受到等级中资深成员的报复。有等级结构的团体的成员，如医学、药学、牙科和护理专业的学生，附属医院和实验室人员，制药公司的雇员，军人，以及被监禁的人。其他弱势对象包括无可救药疾病的病人，住在福利院中的人，失业者或穷人，处于危急状况的病人，少数民族，无家可归者，流浪者，难民，未成年者，和那些无能力给出知情同意的人。

1.62 Well-being (of the trial subjects)

1.62(试验对象的)健康

The physical and mental integrity of the subjects participating in a clinical trial.

参加临床试验受试者的身体和精神的完整性。

ADDENDUM

附录

1.63 Certified Copy

1.63 核证副本

A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

经核实(如注明日期的签字或通过可验证的程序产生的)，与原始记录有相同信息（包括描述数据的上下文、内容和结构）的副本（无论使用何种媒介类型）。

1.64 Monitoring Plan

1.64 监查计划

A document that describes the strategy, methods,responsibilities, and requirements for monitoring the trial.

一份描述试验监查策略、方法、职责和要求的文件。

1.65 Validation of Computerized Systems

1.65 计算机系统验证

A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.

指建立并记录计算机系统符合规定要求的过程，该计算机系统需要持续满足设计要求，至系统退役或过渡至一个新的系统中。验证方法需要基于风险评估，考虑系统的预期用途和系统潜在影响受试者保护和试验结果可靠性的可能。

2. THE PRINCIPLES OF ICH GCP

2.ICH GCP 的原则

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2.1 临床试验的实施应符合源自赫尔辛基宣言的伦理原则，与 GCP 和适用管理要求一致。

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

2.2 在开始一项试验之前，应当权衡该临床试验对于个体受试者和社会的可预见的风险、不方便和预期的受益。只有当预期的受益大于风险时，才可以开始和继续这项临床试验。

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

2.3 受试者的权利、安全和健康是最重要的考虑，应当高于对科学和社会的利益的考虑。

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

2.4 应该有足够的关于试验用药品的非临床和临床资料提供，以支持所计划进行的临床试验。

2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

2.5 进行药物临床试验必须有充分的科学依据，应在试验方案中明确、详细地描述。

2.6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

2.6 临床试验的实施应当遵循事先已经得到研究机构审查委员会(IRB)/独立的伦理委员会(IEC)批准/赞成的试验方案。

2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

2.7 一名合格医生或合格牙医的职责永远是给予对象医疗保健，代表对象作出医学决定。

2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

2.8 参与实施临床试验的每一个人应当在受教育、培训和经验方面都有资格完成他或她的预期任务。

2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

2.9 在参加临床试验前,应获得每一个受试者主动给出的知情同意。

2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

2.10 所有临床试验资料应被妥善的记录、处理和保存,以便确保相关资料能进行准确报告、解释和核对。

ADDENDUM

附录

This principle applies to all records referenced in this guideline, irrespective of the type of media used.

这个原则适用于本指南中的所有记录，不论使用何种类型媒介。

2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

2.11 确保用于鉴别受试者身份的记录的保密性应当得到保护，根据相应的保密规定。

2.12 Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance

with the approved protocol.

2.12 试验用药品应当按照适用的药品生产质量管理规范(GMP)生产、处理和储存。试验用药品应按照已批准的方案使用。

2.13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

2.13 应当建立相应的程序系统来保证试验各方面质量。

ADDENDUM

附录

Aspects of the trial that are essential to ensure human subject protection and reliability of trial results should be the focus of such systems.

系统关注的重点应在确保受试者的保护和试验结果的可靠性这些必不可少方面。

3 INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE(IRB/IEC)

3.机构审评委员会/独立的伦理委员会(IRB/IEC)

3.1 Responsibilities

3.1 职责

3.1.1 An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

3.1.1 IRB/IEC 应当保护所有受试者的权利、安全和健康。应当特别注意那些可能有弱势对象参与的试验。

3.1.2 The IRB/IEC should obtain the following documents:

3.1.2IRB/IEC 应当得到以下文件:

trial protocol(s)/amendment(s),written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g.,advertisements),written information to be provided to subjects,Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfil its responsibilities.

试验方案/修改，研究人员申请用于试验的书面知情同意书及其更新件，受试者招募程序(如广告)，提供给受试者的书面资料，研究者手册(IB)，可得到的安全性资料，受试者可获得的付款和补偿，研究人员的最新简历和/或其他证明其资格的文件，以及 IRB/IEC 履行其职责所需要的任何其他文件。

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:

IRB/IEC 应当在合理的时限内审查所提议的临床研究，提供书面审评意见，明确地确认试验、所审评的文件和日期如下:

-approval/favourable opinion;

批准/赞成意见；

-modifications required prior to its approval/favourable opinion;

在批准/赞成之前所需要的修改；

-disapproval / negative opinion; and

不批准/负面的意见；和

-termination/suspension of any prior approval/favourable opinion.

终止/暂停先前的批准/赞成意见。

3.1.3 The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

3.1.3IRB//IEC 应当参照研究人员最新简历和/或 IRB/IEC 要求的其他相关文件考虑参加所提议试验的研究人员的资格。

3.1.4 The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

3.1.4IRB/IEC 应当根据人类对象的危险度，间隔一定时间对正在进行的试验进行持续的审评，至少每年一次。

3.1.5 The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgement of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects.

3.1.5 在 IRB/IEC 审评中，IRB/IEC 可能需要比 4.8.10 段概述中提供给受试者更多的资料，这些资料在对于增加保护对象的权利、安全和/或健康有意义。

3.1.6 When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

3.1.6 当一个将进行的非治疗试验是由受试者的可接受的合法代表给出知情同意时(见 4.8.12，4.8.14)，IRB/IEC 应当确定，所建议的方案和/或其他文件已经充分说明了相关的伦理学考虑，并符合这一类试验的适用管理要求。

3.1.7 Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e., in emergency situations).

3.1.7 试验方案指出试验受试者或其合法的可接受的代表的不可能先给出知情同意时(见 4.8.15)，IRB/IEC 应当确定所提议的方案和/或其他文件充分说明了相关的伦理学考虑，并符合这一类试验的适用管理要求。

3.1.8 The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

3.1.8IRB/IEC 应当审评支付给受试者款项的数量和方式，以确信没有对试验对象的胁迫问题或不正当影响。给受试这的支付应当按比例分配，而不是完全以受试者完成试验而定。

3.1.9 The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

3.1.9IRB/IEC 应当保证，关于支付给受试者的资料，包括支付方式、数量和支付给试验受试者的时间表已列于知情同意书和将提供给受试者的任何其他书面资料上，应注明按比例支付的方式。

3.2 Composition, Functions and Operations

3.2 组成、职责和操作

3.2.1 The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

3.2.1IRB/IEC 应由合理数目的成员组成，他们全体都有审评和评价科学、医学和所提议试验的伦理学方面问题的资格和经验。建议 IRB/IEC 应包括：

(a) At least five members.

(a)至少 5 名成员；

(b) At least one member whose primary area of interest is in a nonscientific area.

(b)至少 1 名成员关心的主要领域是非科学领域；

(c) At least one member who is independent of the institution/trial site.

(c)至少 1 名成员独立于研究机构/试验单位。

Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

只有那些独立于试验研究者和申办者的 IRB/IEC 成员才能对一个试验的相关事项投票/提出意见。

A list of IRB/IEC members and their qualifications should be maintained.

应当提供一份 IRB/IEC 成员的名单和他们的资格表。

3.2.2 The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

3.2.2IRB/IEC 应当按照书面的操作程序完成其职责，应当保存其活动的书面记录和会议记录，并应当遵守 GCP 和适用的管理要求。

3.2.3 An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.

3.2.3IRB/IEC 应当在达到其书面操作程序中规定的法定人数的正式会议上作出决定。

3.2.4 Only members who participate in the IRB/IEC review and discussion should vote/provide their opinion and/or advise.

3.2.4 只有参加 IRB/IEC 审评和讨论的成员才可投票/提出他们的评价和/或意见。

3.2.5 The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC.

3.2.5 研究者应当提供试验各方面的资料，但不应当参加 IRB/IEC 的审议或 IRB/IEC 的投票/意见。

3.2.6 An IRB/IEC may invite nonmembers with expertise in special areas for assistance.

3.2.6 IRB/IEC 可邀请在特别领域有专门知识的非成员来帮助。

3.3 Procedures

3.3 程序

The IRB/IEC should establish, document in writing, and follow its procedures, which should include:

IRB/IEC 应当建立书面文件和遵循其程序，程序应包括：

3.3.1 Determining its composition (names and qualifications of the members) and the authority under which it is established.

3.3.1 确定其组成(成员的姓名和资格)和授权；

3.3.2 Scheduling, notifying its members of, and conducting its meetings.

3.3.2 安排时间，通知其成员，举行会议；

3.3.3 Conducting initial and continuing review of trials.

3.3.3 对试验进行初始审评和继续审评；

3.3.4 Determining the frequency of continuing review, as appropriate.

3.3.4 酌情确定继续审评的频度；

3.3.5 Providing, according to the applicable regulatory requirements, expedited review and approval/favourable opinion of minor change(s) in ongoing trials that have the approval/favourable opinion of the IRB/IEC.

3.3.5 依照适用的管理要求，为已经获得 IRB/IEC 批准/赞成的正在进行的试验的较小修改提供快速审议和批准/赞成意见；

3.3.6 Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favourable opinion of the trial.

3.3.6 说明在 IRB/IEC 书面签署对试验的批准/赞成意见之前不得接纳对象进入试验；

3.3.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g.,change of monitor(s), telephone number(s)) (see 4.5.2).

3.3.7 说明在方案的适当修改预先得到 IRB/IEC 的书面批准/赞成之前，不能偏离或改变试验方案，除非有必要排除对于受试者的直接危害，或方案的改变只涉及试验的后勤或管理方面(如更换监查员，改变电话号码)(见 4.5.2)；

3.3.8 Specifying that the investigator should promptly report to the IRB/IEC:

3.3.8 说明研究人员应当立即报告 IRB/IEC 的事项：

(a) Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects (see 3.3.7, 4.5.2, 4.5.4).

(a)偏离或改变方案以消除对试验受试者的直接危害(见 3.3.7，4.5.2，4.5.4)；

(b) Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial (see 4.10.2).

(b)增加对象风险的改变和/或明显影响试验实施的改变(见 4.10.2)；

(c) All adverse drug reactions (ADRs) that are both serious and unexpected.

(c)所有严重的和非预期的药品不良反应(ADR)

(d) New information that may affect adversely the safety of the subjects or the conduct of the trial.

(d)对试验的进行或受试者的安全可能有不利影响的新资料。

3.3.9 Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:

3.3.9 确保 IRB/IEC 迅速书面通知研究者/研究究机构的事项：

(a) Its trial-related decisions/opinions.

(a)与试验有关的决定/意见；

(b) The reasons for its decisions/opinions.

(b)IRB/IEC 决定/意见的理由；

(c) Procedures for appeal of its decisions/opinions.

(c)请求 IRB/IEC 决定/意见的程序。

3.4 Records

3.4 记录

The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members,submitted documents, minutes of meetings, and correspondence) for a period of at least 3-years after completion of the trial and make them available upon request from the regulatory authority(ies).

IRB/IEC 应当保留全部有关记录(如书写的程序，成员名，成员的职业/联系表，提交的文件，会议记录，以及往来信件)至完成试验后至少 3 年，并在管理当局需要时可以提供。

The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide

its written procedures and membership lists.

研究者、申办者或管理当局可能会要求 IRB/IEC 提供其书面程序和成员名单。

4.INVESTIGATOR

4.研究者

4.1 Investigator's Qualifications and Agreements

4.1 研究者的资格和协议

4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority (ies).

4.1.1 研究者应当在受教育、培训和经验方面有资格承担实施试验的责任，应当符合适用的管理要求所说明的所有条件，并应当通过现时的个人简历和/或申办者、IRB/IEC 和/或管理当局要求的其他相关文件提供这种资格证明。

4.1.2 The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.

4.1.2 研究者应当充分熟悉在试验方案、研究者手册、产品资料以及申办者提供的其他资料中所述的试验用药品的合适用途。

4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

4.1.3 研究者应当了解并遵循 GCP 和适用的管理要求。

4.1.4 The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

4.1.4 研究者/研究机构应当允许申办者的监查和稽查，以及管理部门的视察。

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

4.1.5 研究者应当有一份有合适资格、并已委派给他们与试验相关的重要任务的人员名单。

4.2 Adequate Resources

4.2 足够的资源

4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

4.2.1 研究者应能证明(如根据以往的数据)在协议的招募期内接纳所需要数目的合适受试者的可能性。

4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

4.2.2 研究者在协议的试验期内应当有足够的时间实施和完成试验。

4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4.2.3 在可预见的试验期内，研究者应当有足够数量的合格职员和充足的设备来正确、安全地实施试验。

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

4.2.4 研究者应当保证所有的试验辅助人员已充分了解试验方案，试验用药品，及他们与试验相关的责任和职能。

ADDENDUM

附录

4.2.5 The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.

4.2.5 研究者负责监督被其授权在本试验中心实施试验相关职责和功能的个体和团体。

4.2.6 If the investigator/institution retains the services of any individual or party to perform trial-related duties and functions, the investigator/institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

4.2.6 如果研究者/机构授权任何个人或团体执行试验相关的责任和职能，研究者应当保证这些被授权的个人或团体有资格执行这些试验相关的职责和功能。研究者应该建立并执行相应的程序以保证试验相关职责、功能的执行与任何数据生成的完整性。

4.3 Medical Care of Trial Subjects

4.3 受试者的医疗保健

4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or a subinvestigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

4.3.1 作为一名研究者或次级研究人员的合格医生(或牙医)应当对与试验有关的所有医学(牙科)决定负责。

4.3.2 During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

4.3.2 在受试者参加一个试验期间或以后，研究者/研究机构应当保证为受试者的任何不良反应，包括与试验有关的临床上有意义的实验室测定值提供合宜的医疗保健。研究者在意识到合并疾病需要医疗保健时，应当通知受试者。

4.3.3 It is recommended that the investigator inform the subject's primary physician about

the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

4.3.3 如果受试者有自己的主管医生并且受试者同意让自己的主管医生知道，建议研究者将受试者参加试验的事通知其主管医生。

4.3.4 Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

4.3.4 尽管一名受试者没有义务给出他/她中途退出试验的理由，研究者仍应当在充分尊重其权利的同时作出合理的努力确认其退出理由。

4.4 Communication with IRB/IEC

4.4 与 IRB/IEC 的交流

4.4.1 Before initiating a trial, the investigator/institution should have written and dated approval/favourable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.

4.4.1 在开始一个试验前，研究者/研究机构应当有 IRB/IEC 对试验方案、知情同意书、知情同意书的更新、对象招募程序(如广告)、以及提供给受试者的任何其他书面资料的书面的、注明日期的批准/赞成意见。

4.4.2 As part of the investigator's/institution's written application to the IRB/IEC, the investigator/institution should provide the IRB/IEC with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB/IEC.

4.4.2 作为研究者/研究机构向 IRB/IEC 书面申请的一部分，研究者/研究机构应当向 IRB/IEC 提供研究者手册的最新版本。如果研究者手册在试验中进行了更新，研究者/研究机构应当向 IRB/IEC 提供更新的研究者手册。

4.4.3 During the trial the investigator/institution should provide to the IRB/IEC all documents subject to review.

4.4.3 在试验期间，研究者/研究机构应当向 IRB/IEC 提供全部需要进行审评的文件。

4.5 Compliance with Protocol

4.5 对试验方案的依从性

4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies) and which was given approval/favourable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

4.5.1 研究者/研究机构应当按照经申办者和(如有必要)管理当局同意、并得到 IRB/IEC 批准/赞成的方案实施试验。研究者/研究机构和申办者应当在方案上或试验合同上签字，确认同意方案。

4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only

logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

4.5.2 研究者在没有取得申办者同意和事先得到 IRB/IEC 对于一个方案修改的审评与书面批准/赞成时，不应当偏离或改变方案，除非必须消除试验对象的直接危险或这些改变只涉及试验的供应或管理方面(如更换监查员，改变电话号码)。

4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

4.5.3 研究者，或由研究者指定的人，应当记录和解释与已批准方案的任何偏离。

4.5.4 The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favourable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

4.5.4 为了消除对试验对象的直接危险，研究者可以没有 IRB/IEC 的预先批准/赞成意见偏离或改变方案。所实施的偏离或改变、改变的理由、以及所提议的方案修改应尽可能快地提交给：

(a) to the IRB/IEC for review and appro val/favourable opinion,

(a)IRB/IEC 审评并得到批准/赞成；

(b) to the sponsor for agreement and, if required,

(b)申办者征得同意和，如果需要；

(c) to the regulatory authority(ies).

(c)管理当局。

4.6 Investigational Product(s)

4.6 试验用药品

4.6.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

4.6.1 在试验单位，试验用药品计数的责任归于研究者/研究机构。

4.6.2 Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution..

4.6.2 只要允许/需要，研究者/研究机构可以/应当将试验单位研究者的/机构对试验用药品计数的责任部分或全部指派给在研究者/研究机构监督下的合适的药师或其他适当的人员。

4.6.3 The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s)

received from the sponsor.

4.6.3 研究者/研究机构和/或受研究者/研究机构指派的一名药师或其他合适的个人，应当保存试验用药品交到试验单位的记录，在试验单位的存货清单，每位受试者的使用记录，和未使用药品交还给申办者或另法处置的记录。这些记录应包括日期、数量、批号/系列号、失效期(如有)、和分配给试验用药品和试验受试者的特别编码。研究者应保持记载有按方案说明给予受试者药量的记录，并应与从申办者处收到的试验用药品总数一致。

4.6.4 The investigational product(s) should be stored as specified by the sponsor (see 5.13.2 and 5.14.3) and in accordance with applicable regulatory requirement(s).

4.6.4 试验用药品应当按申办者的说明储存(见 5.13.2 和 5.14.3)并符合适用的管理要求。

4.6.5 The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.

4.6.5 研究者应当保证试验用药品只按已批准的方案使用。

4.6.6 The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.

4.6.6 研究者或由研究者/研究机构指定的人，应当向每一位受试者解释试验用药品的正确用法，并应在适合于该试验的一定间隔检查每一位受试者完全遵照使用说明用药。

4.7 Randomization Procedures and Unblinding

4.7 随机化程序和破盲

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

研究者应当遵循试验的随机化程序(如果有)，并应保证依照方案打开随机号码。如果试验采用盲法，研究者应当立即记录并向申办者解释试验药品的任何提前破盲（如意外破盲，因严重不良事件破盲）。

4.8 Informed Consent of Trial Subjects

4.8 试验受试者的知情同意

4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB/IEC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to subjects.

4.8.1 在获得和证明知情同意过程中，研究者应当遵循适用的管理规定，应当符合 GCP 和源自赫尔辛基宣言的伦理原则。在开始试验前，研究者应当有 IRB/IEC 对于书面的知情同意书和提供给受试者的其他文字资料的书面批准/赞成意见。

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favourable opinion in advance

of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.

4.8.2 无论何时得到与受试者的知情同意可能相关的新的资料后，提供给受试者的书面知情同意书和其他文字资料都应当进行修改。修改后的书面知情同意书和其他文字资料在使用前都应当得到 IRB/IEC 的批准/赞成。如果有与受试者继续参加试验的愿望可能相关的新资料，应及时通知受试者和受试者的合法可接受代表。这种资料的交流应当被记录下来。

4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

4.8.3 无论是研究人员或是试验职员，都不应强迫或不正当地影响一个受试者参加或继续参加一个试验。

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.4 关于试验的口述或书面的资料，包括书面的知情同意书，都不应当包含会引起受试者或受试者的合法可接受代表放弃或看来像是放弃任何合法权益的语言；或者免除或看来像是免除研究者、机构、申办者或他们的代理由于疏忽应负责任的语言。

4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the IRB/IEC.

4.8.5 研究者或由研究者指定的人，至少应当告诉受试者，或如果受试者不能提供知情同意时告诉受试者的合法可接受的代表，所有与试验有关的方面，包括文字资料和 IRB/IEC 的批准/赞成意见。

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.6 关于试验的口述和书面资料，包括书面知情同意书，所用的语言应当是非技术术语性的实用语言，对于受试者或受试者的合法可接受代表或公正的见证人应当是易懂的。

4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

4.8.7 在可能得到知情同意之前，研究者或研究者指定的人应当让受试者或受试者的合法可接受代表有充足的时间和机会询问关于试验的详细情况和决定是否参加试验。应当回答关于试验的所有问题，让受试者或受试者的合法可接受代表满意。

4.8.8 Prior to a subject’s participation in the trial,the written informed consent form should be signed and personally dated by the subject or by the subject’s legally acceptable representative, and by the person who conducted the informed consent discussion.

4.8.8 在受试者参加试验之前，受试者或受试者的合法可接受代表以及执行知情同意讨论的人应亲自签署知情同意书并注明日期。

4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects,is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and,if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subjecf's legally acceptable representative.

4.8.9 如果一名受试者不能阅读，或一位合法可接受的代表不能阅读，在整个知情同意讨论期间必须有一位公正的见证人在场。在书面的知情同意书和其他文字资料交给受试者后，向受试者或受试者的合法可接受代表进行阅读并解释，在受试者或受试者的合法可接受代表已经口头同意受试者参加试验、并且如果可能已在知情同意书上亲自签字和注明日期后，见证人应当亲自在知情同意书上签字并注明日期。见证人通过签署知情同意书证明，知情同意书和其他文字资料已被准确地向受试者或受试者的合法可接受代表作了解释，受试者或受试者的合法可接受代表显然懂得这些解释，知情同意是受试者或受试者的合法可接受代表自由地给出的。

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

4.8.10 知情同意讨论和提供给受试者的书面的知情同意书以及其他文字资料应当包括对下列问题的解释：

(a) That the trial involves research.

(a)试验涉及的研究。

(b) The purpose of the trial.

(b)试验目的。

(c) The trial treatment(s) and the probability for random assignment to each treatment.

(c)试验治疗和随机分配到各种治疗的可能性。

(d) The trial procedures to be followed, including all invasive procedures.

(d)试验进行的操作，包括所有有创性操作。

(e) The subject's responsibilities.

(e)受试者的责任。

(f) Those aspects of the trial that are experimental.

(f)试验的实验性方面。

(g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

(g) 带给受试者、可能时带给胚胎、胎儿或哺乳婴儿的合理预见的危险或不方便。

(h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

(h) 可合理预见的受益。不存在预期的临床受益时，受试者应当知道这一点。

(i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

(i)受试者可能得到的可替代治疗程序或措施，以及这些治疗的重要潜在受益和风险。

(j) The compensation and/or treatment available to the subject in the event of trial-related injury.

(j)在与试验有关的伤害事件中受试者可获得的补偿和/或治疗。

(k) The anticipated prorated payment, if any, to the subject for participating in the trial.

(k) 给参加试验受试者的预期的按比例分配的支付（如果有）。

(l) The anticipated expenses, if any, to the subject for participating in the trial.

(l)受试者因参加试验的预期花费(如果有)。

(m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

(m)受试者参加试验是自愿的，可以拒绝参加试验，在任何时候退出试验而不会受到处罚或损失本来受试者有权利得到的利益。

(n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form,the subject or the subject's legally acceptable representative is authorizing such access.

(n) 监查员、稽查员、IRB/IEC 和管理当局将被准予在不违反对象的保密性、在适用法律与规定准许的程度直接访问受试者的原始医学记录以查证临床试验程序和/或数据，受试者或其的合法可接受的代表通过签署书面的知情同意书授权这种访问。

(o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published,the subject's identity will remain confidential.

(o) 在适用法律和/或规定允许的范围，能鉴别受试者的记录应保密，不得公开这些记录。如果试验结果发表，受试者鉴别仍然是保密的。

(p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

(p) 如果得到与受试者继续参加试验的愿望可能相关的资料，受试者或其的合法可接受代表将得到及时通报。

(q) The person(s) to contact for further information regarding the trial and the rights of

trial subjects, and whom to contact in the event of trial-related injury.

(q) 需要进一步了解有关试验资料和试验受试者的权利时的联系人，以及在发生与试验有关的伤害时的联系人。

(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

(r )受试者参加试验可能被终止的可预见情况和/或理由。

(s) The expected duration of the subject's participation in the trial.

(s)受试者参加试验的预期持续时间。

(t) The approximate number of subjects involved in the trial.

(t)参加试验受试者的大约人数。

4.8.11 Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

4.8.11 在参加试验前，受试者或其合法的可接受代表应收到一份已签署并注明日期的书面知情同意书的复印件和其他提供给受试者的书面资料。受试者参加试验期间，也应当收到已签署并注明日期的知情同意书的更新的复印件和提供给受试者的书面资料的修改文本。

4.8.12 When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

4.8.12 当一个临床试验(治疗的或非治疗的)包括那些只能由其合法可接受代表表示同意进入试验的受试者时(如未成年人，或严重痴呆病人)，应当在对象能理解的程度告知受试者关于试验的信息。如果可能，受试者应当亲自签署书面的知情同意并注明日期。

4.8.13 Except as described in 4.8.14, a non-therapeutic trial (i.e., a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

4.8.13 除非如 4.8.14 所描述的情况外，一个非治疗试验(如对于对象没有可预期的直接临床好处的试验)应当在那些亲自同意并在书面的知情同意书上签字和注明日期的受试者中进行。

4.8.14 Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

4.8.14 只要符合下列条件，非治疗试验可以在由合法可接受代表同意的受试者中进行:

(a) The objectives of the trial can not be met by means of a trial in subjects who can give informed consent personally.

(a) 试验的目的不能通过在能亲自给出知情同意的受试者中进行的试验达到。

(b) The foreseeable risks to the subjects are low.

(b)受试者的可预见风险很低。

(c) The negative impact on the subject's well-being is minimized and low.

(c) 对于受试者健康的负面影响被减到最小，并且是低的。

(d) The trial is not prohibited by law.

(d)法律不禁止该试验。

(e) The approval/favourable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/ favourable opinion covers this aspect.

(e) 明确地寻求 IRB/IEC 对接纳这些受试者的批准/赞成意见；书面的批准/赞成意见同意接纳这些受试者。

Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

除非被证明是一个例外，这类试验应当在具有预期使用试验用药品的疾病或状况的病人中进行。这些试验中的受试者应当受到特别密切地监查，如果他们显得过分痛苦,应当退出试验。

4.8.15 In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative,if present,should be requested. When prior consent of the subject is not possible,and the subject's legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere,with documented approval/favourable opinion by the IRB/IEC, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see 4.8.10) should be requested.

4.8.15 在紧急情况下，不可能事先得到受试者的知情同意时，应该请求受试者的合法可接受代表(如果在场)的同意。当受试者的事先知情同意不可能、并且受试者的合法可接受代表不在场时，受试者的接纳需要按方案和/或其他文件中描述的、得到 IRB/IEC 的书面批准/赞成意见的方法进行，以保护受试者的权利、安全和健康，并保证依从适用的管理要求。应尽可能快地通知受试者或其的合法可接受代表关于试验的事，并应得到他们继续参加试验和其他事项(见 4.8.10)的知情同意。

4.9 Records and Reports

4.9 记录和报告

ADDENDUM

附录

4.9.0 The investigator/institution should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail).

4.9.0 研究者/机构应当保留足够和准确的原始文件和试验记录，包括中心每个试验受试者相关的观察。源数据应该是有来源的、清晰的、时间一致的、原始的、准确的和完整的。源数据的修改应该是可溯源的，不能遮掩最初的记录，必要时应进行解释（例如：通过稽查轨迹）。

4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

4.9.1 研究者应当保证给申办者的病例记录表(CRF)和所有需要的报告中的数据的准确性、完整性、易辨认和及时性。

4.9.2 Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

4.9.2CRF 中来自源文件的数据应当与源文件一致，如有不一致应作出解释。

4.9.3 Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections (see 5.18.4 (n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

4.9.3CRF 中数据的任何改变或更正，应当注明日期、姓名首字母和说明(如有必要)，并应当使原来的记录依然可见(即应保留核查痕迹)；这同样适用于文字和电子的改变或更正(见 5.18.4(n))。申办者应当向研究者和/或研究者指定的代表提供关于进行这种更正的指南。申办者应当有书面的程序以保证在 CRF 中由申办者指定的代表作出的改变或更正是有记录的、有必要的，并得到研究者的认可。研究者应当保留改变和更正的记录。

4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.

4.9.4 研究者/研究机构应当按《实施临床试验的基本文件》(见 8.)所述和适用管理要求保存试验文件。研究者/研究机构应当采取措施防止这些文件的意外或过早毁坏。

4.9.5 Essential documents should be retained until at least 2-years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2-years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see 5.5.12).

4.9.5 基本文件应当保留到最后批准在一个 ICH 地区上市后至少 2 年，和直到在一个 ICH 地区没有未决的或仍在考虑的上市应用，或试验用药品的临床研究正式停止后至少已过去 2 年，但是，如果适用的管理要求需要或与申办者签署的协议需要，这些文件应当被保存更长时间。申办者有责任通知研究者/研究机构，到什么时候这些文件不必再保存(见 5.5.12)。

4.9.6 The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

4.9.6 试验的财务方面事宜应在申办者与研究者/研究机构的协议书中写明。

4.9.7 Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

4.9.7 根据监查员、稽查员、IRB/IEC 或管理当局的要求，研究者/研究机构应当提供他们查阅所需的与试验有关的全部记录。

4.10 Progress Reports

4.10 进展报告

4.10.1 The investigator should submit written summaries of the trial status to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.

4.10.1 研究者应当每年一次，或应 IRB/IEC 要求的频度向 IRB/IEC 提交书面的试验情况摘要。

4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8) and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.

4.10.2 研究者应当迅速向申办者、IRB/ICE(见 3.3.8)和(如果合适)向研究机构提供关于明显影响试验实施和/或增加受试者风险的任何改变的书面报告。

4.11 Safety Reporting

4.11 安全性报告

4.11.1 All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.

4.11.1 除了试验方案或其他文件(如研究者手册)认为不必即时报告的那些严重不良事件(SAE)以外，所有 SAE 都应当立即向申办者报告。即时报告应理解为迅速的详细书面报告。即时随访报告中的对象鉴别应当采用指定给试验对象的独特号码，而不是对象姓名、个人身份号码和/或地址。研究者还应当服从关于向管理当局和 IRB/IEC 报告非预期的药物严重不良反应的适用管理要求。

4.11.2 Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

4.11.2 在试验方案中被确定为对安全性评价是关键的不良事件和/或实验室异常应当按照报告要求和申办者在方案中说明的时限内向申办者报告。

4.11.3 For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports).

4.11.3 对于所报告的死亡事件，研究者应当向申办者和 IRB/IEC 提供所需要的全部附加资料(如解剖报告和最终医学报告)。

4.12 Premature Termination or Suspension of a Trial

4.12 试验的中止或暂停

If the trial is prematurely terminated or suspended for any reason, the

investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition:

如果一个试验因为任何理由过早地停止或暂停，研究者/研究机构应当迅速通知试验对象，应当保证对象的合适治疗和随访，和根据适用的管理要求应当通知管理当局。另外：

4.12.1 If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB/IEC, and should provide the sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.

4.12.1 如果研究者未与申办者事先协议便中止或暂停一个试验，研究者应当通知研究机构，研究者/研究机构应当立即通知申办者和 IRB/IEC，并应向申办者和 IRB/IEC 提供中止或暂停试验的详细书面解释。

4.12.2 If the sponsor terminates or suspends a trial (see 5.21), the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB/IEC and provide the IRB/IEC a detailed written explanation of the termination or suspension.

4.12.2 如果申办者终止或暂停一个试验(见 5.21)，研究者应当立即通知研究机构，研究者/研究机构应立即通知 IRB/IEC 并向 IRB/IEC 提供终止和暂停的详细书面解释。

4.12.3 If the IRB/IEC terminates or suspends its approval/favourable opinion of a trial (see 3.1.2 and 3.3.9), the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

4.12.3 如果 IRB/IEC 终止或暂停它对一个试验的批准/赞成意见(见 3.12 和 3.3.9)，研究者应当通知研究机构，研究者/研究机构应当立即通报申办者并提供终止或暂停的详细书面解释。

4.13 Final Report(s) by Investigator

4.13 研究者的最终报告

Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB/IEC with a summary of the trial's outcome, and the regulatory authority(ies) with any reports required.

在试验完成后，研究者应当通知研究机构，研究者/研究机构应当向 IRB/IEC 提供试验结果的摘要，向管理当局提供所需要的所有报告。

5. SPONSOR

5.申办者

ADDENDUM

附录

5.0 Quality Management

5.0 质量管理

The sponsor should implement a system to manage quality throughout all stages of the trial process.

申办者应该建立一个系统来管理试验过程中的所有阶段的质量。

Sponsors should focus on trial activities essential to ensuring human subject protection and the reliability of trial results. Quality management includes the design of efficient clinical trial protocols and tools and procedures for data collection and processing, as well as the collection of information that is essential to decision making.

申办者应该关注确保受试者得到保护和试验结果可靠性的试验活动。质量管理包括有效的临床试验方案的设计，数据收集、处理的工具和程序的设计，以及临床决策必需信息的收集。

The methods used to assure and control the quality of the trial should be proportionate to the risks inherent in the trial and the importance of the information collected. The sponsor should ensure that all aspects of the trial are operationally feasible and should avoid unnecessary complexity, procedures, and data collection. Protocols, case report forms, and other operational documents should be clear, concise, and consistent.

保证和控制试验质量的方法应该与试验内在的风险和收集信息的重要性相称。申办者应该确保试验的所有方面都是可操作的，避免不必要的复杂性、过程和数据收集。方案、病例报告表和其它操作文件应该清晰、简洁、前后一致。

The quality management system should use a risk-based approach as described below.

质量管理系统应该使用基于风险的方法，如下所述。

5.0.1 Critical Process and Data Identification

5.0.1 关键流程和数据识别

During protocol development, the sponsor should identify those processes and data that are critical to ensure human subject protection and the reliability of trial results.

在方案制定过程中，申办者应该识别对确保受试者得到保护和试验结果可靠至关重要的流程和数据。

5.0.2 Risk Identification

5.0.2 风险识别

The sponsor should identify risks to critical trial processes and data. Risks should be considered at both the system level (e.g., standard operating procedures, computerized systems, personnel) and clinical trial level (e.g., trial design, data collection, informed consent process).

申办者应该识别关键流程和数据的风险。申办者需要在两个层面考虑风险，系统层面（例如：标准操作规程，计算机系统，人员）和临床试验层面（例如：试验设计，数据收集，知情同意过程）。

5.0.3 Risk Evaluation

5.0.3 风险评估

The sponsor should evaluate the identified risks, against existing risk controls by considering:

申办者应该评估经确定的风险，对现有的风险控制考虑：

(a) The likelihood of errors occurring.

（a）错误发生的可能性；

(b) The extent to which such errors would be detectable.

（b）此类错误可被察觉的程度；

(c) The impact of such errors on human subject protection and reliability of trial results.

（c）错误对受试者保护和试验数据可靠性的影响；

5.0.4 Risk Control

5.0.4 风险控制

The sponsor should decide which risks to reduce and/or which risks to accept. The approach used to reduce risk to an acceptable level should be proportionate to the significance of the risk. Risk reduction activities may be incorporated in protocol design and implementation, monitoring plans, agreements between parties defining roles and responsibilities, systematic safeguards to ensure adherence to standard operating procedures, and training in processes and procedures.

申办者应该决定哪些风险需要降低，哪些风险可被接受。将风险降低至可接受程度的方法应该与风险的重要性相称。降低风险的内容应该在方案设计和实施，监查计划，定义双（多）方角色和责任的协议，系统安全措施中体现，以确保遵循标准操作规程，过程和程序的培训。

Predefined quality tolerance limits should be established, taking into consideration the medical and statistical characteristics of the variables as well as the statistical design of the trial, to identify systematic issues that can impact subject safety or reliability of trial results. Detection of deviations from the predefined quality tolerance limits should trigger an evaluation to determine if action is needed.

申办者应预先设定质量容许限，统计设计试验时要考虑变量的医学和统计学特征，定义能影响受试者安全和试验结果可靠性的系统性问题。发现试验偏离预先设定的质量容许限时，要进行评估以确定是否要采取措施。

5.0.5 Risk Communication

5.0.5 风险沟通

The sponsor should document quality management activities. The sponsor should communicate quality management activities to those who are involved in or affected by such activities, to facilitate risk review and continual improvement during clinical trial execution.

申办者应该记录质量管理活动。申办者应该与相关人员或受其活动影响的人员沟通质量管理活动，促使在临床试验执行中进行风险回顾和不断改进。

5.0.6 Risk Review

5.0.6 风险回顾

The sponsor should periodically review risk control measures to ascertain whether the implemented quality management activities remain effective and relevant, taking into account emerging knowledge and experience.

申办者应该定期回顾风险控制措施来确定所实施的质量管理活动依然有效、可行，要考虑新出现的知识和经验。

5.0.7 Risk Reporting

5.0.7 风险报告

The sponsor should describe the quality management approach implemented in the trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in the clinical study report (ICH E3, Section 9.6 Data Quality Assurance).

申办者应该在临床试验报告中描述试验中实施的质量管理办法，总结严重偏离预先设定的质量容许限的事件及补救措施（ICH3，9.6 节数据质量保证）。

5.1 Quality Assurance and Quality Control

5.1 质量保证和质量控制

5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

5.1.1 申办者负责按照书面 SOP 执行和维持质量保证和质量控制系统，保证试验的实施和数据的产生、记录和报告遵循试验方案/GCP、及适用的管理要求。

5.1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial related sites, source data/documents , and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

5.1.2 申办者有责任保护各有关方面的协议，保证申办者方以监查和稽查为目的直接访问(见 1.21)各有关试验单位、源数据/文件、报告，以及保证国内和国外管理当局的视察。

5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

5.1.3 在数据处理的每一阶段都应当有质量控制，以保证所有的数据是可靠的并已经得到正确处理。

5.1.4 Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.

5.1.4 申办者和研究者/研究机构以及参与临床试验的其他方应当订立书面协议；协议可以是方案的一部分，也可以是单独的协议。

5.2 Contract Research Organization (CRO)

5.2 合同研究机构(CRO)

5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.

5.2.1 申办者可以将与试验有关的责任和任务部分或全部转移给一个 CRO，但是试验数据的质量和完整性的最终责任永远在申办者。CRO 应当建立质量保证和质量控制。

5.2.2 Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.

5.2.2 转移给 CRO 的或 CRO 承担的任何与试验有关的责任和职能应当有书面说明。

ADDENDUM

附录

The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including trial-related duties and functions that are subcontracted to another party by the sponsor's contracted CRO(s).

申办者应该监督任何试验相关的责任和职能都被贯彻实施，包括由 CRO 外包给第三方的责任和职能。

5.2.3 Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.

5.2.3 没有明确转移给 CRO 或由 CRO 承担的任何与试验有关责任和职能仍然由申办者承担。

5.2.4 All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial related duties and functions of a sponsor.

5.2.4 在本指导原则中涉及申办者的一切也适用于一个 CRO，就像 CRO 已经承担了一个申办者的与试验相关责任和职能。

5.3 Medical Expertise

5.3 医学专家

The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose.

申办者应当指定有合适资格的医学人员，他们能迅速对试验有关疑问或问题提出建议。如果必要，可以任命外来顾问。

5.4 Trial Design

5.4 试验设计

5.4.1 The sponsor should utilize qualified individuals (e.g., biostatisticians, clinical pharmacologists, and physicians) as appropriate,throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports.

5.4.1 在试验过程的各个阶段，从设计试验方案、CRF、计划分析到分析和准备中期与最终临床试验报告，申办者应当任用有合适资格的人(如生物统计学家，临床药理学家和医生)。

5.4.2 For further guidance: Clinical Trial Protocol and Protocol Amendment(s) (see 6.), the ICH Guideline for Structure and Content of Clinical Study Reports, and other appropriate ICH guidance on trial design, protocol and conduct.

5.4.2 进一步的指导原则：《临床试验方案和方案修改》(见 6.)，《ICH 临床试验报告的结构和内容指导原则》和关于试验设计、方案和执行的其他 ICH 指导原则。

5.5 Trial Management,Data Handling,and Record Keeping

5.5 试验管理、数据处理和记录保存

5.5.1 The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.

5.5.1 申办者应当任用有合适资格的人监督试验的全面实施、处理数据、核对数据，进行统计分析和准备试验报告。

5.5.2 The sponsor may consider establishing an independent data-monitoring committee (IDMC),to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial. The IDMC should have written operating procedures and maintain written records of all its meetings.

5.5.2 申办者应考虑建立一个独立的数据监查委员会(IDMC),定期评价临床试验的进展，包括安全性数据和关键的有效性终点；向申办者建议是否继续、修改或停止试验。IDMC 应当有书面的操作程序并保存它所有的会议记录。

5.5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

5.5.3 应用电子试验数据处理和/或遥控电子试验数据系统时，申办者应当：

(a) Ensure and document that the electronic data processing system(s),conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e., validation),

(a)确保并证明电子数据处理系统符合申办者所设定的关于完整、准确性、可靠性和一致预期的性能(如数据确认),要求。

ADDENDUM

附录

The sponsor should base their approach to validation of such systems on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.

申办者应该给予他们的方法验证这些系统，进行风险评估，考虑系统的使用目的和系统影响受试者保护和试验结果可靠性的可能性。

(b) Maintains SOPs for using these systems.

(b) 有使用这些系统的 SOP。

ADDENDUM

附录

The SOPs should cover system setup, installation, and use. The SOPs should describe system validation and functionality testing, data collection and handling, system maintenance, system security measures, change control,data backup, recovery, contingency planning, and decommissioning. The responsibilities of the sponsor, investigator, and other parties with respect to the use of these computerized systems should be clear, and the users should be provided with training in their use.

SOP 应该包含系统设置、安装和使用。SOP 应该描述系统验证、功能测试，数据收集和处理，系统维护、系统安全措施、变更控制，数据备份、恢复，应急计划和系统退役。使用这些计算机系统的申办者、研究者和其它人员的职责应该清晰，使用前应当为用户提供相关培训。

(c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail),

(c) 保证系统的设计允许数据修改按如下方式进行：数据的改变被记录下来而不删除已经录入的数据(即保留稽查痕迹、数据痕迹和编辑痕迹),

(d) Maintain a security system that prevents unauthorized access to the data.

(d) 有一个防止未经授权访问数据的安全系统。

(e) Maintain a list of the individuals who are authorized to make data changes (see 4.1.5 and 4.9.3),

(e)有一份被授权修改数据的人员名单(见 4.1.5 和 4.9.3)。

(f) Maintain adequate backup of the data.

(f)保存足够的数据备份。

(g) Safeguard the blinding,if any (e.g.,maintain the blinding during data entry and processing),

(g)如采用盲法，保护盲法安全(在数据输入和处理期间维持盲法),

ADDENDUM

附录

(h) Ensure the integrity of the data including any data that describe the context, content, and structure. This is particularly important when making changes to the computerized systems, such as software upgrades or migration of data.

(h)确保数据的完整性，包括任何描述背景、内容和结构的数据。保证数据的完整性特别重要，尤其是当计算机系统需要进行修改时，如软件升级或数据转移。

5.5.4 If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.

5.5.4 如果在处理中数据作了转换，将原始数据和观测值与处理后的数据进行比较。

5.5.5 The sponsor should use an unambiguous subject identification code (see 1.58),that allows identification of all the data reported for each subject.

5.5.5 申办者应当使用明确的对象识别码(见 1.58),以鉴别所报告的每一位受试者的所有数据。

5.5.6 The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial (see 8. Essential Documents for the Conduct of a Clinical Trial),

5.5.6 申办者或数据的其他拥有者应当保留申办者方的有关试验的所有基本文件(见 8.实施临床试验的基本文件),

5.5.7 The sponsor should retain all sponsor-specific essential documents in conformance

with the applicable regulatory requirement(s),of the country(ies),where the product is approved, and/or where the sponsor intends to apply for approval(s),

5.5.7 申办者应当保留所有申办者方的、与产品被批准和/或申办者打算申请批准的国家的适用管理要求一致的基本文件。

5.5.8 If the sponsor discontinues the clinical development of an investigational product (i.e., for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least 2-years after formal discontinuation or in conformance with the applicable regulatory requirement(s),

5.5.8 如果申办者停止一个试验用药品的临床研究(如某个或所有适应症，给药途径，或剂型),申办者应当保留所有申办者方的基本文件至正式停止后至少 2 年，或与适用管理规定一致。

5.5.9 If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the regulatory authorities.

5.5.9 如果申办者停止一个试验用药品的临床研究，申办者应当通报所有研究者/研究机构和所有管理部门。

5.5.10 Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirement(s),

5.5.10 数据所有权的转移应当根据适用的管理要求向适当的部门报告。

5.5.11 The sponsor specific essential documents should be retained until at least 2-years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2-years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s),or if needed by the sponsor.

5.5.11 申办者方的基本文件应当被保留到最后批准在一个 ICH 地区上市应用之后至少 2 年，和直至在一个 ICH 地区没有未决的或仍在考虑的上市应用，或试验用药品的临床研究正式停止后已过去至少 2 年。但如果适用管理要求需要或申办者要求，这些文件应当被保留更长时间。

5.5.12 The sponsor should inform the investigator(s),institution(s),in writing of the need for record retention and should notify the investigator(s),institution(s),in writing when the trial related records are no longer needed.

5.5.12 申办者应当以书面通知研究者/研究机构关于记录保存的要求，当试验相关记录不再需要时应书面通报研究者/研究机构。

5.6 Investigator Selection

5.6 研究者的选择

5.6.1 The sponsor is responsible for selecting the investigator(s),institution(s), Each investigator should be qualified by training and experience and should have adequate resources (see 4.1, 4.2),to properly conduct the trial for which the investigator is selected. If organization of a coordinating committee and/or selection of coordinating investigator(s),are to be utilized in multicentre trials, their organization and/or selection are the sponsor's responsibility.

5.6.1 申办者有责任选择研究者及研究机构。每一个研究者应当是通过培训合格的和有经验的，应当有足够的资源(见 4.1，4.2),确地实施其被选择来进行的试验。如果在多中心试验中将组织一个协调委员会组织和/或选择协调研究者，他们的组织和/或选择是申办者的责任。

5.6.2 Before entering an agreement with an investigator/institution to conduct a trial, the sponsor should provide the investigator(s),institution(s),with the protocol and an up-to-date Investigator's Brochure, and should provide sufficient time for the investigator/institution to review the protocol and the information provided.

5.6.2 在与研究者/研究机构签署一个进行试验的协议之前，申办者应当向研究者/研究机构提供试验方案和最新的研究者手册，并应当提供足够的时间让研究者/研究机构去审议方案和所提供的资料。

5.6.3 The sponsor should obtain the investigator's/institution's agreement:

5.6.3 申办者应当得到研究者/研究机构的同意：

(a) to conduct the trial in compliance with GCP,with the applicable regulatory requirement(s),(see 4.1.3), and with the protocol agreed to by the sponsor and given approval/favourable opinion by the IRB/IEC (see 4.5.1),

(a)按照 GCP、适用管理要求(见 4.1.3),经申办者同意、IRB/IEC 批准/赞成(见 4.5.1),方案实施临床试验；

(b) to comply with procedures for data recording/reporting;

(b)遵循数据记录/报告程序；

(c) to permit monitoring, auditing and inspection (see 4.1.4),and

(c)允许监查、稽查和视察(见 4.1.4),及

(d) to retain the trial related essential documents until the sponsor informs the investigator/institution these documents are no longer needed (see 4.9.4 and 5.5.12).

(d)保留与试验有关的基本文件直至申办者通知研究者/研究机构这些文件不再需要为止(见 4.9.4 和 5.5.12)。

The sponsor and the investigator/institution should sign the protocol, or an alternative document, to confirm this agreement.

申办者和研究者/研究机构应当共同签署方案或另外一个文件以确认协议。

5.7 Allocation of Responsibilities

5.7 责任的分配

Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.

在开始一个试验前，申办者应当定义、规定和分配与试验相关的责任和职能。

5.8 Compensation to Subjects and Investigators

5.8 给受试者和研究者的补偿

5.8.1 If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage),the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.

5.8.1 如果适用管理要求需要，申办者应当提供保险或应当补偿(法律和财政的范围),究者/研究机构因试验而提出的要求，但因治疗不当和/或过失所致的除外。

5.8.2 The sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s),

5.8.2 申办者的保险单和程序应当说明符合适用管理要求的与试验相关的伤害事件中试验对象治疗的费用。

5.8.3 When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s),

5.8.3 试验受试者收到补偿时，补偿的方法和方式应当符合适用管理要求。

5.9 Financing

5.9 财务

The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

试验的财务方面内容应当列入申办者和研究者/研究机构之间的协议中。

5.10 Notification/Submission to Regulatory Authority(ies)

5.10 向管理当局通报/提交

Before initiating the clinical trial(s), the sponsor (or the sponsor and the investigator, if required by the applicable regulatory requirement(s), should submit any required application(s),to the appropriate authority(ies),for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s), to begin the trial(s), Any notification/submission should be dated and contain sufficient information to identify the protocol.

在开始临床试验之前，申办者(或适用管理要求需要，申办者与研究者),当向相应的管理部门提交所需要的申请表，供审评、接受和/或许可(如适用管理要求需要),始试验。通报/提交的资料应当注明日期，并包括足够鉴定试验方案的资料。

5.11 Confirmation of Review by IRB/IEC

5.11IRB/IEC 审评的确认

5.11.1 The sponsor should obtain from the investigator/institution:

5.11.1 申办者应当从研究者/研究机构方得到:

(a) The name and address of the investigator's/institution's IRB/IEC.

(a)研究者/研究机构方的 IRB/IEC 成员的姓名和地址。

(b) A statement obtained from the IRB/IEC that it is organized and operates according to GCP and the applicable laws and regulations.

(b)IRB/IEC 关于其组织和操作符合 GCP 和适用法律法规的陈述。

(c) Documented IRB/IEC approval/favourable opinion and, if requested by the sponsor, a current copy of protocol, written informed consent form(s),and any other written

information to be provided to subjects, subject recruiting procedures, and documents related to payments and compensation available to the subjects, and any other documents that the IRB/IEC may have requested.

(c)书面的 IRB/IEC 批准/赞成意见；如果申办者要求，最新的试验方案、书面知情同意书和其他将提供给受试者的书面资料的复印件，受试者接纳程序，和给予受试者的支付和补偿的有关文件，以及 IRB/IEC 所要的其他文件。

5.11.2 If the IRB/IEC conditions its approval/favourable opinion upon change(s),in any aspect of the trial, such as modification(s),of the protocol, written informed consent form(s),and any other written information to be provided to subjects, and/or other procedures, the sponsor should obtain from the investigator/institution a copy of the modification(s),made and the date approval/favourable opinion was given by the IRB/IEC.

5.11.2 如果 IRB/IEC 以修改试验的某个方面作为批准/赞成的条件，如修改方案，书面的知情同意书和其他提供给受试者和/或其他程序的书面资料，申办者应当从研究者及研究机构得到已作出修改的副本和 IRB/IEC 给出批准/赞成日期。

5.11.3 The sponsor should obtain from the investigator/institution documentation and dates of any IRB/IEC reapprovals/re-evaluations with favourable opinion, and of any withdrawals or suspensions of approval/favourable opinion.

5.11.3 申办者应当从研究者/研究机构得到所有 IRB/IEC 给出赞成意见的再批准/再评价，以及撤消或暂停批准/赞成的文件和日期。

5.12 Information on Investigational Product(s)

5.12 有关试验用药品的资料

5.12.1 When planning trials, the sponsor should ensure that sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

5.12.1 计划试验时，申办者应当保证有足够的非临床研究和/或临床研究的安全性与有效性数据支持所研究的试验人群暴露的给药途径、剂量和持续时间。

5.12.2 The sponsor should update the Investigator's Brochure as significant new information becomes available (see 7. Investigator's Brochure),

5.12.2 当有重要的新资料时，申办者应当更新研究者手册(见 7.研究者手册),

5.13 Manufacturing, Packaging, Labelling, and Coding Investigational Product(s)

5.13 试验用药品的生产、包装、标签和编码

5.13.1 The sponsor should ensure that the investigational product(s),(including active comparator(s),and placebo, if applicable),is characterized as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labelled in a manner that protects the blinding, if applicable. In addition, the labelling should comply with applicable regulatory requirement(s),

5.13.1 申办者应当保证试验用药品(包括活性对照品和安慰剂),有适合产品开发阶段的特性，按照适用的 GMP 生产、编码和标签的方式应适合于保护盲法。此外，标签应当符合适用管理要求。

5.13.2 The sponsor should determine, for the investigational product(s), acceptable storage temperatures, storage conditions (e.g., protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor

should inform all involved parties (e.g., monitors, investigators, pharmacists, storage managers),of these determinations.

5.13.2 申办者应当确定试验用药品的允许储存温度、储存条件(如避光),储存时间、重组溶液和程序，以及必要时药物的输注装置。申办者应当将这些决定通知所有有关各方(如监查员、研究者、药师、储存管理人员),

5.13.3 The investigational product(s),should be packaged to prevent contamination and unacceptable deterioration during transport and storage.

5.13.3 试验用药品的包装应当能防止在运输和储存期间受污染和不可接受的变质。

5.13.4 In blinded trials, the coding system for the investigational product(s),should include a mechanism that permits rapid identification of the product(s),in case of a medical emergency, but does not permit undetectable breaks of the blinding.

5.13.4 在盲法试验中，试验用药品的编码系统应当包括一种在医学紧急情况下允许迅速鉴别药品、但不允许不可监测的破盲机制。

5.13.5 If significant formulation changes are made in the investigational or comparator product(s),during the course of clinical development, the results of any additional studies of the formulated product(s),(e.g., stability, dissolution rate, bioavailability),needed to assess whether these changes would significantly alter the pharmacokinetic profile of the product should be available prior to the use of the new formulation in clinical trials.

5.13.5 在临床研究期间如果试验用药品或对照产品的配方有明显改变，应当在新制剂用于临床试验之前获得制剂产品的附加研究结果(如稳定性、溶出速率，生物利用度),以评价这些改变是否明显改变产品药代动力学特征。

5.14 Supplying and Handling Investigational Product(s)

5.14 试验用药品的供应和管理

5.14.1 The sponsor is responsible for supplying the investigator(s),institution(s),with the investigational product(s),

5.14.1 申办者负责向研究者/研究机构提供试验用药品。

5.14.2 The sponsor should not supply an investigator/institution with the investigational product(s),until the sponsor obtains all required documentation (e.g., approval/favourable opinion from IRB/IEC and regulatory authority(ies),.

5.14.2 申办者在得到全部所需要文件(如 IRB/IEC 和管理当局的批准/赞成意见),前不得向研究者/研究机构提供试验药物。

5.14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s),for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s),to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s),.

5.14.3 申办者应当确保书面操作程序包含研究者/研究机构应当遵循的关于试验用药品的处理和储存的说明及其文件。程序应当说明适当和安全地接收、处理、储存、分发、从对象处取回未使用的药物以及将未使用的试验用药品返回给申办者(或经申办者授权并遵照适用管理要求销毁),

5.14.4 The sponsor should:

5.14.4 申办者应当:

(a) Ensure timely delivery of investigational product(s),to the investigator(s),

(a)确保按时将试验用药品送达研究者。

(b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s),(see 8. Essential Documents for the Conduct of a Clinical Trial),

(b)保存证明运输、接收、分发、收回和销毁试验用药品的记录(见 8.实施临床试验的基本文件)。

(c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g., for deficient product recall, reclaim after trial completion, expired product reclaim),

(c)有一个取回试验用药品和记录取回的规定(如有缺陷产品的收回，在试验结束后归还，过期药品归还)。

(d) Maintain a system for the disposition of unused investigational product(s),and for the documentation of this disposition.

(d)有一个处置未使用研究药品和记录这种处置的规定。

5.14.5 The sponsor should:

5.14.5 申办者应当:

(a) Take steps to ensure that the investigational product(s),are stable over the period of use.

(a)采取步骤以保证试验用药品在整个使用期内的稳定性。

(b) Maintain sufficient quantities of the investigational product(s),used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

(b)维持足够数量的用于试验中的试验用药品，以在万一有必要时再确认其规格，并保存批样分析和特性记录。只要产品稳定性许可，样品应当被保到试验数据分析完成或适用管理要求的需要时间，取两者中较长的期限。

5.15 Record Access

5.15 记录访问

5.15.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s),institution(s),provide direct access to source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.

5.15.1 申办者应当确保在方案中或其他书面协议中已经说明，研究者/研究机构应允许试验有关的监查员、稽查员、IRB/IEC 审评和管理部门视察直接访问原始数据。

5.15.2 The sponsor should verify that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, IRB/IEC review, and regulatory inspection.

5.15.2 申办者应当核实，每一例对象已经书面同意，在进行与试验有关的监查、稽查、IRB/IEC 审评和管理部门视察时直接访问他/她的原始医学记录。

5.16 Safety Information

5.16 安全性资料

5.16.1 The sponsor is responsible for the ongoing safety evaluation of the investigational product(s),

5.16.1 申办者负责试验用药品正在进行的安全性评价。

5.16.2 The sponsor should promptly notify all concerned investigator(s),institution(s),and the regulatory authority(ies),of findings that could affect adversely the safety of subjects, impact the conduct of the trial, or alter the IRB/IEC's approval/favourable opinion to continue the trial.

5.16.2 申办者应当立即通知所有有关研究者/研究机构和管理当局关于可能对受试者的安全性有不良影响、影响试验实施的或改变 IRB/IEC 对继续试验的批准/赞成的发现。

5.17 Adverse Drug Reaction Reporting

5.17 药品不良反应报告

5.17.1 The sponsor should expedite the reporting to all concerned investigator(s),institutions(s), to the IRB(s),IEC(s), where required, and to the regulatory authority(ies),of all adverse drug reactions (ADRs),that are both serious and unexpected.

5.17.1 申办者应当迅速向所有有关研究者/研究机构、有关的 IRB/IEC、管理当局报告所有严重的和非预期的药品不良反应。

5.17.2 Such expedited reports should comply with the applicable regulatory requirement(s),and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

5.17.2 这种快速报告应当符合适用管理要求和《ICH 临床安全性数据管理指导原则：快速报告的定义和标准》。

5.17.3 The sponsor should submit to the regulatory authority(ies),all safety updates and periodic reports, as required by applicable regulatory requirement(s),

5.17.3 申办者应当根据使用管理要求向管理当局提交全部安全性更新和定期报告。

5.18 Monitoring

5.18 监查

5.18.1 Purpose

5.18.1 目的

The purposes of trial monitoring are to verify that:

试验监查的目的是核实：

(a) The rights and well-being of human subjects are protected.

(a)受试者的权利和健康得到保护。

(b) The reported trial data are accurate, complete, and verifiable from source documents.

(b)所报告的试验数据是准确和完整的，并能从原始文件得到证实。

(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s),

(c)试验的实施符合最近批准的方案/方案修改，符合 GCP 和适用管理要求。

5.18.2 Selection and Qualifications of Monitors

5.18.2 监查员的选择和资格

(a) Monitors should be appointed by the sponsor.

(a)监查员应当由申办者指定。

(b) Monitors should be appropriately trained, and should have the scientific and/or clinical knowledge needed to monitor the trial adequately. A monitor's qualifications should be documented.

(b)监查员应当受过合适的培训，应当有足够的监查试验的科学和/或临床知识。监查员的资格应当有文件证明。

(c) Monitors should be thoroughly familiar with the investigational product(s), the protocol, written informed consent form and any other written information to be provided to subjects,the sponsor's SOPs,GCP,and the applicable regulatory requirement(s).

(C)监查员应当透彻了解试验用药品、研究方案、知情同意书和其他提供给受试者的书面资料、申办者的各种 SOP、GCP 和适用管理要求。

5.18.3 Extent and Nature of Monitoring

5.18.3 监查的范围和性质

The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the obje…