Module 4: Investigator Qualifications and Responsibilities

1. Module 4

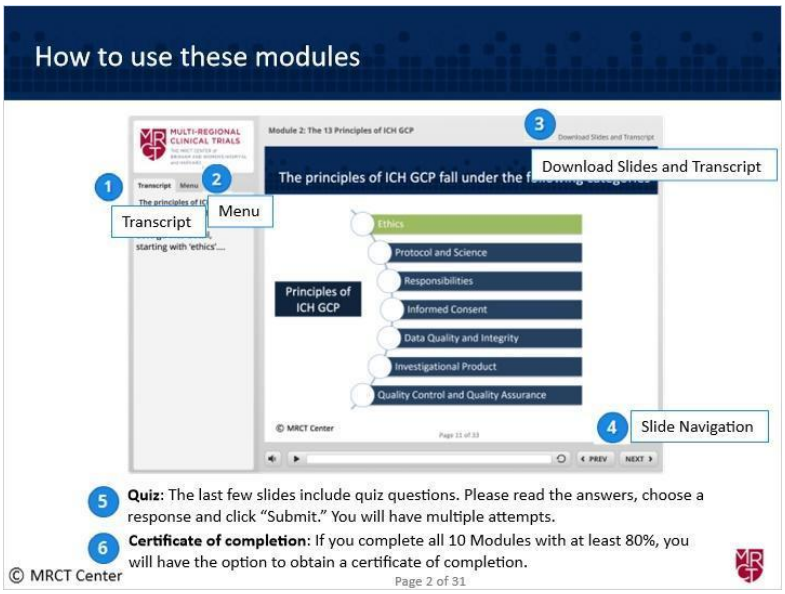
1.1 Interpretation and application of ICH E6(R2)

ICH E6(R2)的解读和应用

Notes:

Welcome to Module 4 of this training on the interpretation and application of ICH E6(R2).	欢迎来到 ICH E6(R2)解读和应用培训的第四讲。

~~*1.2 How to use these modules*~~



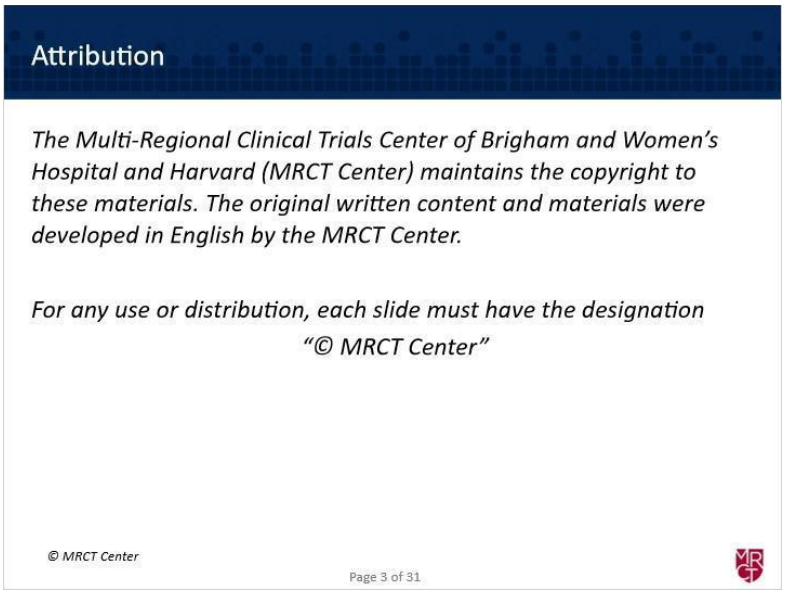
~~Notes:~~

~~We want to familiarize you with how to use these modules. First, you can click on Transcript on the left side to read along with the audio. Second, if you click on Menu, next to Transcript, you can see where you are in this module. You can also go back to slides that you have previously viewed and listened to.~~ ~~Third, you can click on the upper right on "Download Slides and Transcript" to view a printable PDF of the slides and transcript of the module. You can also click a link to the Guidelines for Good Clinical Practice.~~ ~~Fourth, to move to the next slide, click "Next" after you listen to the audio. Click "Prev" to go to the previous slide.~~ ~~Fifth, the last few slides include quiz questions. Please read the answers, choose a response and click "Submit." You will have multiple chances to answer correctly.~~ ~~Sixth, if you complete all 10 Modules with at least 80%, you will have the option to obtain a certificate of completion.~~	~~让我们来熟悉一下这一系列的课程的操作页面。第一，你可以点击左边的 Transcript，跟着音频阅读文字。第二，点击 Transcript 旁边的 Menu，你可以看到正在浏览的页面位置。你也可以通过 Menu 回到之前浏览过的幻灯片。~~ ~~第三，你可以点击右上角的 Download Slides and Transcript，查看这一讲幻灯片和文稿的 PDF 可打印版本。你也可以点击链接查看《药品临床试验管理规范》。~~ ~~第四，每一页幻灯片学习完成后，你可以点击 NEXT，开始学习下一张幻灯片。你也可以点击 Prev,回到上一张幻灯片。~~ ~~第五，最后几张幻灯片有小测验。请阅读选项，选择你认为正确的答案，然后点击 Submit。小测验没有次数限制。~~

	~~第六，如果你完成所有 10 讲课程，每个课程测验成绩都在 80%以上，你可以获得该课程证书。~~

1.3 Attribution

归属权



Notes:

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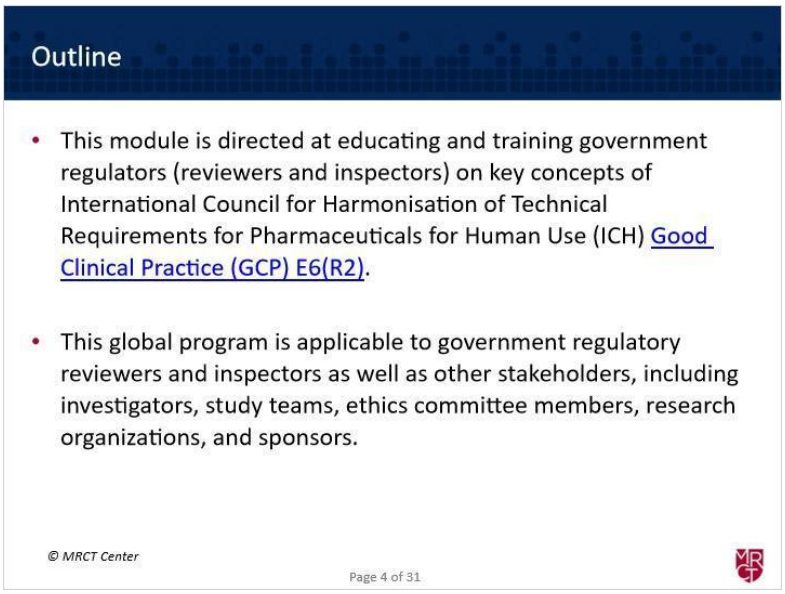
~~*1.4 Outline*~~

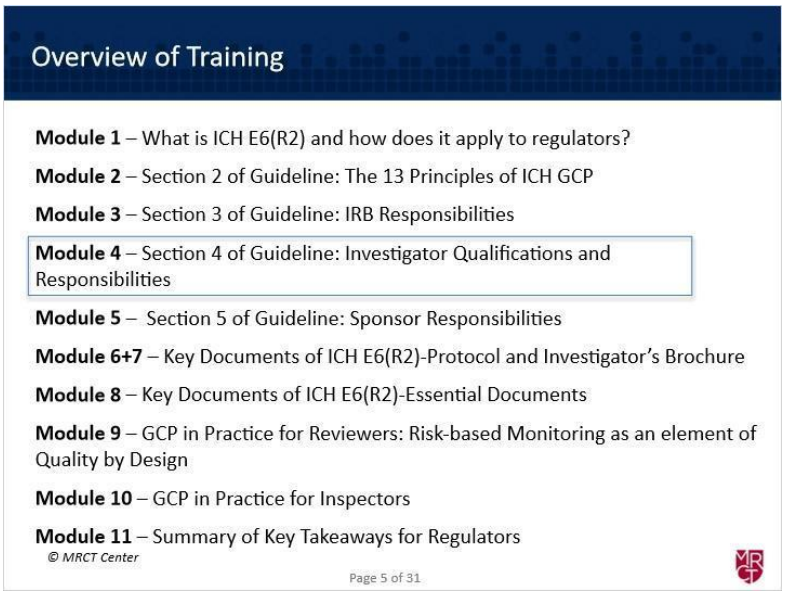


~~Notes:~~

~~Overall this training is directed at educating and training government regulatory reviewers and inspectors (as well as other stakeholders including investigators, study teams, ethics committee members, research organizations, and sponsors) on key concepts of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) E6(R2).~~	~~本课程旨在教育和培训政府监管部门的审评员和检查员（以及其他利益相关者，包括研究者、研究团队、伦理委员会成员、研究机构、以及申办者）了解国际人用药品注册技术要求协调委员会（ICH）药物临床试验质量管理规范（GCP）E6(R2)的关键概念。~~

~~*1.5 Overview of Training*~~

~~培训概览~~

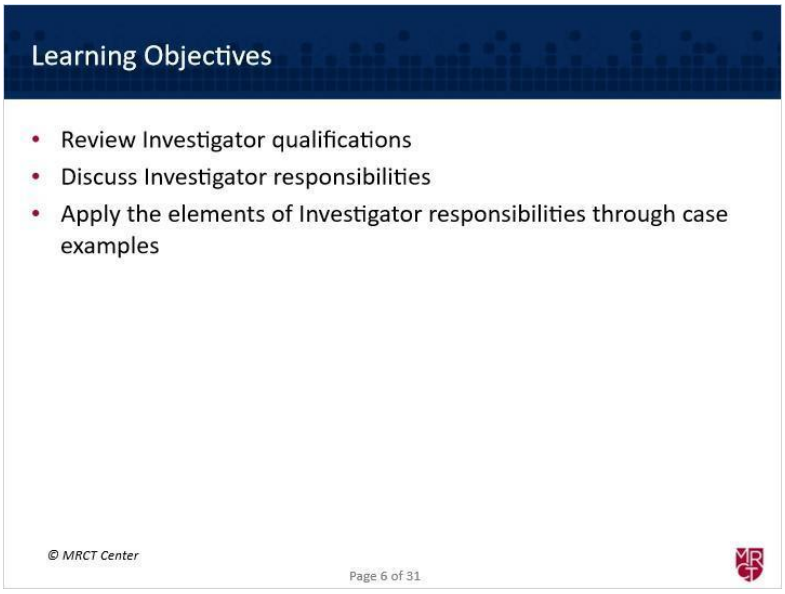


Notes:

In Module 4 we will focus on describing investigator qualifications and responsibilities as outlined in the guideline.	第四讲的重点是 GCP 指南中研究者的资质和责任。

1.6 Learning Objectives

教学目标



Notes:

This module will focus on the Investigator. The learning objects are to: 1. Review Investigator qualifications, specifically the criteria that make an individual qualified to be an investigator 2. Discuss Investigator responsibilities, emphasizing new sections added with the E6(R2) revisions. 3. Apply elements of the Investigator responsibilities through case examples.	本讲重点关注研究者。学习目标包括： 1. 审查研究者的资质，即个人是否可以作为研究者的具体标准。 2. 审查研究者的资质，即个人是否可以作为研究者的具体标准。 3. 通过案例，掌握研究者责任要素的应用。

1.7 Investigator Qualifications & Agreements

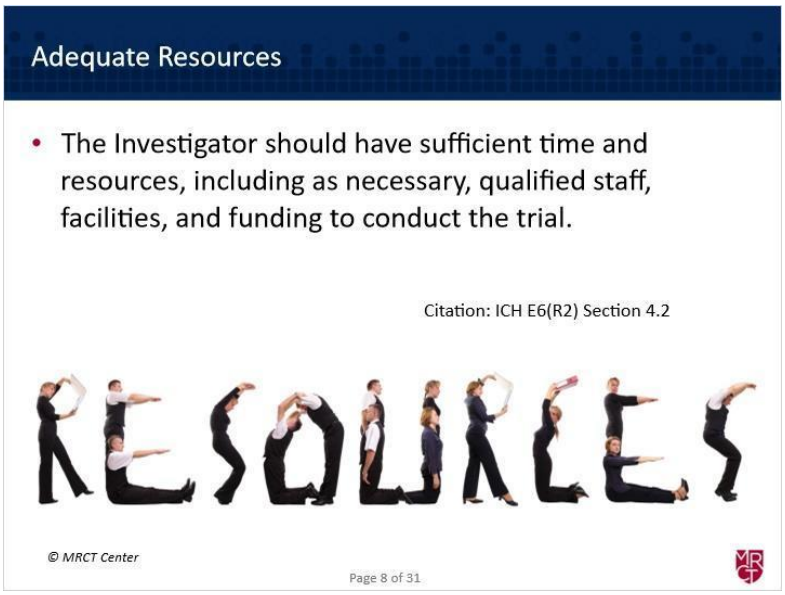
研究者资质和协议

Notes:

ICH GCP E6(R2) defines an Investigator as “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”	ICH GCP E6(R2) 将研究者定义为 “负责在一个临床试验现场实施临床试验的人。如果在临床试验现场是由一个团队实施试验，则研究者指的是这个团队的负责人，也称主要研究者。”
The Investigator should be qualified to assume responsibility for the conduct of the trial. The Investigators qualifications, including education, training, and experience should be documented and provided in a curriculum vitae, or CV, and/or other relevant documentation.	研究者应当有资质承担实施临床试验的责任。 研究者的资质，包括所受教育、培训和经验，应在简历和/或其他相关文件中提供并存档。
The Investigator should be familiar with applicable regulatory requirements including national regulations, institutional requirements and Good Clinical Practices, and be thoroughly familiar with the investigational product to be used in the trial.	研究者应熟悉适用的法规要求，包括国家法规、机构要求和 GCP，并充分熟悉该临床试验用产品。
During and after the clinical trial, the Investigator should permit the sponsor to monitor or audit and/or national regulatory authorities to conduct inspections of the study files.	在临床试验期间和临床试验结束后，研究者应当允许申办者进行监查和稽查，以及国家管理部门对研究文件的检查。

1.8 Adequate Resources

充足的资源



Notes:

In order to conduct a trial, the Investigator needs to have sufficient time and resources to conduct the trial within the agreed trial period. Adequate resources include: ● Sufficient time to properly conduct and complete the trial ● Available facilities and funding to support the trial ● The ability to recruit the required number of subjects ● And if needed, qualified staff that are adequately trained on the protocol, investigational products, and their trial-related duties and functions.	为进行临床研究，研究者在协议的试验期内应当有足够的时间和资源实施和完成试验。 足够的资源包括： 充足的时间用以合理实施和完成临床试验 充足的设备和资金用以支持临床研究 具备招募足够数量受试者的能力，以及 受过关于临床试验方案、临床试验用产品及临床试验相关职责和职能的合格职员。

1.9 Investigator Responsibilities

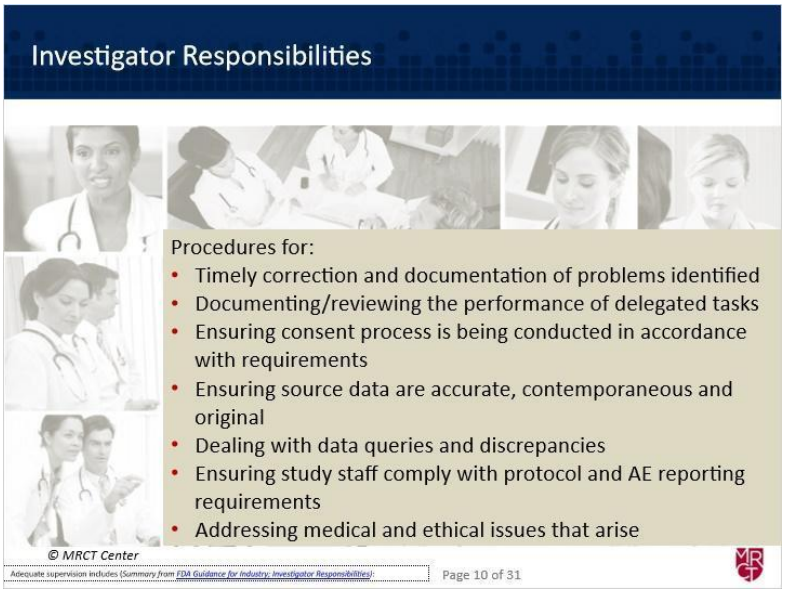
研究者责任

Notes:

As stated in GCP section 4.2.4, the Investigator should ensure that all persons assisting with the trial are adequately informed of the protocol, the investigational product or products, and their trial-related duties. This is called Investigator delegation. ● Investigators can delegate significant trial-related tasks to a study team, but cannot delegate responsibilities. ● Delegation is appropriate if the study staff is qualified by education, training, and experience ● Delegation should be documented on a delegation of responsibility log or signature sheet as identified in section 8.3.24 of the GCP guidelines.	如 GCP 第 4.2.4 节所述，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、临床试验用产品及他们各自与试验相关的职责。这叫做研究者委派。 研究者可以将临床试验相关重要的任务分配给研究团队，但不能将责任转移给他人。 只有当被委派的研究人员在教育、培训和经验方面都合格时，委派才是合理的。 任务分配应按照 GCP 指南 8.3.24 节的规定，记录在职责委派日志或签名表上。
If the Investigator chooses to delegate tasks to study team, the Investigator much provide adequate training. The training must be specific for the protocol, regulatory requirements, and the specific delegated tasks. A training log can be used to document the protocol specific training.	如果研究者选择将任务分配给研究团队，那么研究者必须为其提供充分的培训。 培训内容必须针对临床方案、法规要求和分配的具体任务。 培训日志可以记录为该临床方案的实施进行的培训。

1.10 Investigator Responsibilities

研究者责任



Notes:

The revised E6(R2) guidelines included new information about the investigator's responsibilities to provide adequate supervision to the study team. As stated in section 4.2.5, supervision is required to any individual or party that is delegated study related tasks. The extent of supervision will be appropriate to the staff, nature of the trial, and subject population. Adequate supervision could include: - Routine Meetings with the staff and monitor - Procedures for:	修订后的 E6(R2)指南对研究者在充分监督团队的责任方面包含了新内容。 如 4.2.5 节所述，被委派（临床）研究相关工作的任何个人或团体都必须受到监督。 监督的范围应当与参与临床试验的工作人员、临床试验的类型及受试人群相匹配。 充分监督可以包括： - 与工作人员和监查员的例会 - 以下内容相关的规程实施：

Timely correction and documentation of problems identified	及时记录和纠正发现的问题
Documenting/reviewing the performance of delegated tasks	记录/审评委派任务的执行情况
Ensuring consent process is being conducted in accordance with requirements	确保知情同意过程按照要求进行
Ensuring source data are accurate, contemporaneous and original	确保源数据准确、同步，且必须是原始的
Dealing with data queries and discrepancies	处理有疑问的和不一致的数据
Ensuring study staff comply with protocol and AE reporting requirements	确保研究人员遵照临床试验方案和 AE 报告要求
Addressing medical and ethical issues that arise	解决临床试验中出现的医学和伦理问题

1.11 Investigator Responsibilities

研究者责任

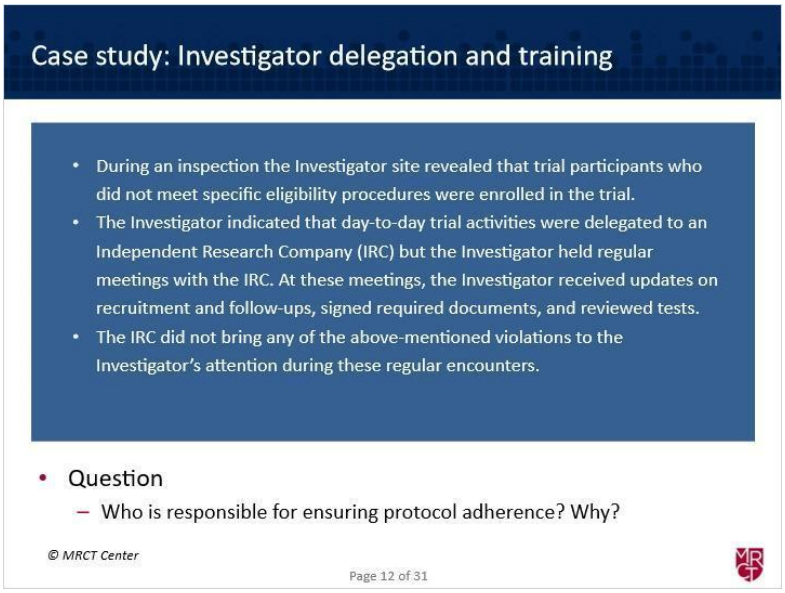
Notes:

In addition to the Investigator's own staff, he/she is responsible to provide oversight of other parties retained for trial services. Section 4.2.6 of the revised GCP guidelines states that	除研究者自己团队的工作人员外，研究者还应对为该临床试验提供服务的各方进行监督。修订后

oversight should be provided to any individual or party retained to perform trial specific duties and functions. The Investigator should ensure the individual or party is qualified to perform the delegated duties and functions and implement procedures to ensure integrity of the work performed and any data generated.	的 GCP 第 4.2.6 节规定，应向被聘用以履行临床试验特定职责和职能的任何个人或团体进行监督。 研究者应确保被委派的个人或团体有资格履行被委派的职责和职能，并能遵守实施程序，从而确保临床试验相关工作和生成数据的完整性。

1.12 Case study: Investigator delegation and training

案例分析：研究者委派和培训



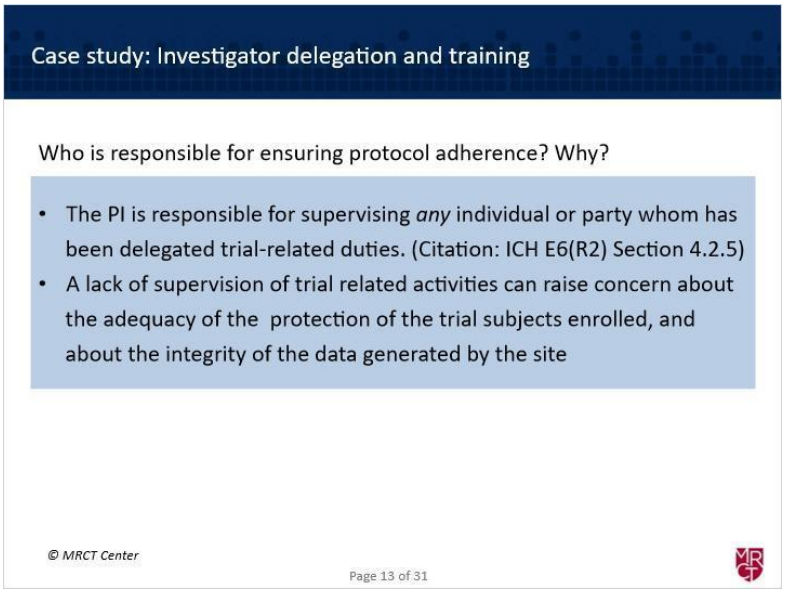
Notes:

To emphasize the Investigator's responsibility, let's review a brief case study. Here is a situation where the Investigator delegated trial related activities to an Independent Research Company. Let's see what happens:	为强调研究者责任，我们来看一个简短的案例。在这个案例中，研究者将临床试验相关的一些活动委托给了一个独立研究公司。 让我们看看发生了什么：
● During an inspection the Investigator site revealed that trial participants who did not meet	在对该临床试验进行检查时，临床现场透露有不

specific eligibility procedures were enrolled in the trial. ● In response to the finding, the Investigator indicated that day-to-day trial activities were delegated to an Independent Research Company (IRC) but the Investigator held regular meetings with the IRC. At these meetings, the Investigator received updates on recruitment and follow-ups, signed required documents, and reviewed tests. ● The IRC did not bring any of the above-mentioned violations to the Investigator's attention during these regular encounters.	符合入组标准的参与者被纳入该临床试验。 研究者回应调查结果表示，临床试验的日常活动委托给了独立研究公司 (IRC)，研究者与 IRC 定期召开会议。在这些会议上，研究者收到了到临床试验的入组情况和随访相关的更新信息，签署必要的文件，以及对实验室结果进行审核。 IRC 没有在例会上提出过任何上述违规行为引起研究者关注。

1.13 Case study: Investigator delegation and training

案例分析：研究者委派和培训



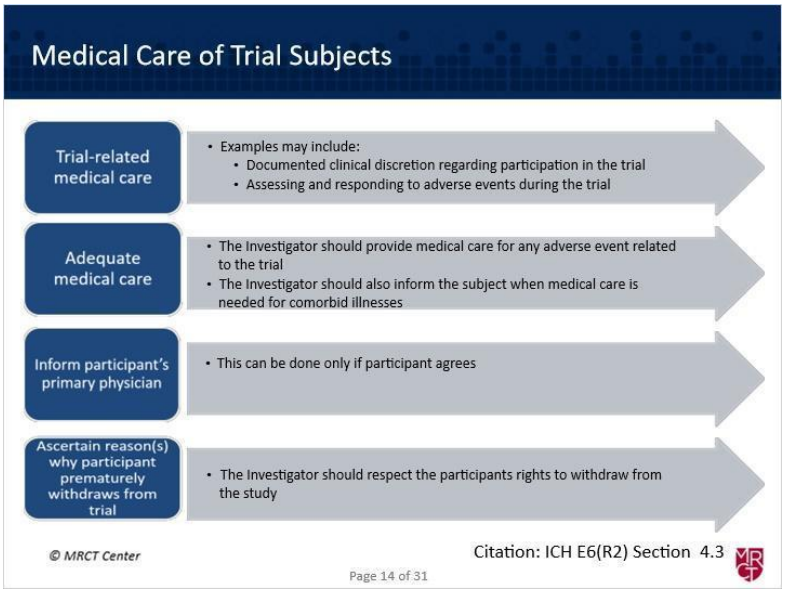
Notes:

In this situation, who is responsible for ensuring protocol adherence. And why?	这种情况下，谁应该负责确保遵守临床研究方案？为什么？

The PI is responsible for supervising any individual or party whom has been delegated trial related duties. Beyond the statements in ICH GCP, a lack of supervision of trial related activities can raise concern about the adequacy of the protection of the trial participants enrolled, and about the integrity of the data generated by the site.	答案是，主要研究者应对临床研究中被委托的任何个人或团体的职责进行监督。 除了 ICH GCP 要求研究者监督这一原因，如果缺乏对临床试验相关活动的监督，还可能引起担忧：入组临床试验的参与者是否得以充分保护？临床现场生成的数据是否完整？

1.14 Medical Care of Trial Subjects

临床受试者的医疗保健



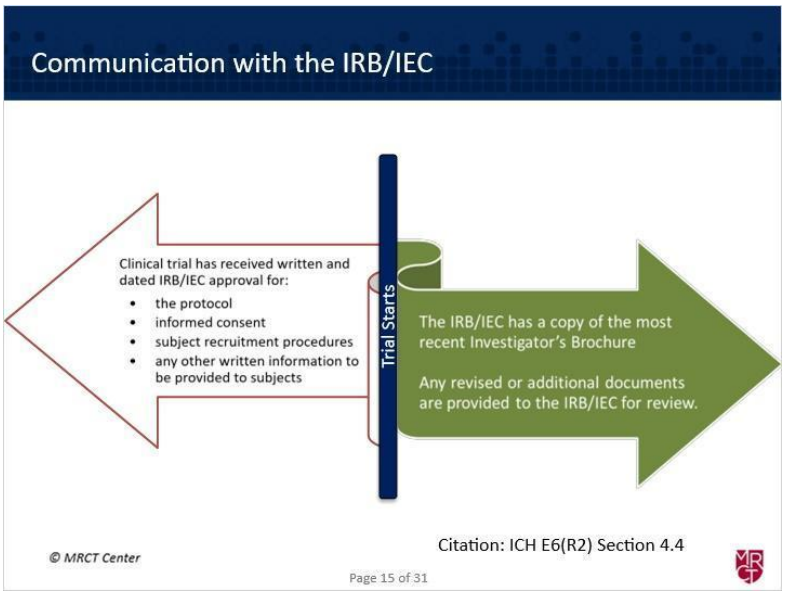
Notes:

According to GCP section 4.3.1, a qualified physician, or dentist when appropriate, who is the Investigator or Sub-Investigator for the trial should be responsible for all trial-related medical or dental decisions. If medical care is given	如 GCP4.3.1 节所述，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决定负责。如果临床试验期间有参与者需

during the trial the Investigator should ensure that there is documented clinical discretion regarding the care and the participants participation in the trial. When needed, the Investigator should ensure a participant receives trial-related medical care including assessing and responding to adverse events during the trial.	要医疗保健，则研究者应确保医疗保健及临床试验参与相关的临床判断记录在案。必要时，研究者应确保参与者接受了与临床试验相关的医疗保健，包括在临床试验期间对不良事件的评估和应对。
If the participant experiences an adverse event related to the trial, the Investigator should provide medical care. The investigator should also inform the subject when medical care is needed for a comorbid illness.	如果参与者出现与临床试验相关的不良事件，研究者应提供医疗保健。当受试者因共患病需要医疗保健时，研究者应该告知受试者。
ICH GCP E6(R2) recommends that investigators inform the participant's primary physician about their patient's participation in the trial, however this can only be done if the participant agrees.	ICH GCP E6(R2) 推荐，在参与者同意让自己的主治医生知道的前提下，研究者应告知参与者的主治医生关于该患者将参与临床试验的情况。
If a participant withdraws prematurely from the trial, the Investigator should make a reasonable effort to ascertain the reason why the participant is withdrawing. However, the subject is not obliged to do so and the Investigator should respect the participants rights to withdraw from the study.	如果参与者中途退出临床试验，研究者应作出合理的努力确认其退出理由。但是，参与者没有义务给出其退出试验的理由，研究者应充分尊重参与者的权利。

1.15 Communication with the IRB/IEC

与 IRB/IEC 的沟通

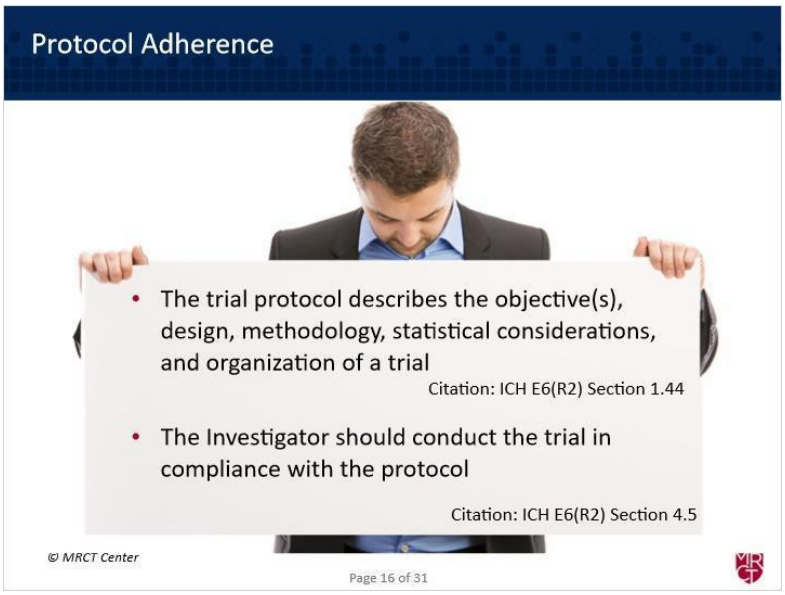


Notes:

The Investigator must ensure good communication with the IRB/IEC. Prior to beginning the trial, the Investigator should ensure that the clinical trial has received written and dated IRB/IEC approval for the protocol, informed consent, subject recruitment procedures, and any other written information to be provided to subjects. The Investigator should also ensure the IRB/IEC has a copy of the most recent Investigator's Brochure. As the trial continues, the Investigator must provide the IRB/IEC with any revised or new document for review and approval.	研究者必须与机构审查委员会/独立伦理委员会（IRB/ IEC）保持良好沟通。临床试验开始之前，研究者应确保临床试验方案、知情同意书、受试者招募程序，以及其他提供给受试者的书面信息已经得到 IRB/IEC 的书面批准。研究者还应该确保 IRB/IEC 有最新的研究者手册。随着临床试验的继续，任何文件有修订或新增时，研究者都必须提交至 IRB/IEC 以供审查和批准。

1.16 Protocol Adherence

遵循临床方案

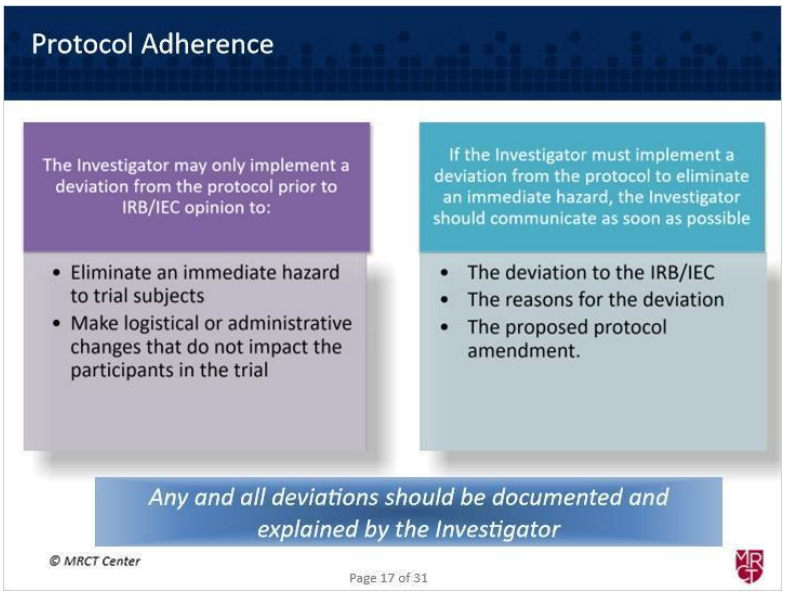


Notes:

The GCP ICH definition of protocol states that that it describes the objectives, design, methodology, statistical considerations, and organization of a trial. The Investigator should conduct the trial in compliance with the protocol at all times. Any and all deviations should be documented and explained by the Investigator. See next slide for more details.	GCP ICH 将临床试验方案定义为对临床试验的目标、设计、方法学、统计学考量及临床试验的组织。研究者必须时刻严格遵照方案实施。 相对方案发生的任何偏差都必须记录在案并由研究者进行解释。详情请见下一张幻灯片。

1.17 Protocol Adherence

遵循临床方案

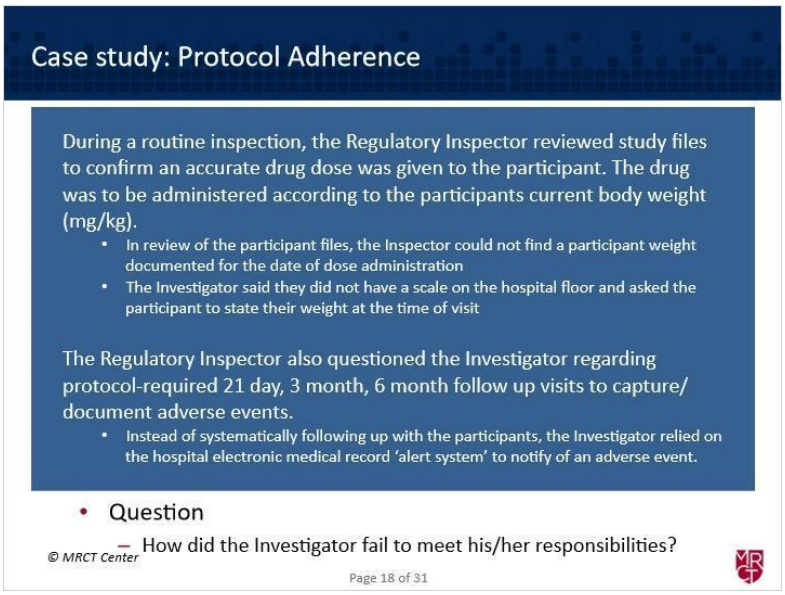


Notes:

Deviations, or changes to the protocol, may be implemented, without IRB/IEC opinion in limited situations. Specifically, a deviation should be implemented only to eliminate an immediate hazard to trial subjects without prior IRB/IEC opinion or to make logistical or administrative changes (change of telephone numbers)	特殊情况下，不需要 IRB/IEC 的意见，可以偏离或更改临床方案实施临床试验。具体来说，只有在排除对受试者的直接危害，或方案的改变只涉及试验的后勤或管理方面(如改变电话号码)，才可以偏离临床试验方案。
If the Investigator must implement a deviation from the protocol to eliminate an immediate hazard, the Investigator should communicate, as soon as possible, the deviation to the IRB/IEC, and provide details regarding the reasons for the deviation and the proposed protocol amendment. If required, the sponsor and the regulatory authorities should be notified and/or consulted as well.	如果研究者必须通过实施偏离临床试验方案的举措来消除直接危害，研究者应尽快就该偏差与 IRB/IEC 沟通，并提供偏差的原因和对临床试验方案修订的详细信息。如有要求，申办者和药政机构应该知晓该临床方案的偏差，提供建议。

1.18 Case study: Protocol Adherence

案例分析：遵循临床方案



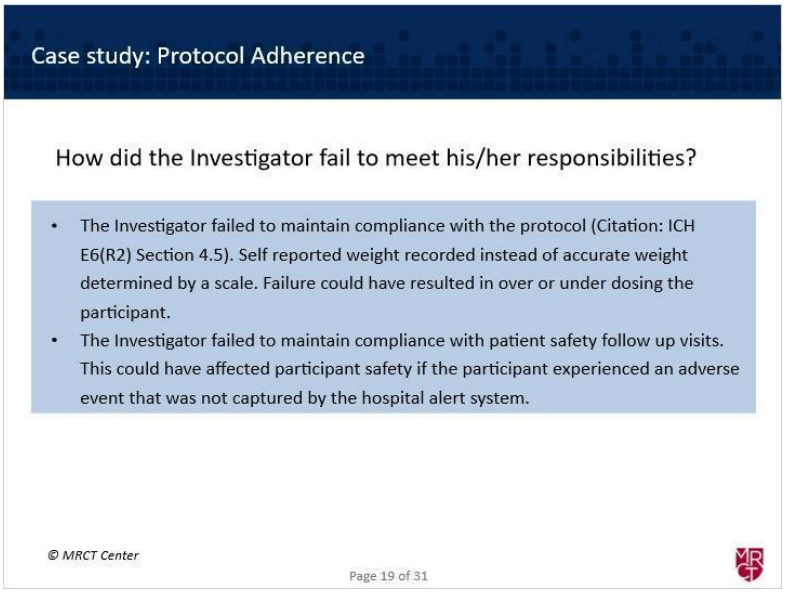
Notes:

Let's look at another case study – this time about protocol adherence: During a routine inspection at a clinical site, the Regulatory Inspector reviewed study files to confirm an accurate drug dose was given to the participant. The drug was to be administered according to the participants current body weight (mg/kg). ● In review of the participant files, the Inspector could not find a participant weight documented for the date of dose administration ● The Investigator said they did not have a scale on the hospital floor and asked the participant to state their weight at the time of visit ● The Regulatory Inspector also questioned the Investigator regarding protocol-required 21 day, 3 month, 6 month follow up visits to capture/document adverse events. ● Instead of systematically following up with the participants, the Investigator relied on the hospital electronic medical record 'alert system' to notify of an adverse event	我们来看另一个案例。这个案例是关于临床试验方案遵守的。 在对临床现场常规检查时，监管机构的检查员审查了临床试验相关的文件，以确认该临床试验向参与者提供了准确的药物剂量。 该药物的给药剂量应根据该参与者的体重而定(mg/kg)。 在审查受试者记录时，检查员没有找到给药当天受试者的体重记录。 研究者称医院该楼层没有体重秤，所以研究人员是在参与者到访后让他们自报体重。 监管检查员还询问了研究者关于临床方案要求的在给药后 21 天、3 个月、6 个月收集/记录不良事件的随访记录。 研究者回应，医院电子医疗记录的"警报系统"会报告不良事件，而不是系统性地对参与者进行随访。

How did the Investigator fail to meet his/her responsibilities?	研究者为何未能履行其职责？

1.19 Case study: Protocol Adherence

案例分析：遵循临床方案

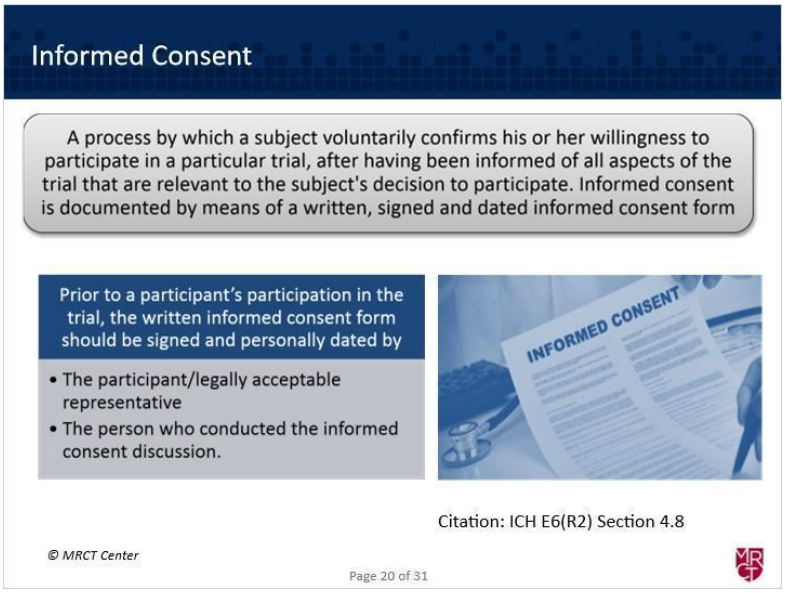


Notes:

The Investigator failed to maintain compliance with the protocol. The drug was to be administered according to the participant's current body weight (mg/kg). Instead of getting an accurate participant weight prior to drug administration, the Investigator relied on participant self-report. The self-report may not be accurate and could have led to over or under dosing the participant. The Investigator failed to maintain compliance with patient safety follow up visits. In turn, this could have affected participant safety if the participant experienced an adverse event that was not captured by the hospital alert system.	研究者未遵守临床试验方案。该药物应根据参与者当时的体重计算剂量进行给药(mg/kg)。研究者没有在给药前获得准确的参与者体重，而是依靠参与者的自我报告。参与者自我报告的体重可能是不准确的，可能会因导致参与者过度用药或用药不足。 研究者未遵守临床研究方案进行确保患者安全的随访。如果患者出现不良事件但没有被医院的警报系统获取，患者安全将会受到影响。

1.20 Informed Consent

知情同意

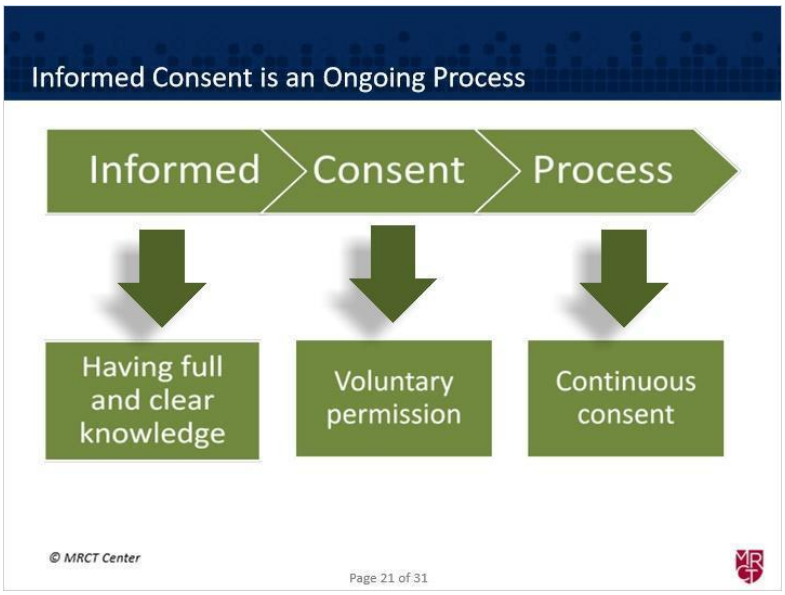


Notes:

Informed consent is defined in ICH GCP Section 1.28 as 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. Prior to a participant starting trial related procedures, the written informed consent form should be signed and personally dated by the participant or legally acceptable representative and the person who conducted the informed consent discussion.	ICH GCP 第 1.28 节将知情同意定义为："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。 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签署日期。

1.21 Informed Consent is an Ongoing Process

知情同意是一个持续的过程



Notes:

The Investigator must ensure the subject has provided and documented informed consent.	研究者必须确认受试者提交和签署知情同意书。
Every point of contact with the participant is an opportunity to verify their understanding of the research and reiterate their willingness to continue participating.	每次与参与者接触都是与参与者确认是否对临床试验足够了解以及是否愿意继续参与的机会。
The Informed consent should be revised whenever important new information becomes available that may be relevant to the subject's consent.	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，都应修改书面知情同意书。
Any changes to the written informed consent should receive IRB/IEC approval in advance of use.	对书面知情同意书的任何更改都应在使用该版本前获得 IRB/IEC 批准。

1.22 Records and Reports

记录和报告

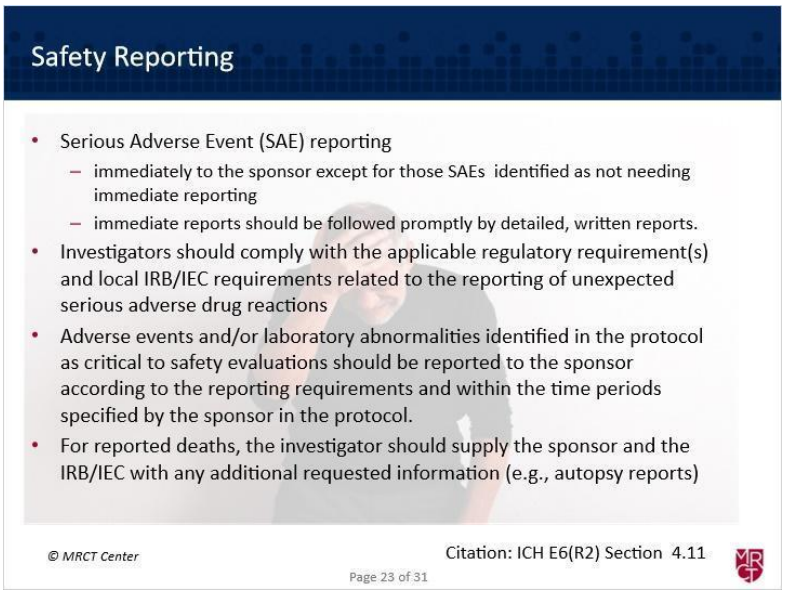
Notes:

A clinical trial generates a tremendous amount of information about the participants in the trial. This information is frequently referred to as source documents. As presented in section 4.9 of the GCP guidelines, the Investigator should maintain source documents and trial records of all trial participants. These documents should be accurate and include all pertinent and relevant observations. Records include: Essential documents Informed consent documents Subject Data (For more detailed information about source data and trial records, see module 8 of this course): Documents should be retained until at least 2-years after the last approval of a marketing application in an ICH region or at least 2 years after formal discontinuation of clinical development The Investigator should always check with the Sponsor before destroying documents	一项临床试验会生成有关参与者的大量信息。这些信息将会作为源文件被频繁引用。如 GCP 指南 4.9 节所述，研究者应保留所有源文件及临床试验所有参与者的相关记录。这些源文件内容必须准确并包含所有相关的观察记录。 记录包括： 基本文件 知情同意书 受试者数据 （与源数据和临床试验记录相关的更多细节，请参考该课程第 8 讲）： 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，或临床试验正式停止后已过去至少 2 年。 研究者在销毁文件之前必须与申办者确认

Local regulatory authorities or IRB/IECs may have different requirements	地方监管机构或 IRB/IEC 可能对此另有规定
The Investigator is responsible for maintaining adequate and accurate source documents and trial records	研究者应当保留足够和准确的原始文件和试验记录。
the revisions to ICH GCP E6(R2) stated that the investigator or institution should maintain adequate and accurate source documents that include all pertinent observations related to the participant. The guidelines describe the ALCOA-C principles.	修订后的 ICH GCP E6(R2)规定，研究者/机构应当保留足够和准确的原始文件和试验记录，包括每位参与者相关的观察。
ALCOA-C stands for: Attributable, legible, contemporaneous, original, accurate, and complete	ALCOA-C 指的是: 可追溯的、清晰的、同步的、原始的、准确的和完整的
Monitors and Inspectors should be able to identify and trace changes via an audit trail	监查员和检查员应能通过审计追踪来识别和跟踪变更

1.23 Safety Reporting

安全性报告

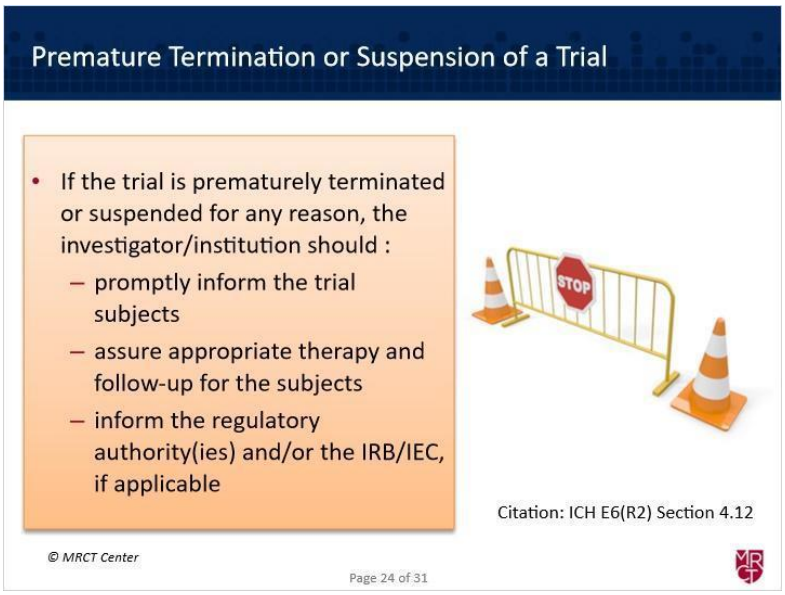


Notes:

Safety reporting by the Investigator is described in section 4.11 of the GCP guidance. GCP 指南的 4.11 节是关于研究者发起的安全性报告。	GCP 指南的 4.11 节是关于研究者发起的安全性报告。
All 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.	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。
The immediate reports should be followed promptly by detailed, written reports.	即时报告之后应迅速提交详细的书面报告。
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.	研究者还应当遵循监管当局和 IRB/IEC 关于非预期的药物严重不良反应的报告要求。
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.	在试验方案中被确定为对安全性评价有关键影响的不良事件和/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。
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).	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)。

1.24 Premature Termination or Suspension of a Trial

提前终止或暂停临床试验



Notes:

There is a chance that any trial could be prematurely terminated or suspended. Unexpected and serious adverse events are one reason why this might happen. The Investigator, sponsor, or IRB/IEC may terminate or suspend the study. If the trial is prematurely terminated or suspended for any reason, the investigator/institution should: - promptly inform the trial subjects - assure appropriate therapy and follow-up for the subjects - inform the regulatory authority(ies) and/or the IRB/IEC, if applicable	任何临床试验都有提前终止或暂停的可能性。非预期及严重的不良事件可能是导致临床试验提前终止或暂停的原因之一。研究者、申办者或者 IRB/IEC 都可以要求终止或暂停临床试验。如果一个临床试验因任何原因被提前终止或暂停，研究者/研究机构应当： 马上通知临床试验的受试者 确保为受试者提供适当的治疗及随访 如有规定，通知监管当局和/或 IRB/IEC

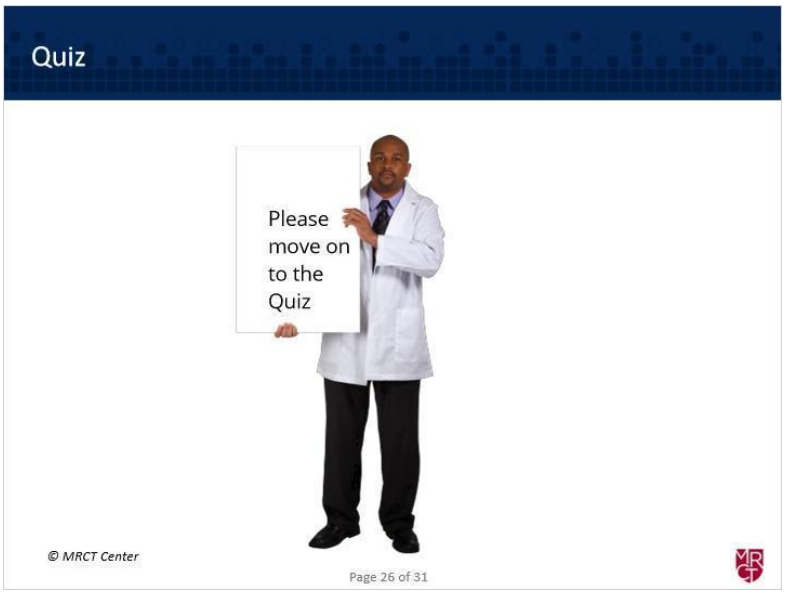
1.25 Summary

小结

Notes:

This module reviewed the Investigator's Responsibilities. In summary: The Investigator's role in conducting clinical trials requires adequate: - qualifications as can be found in a CV - resources, including adequately trained study staff - oversight of all individuals or parties performing trial-related duties. The Investigator is responsible for ensuring compliance with the protocol, patient safety, and informed consent of trial participants. Records and reports provide evidence that the Investigator has: adequately trained the staff, maintained compliance with the protocol, and collected all pertinent data from the subjects.	本模块讲解了研究者的职责。让我们总结一下： 临床试验的研究者必须: 具有足够的资质并在简历里有所体现 具有足够的资源，包括训练有素的研究人员 具有足够的能力监督实施临床试验的个人或团体 研究者负责确保临床方案的遵守、患者的安全以及参与者的知情同意。 临床试验相关的记录和报告为研究者在充分培训研究人员、严格遵循临床试验方案以及收集受试者数据方面提供证据。

1.26 Quiz



Notes:

Let us review some of the key points of this module via the following quiz. Take a moment to answer the questions. Please read them at your own pace. When complete, click Submit.