TransCelerate BIOPHARMA INC.

# ICH E6 R2: Guideline for Clinical Practice

*Integrated Addendum*

# Delegation and Training Module

# Delegation & Training Module

## Section 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."

Many of the addendum changes to Investigator Responsibilities are a clarification of the existing GCP requirements and expectations of regulators). These expectations of the PI are now explicitly stated and oversight of all individuals delegated study tasks – including contracted staff working for an investigator on a clinical trial should be included in the Investigator's oversight plan and actions should be taken to ensure compliance. The investigator is responsible for implementing corrective and preventive action in the event of non compliance.

# Delegation & Training Module

## Section 4.2.6

"If the investigator/institution retains the services of any 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."

The enhanced oversight requirements apply to investigators delegating tasks and institutions using services of third parties when conducting a clinical study . For example, the protocol requires specialty assessments which cannot be conducted at the primary location due to equipment needs and/or staff qualifications (e.g. ophthalmology or dental assessments are required for a diabetes study conducted at a primary care center). These responsibilities for enhanced oversight were not explicitly stated in ICH GCP previously, however it is an expectation that investigators oversee the conduct of the study at these additional locations to ensure that there is compliance to the protocol and GCP/local authority requirements. This includes the implementation of effective corrective and preventive actions which may be necessary in response to non compliance or issues. The PI is clearly responsible for ensuring that all parties involved in trial-related activities are qualified and procedures are in place to meet the requirements of ICH GCP .

# Certificate of Completion

**This is to certify that :**

**Has completed reviewing the Topic:**

**ICH E6 R2: Guideline for Clinical Practice Integrated Addendum; Delegation and Training Module, on:** (insert date below)

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