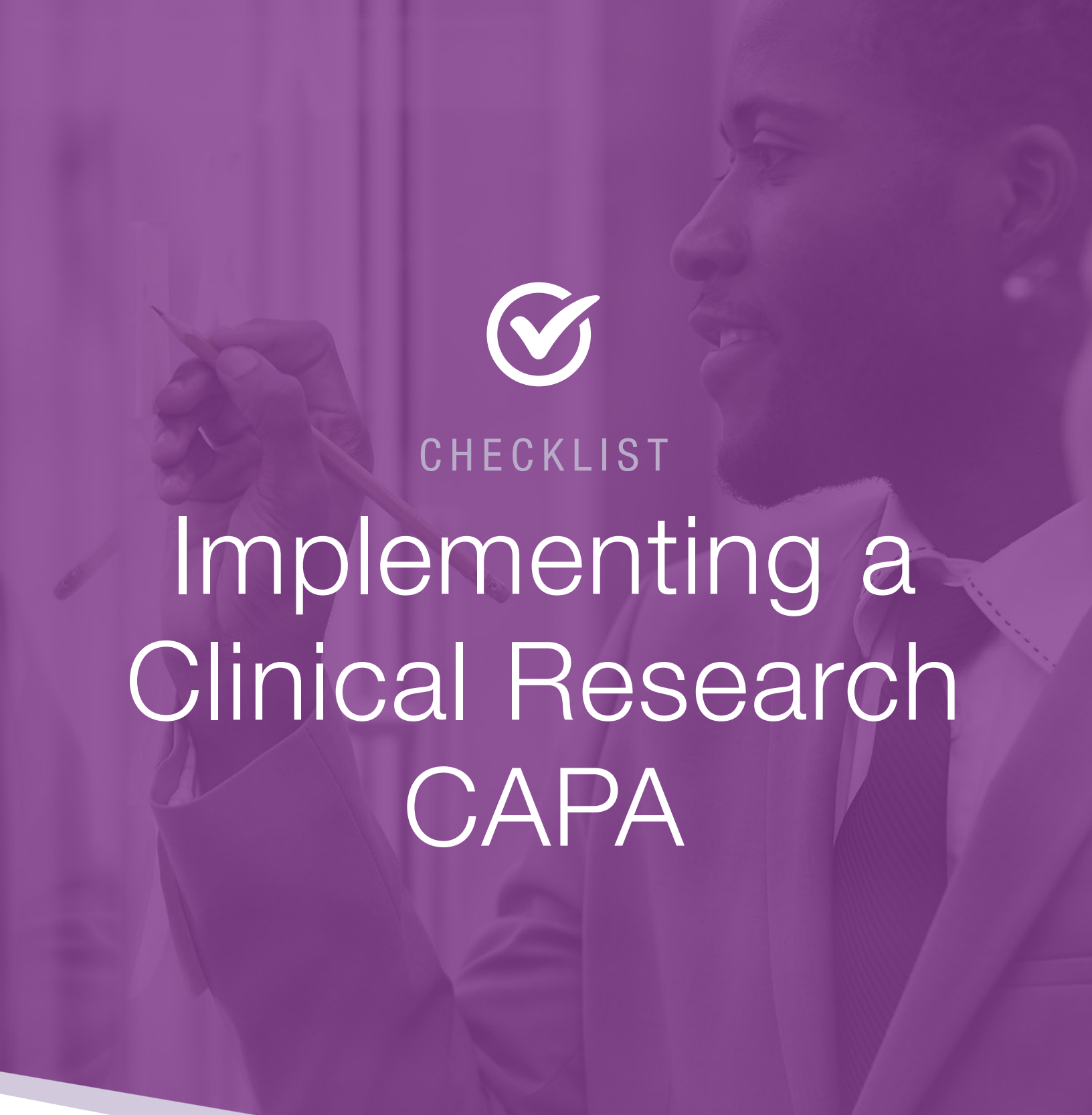

CHECKLIST

Implementing a Clinical Research CAPA

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A well-written CAPA consists of the following sections:

1. **A brief summary of the problem.**

2. **A detailed narrative of what occurred that includes subject ID(s), date(s) of occurrence, visits/ assessments,that are affected, etc.**

    a. Reference the applicable regulations, protocol requirements, IRB policies, SOPs, 1572 requirements and agreements that were not appropriately followed

    b. If applicable, explain how the issue did or could potentially affect subject safety and/or the study data

3. **Summarize the investigation and root cause analysis strategy.**

4. **Describe the root cause.**

5

List the correction(s). ISO 9000:2005(E) defines a correction as an action to eliminate a detected nonconformity. How will the immediate problem be corrected?

Examples of corrections include:

- Re-obtaining informed consent on the correct version of an ICF
- Locating and securing the investigational product
- Rescheduling a follow-up visit that was not completed
- Reporting the problem to the sponsor and/or IRB according to sponsor and IRB requirements.

The sponsor and IRB may provide further instructions.

6

List and explain the corrective action(s). ISO 9000:2005(E) defines corrective action as an action to eliminate the cause of a detected nonconformity or other undesirable situation.

What will prevent the problem from continuing or recurring? Note that the appropriate actions will be dependent on the root cause and that multiple corrective actions may be needed.

Examples of corrective actions include:

- Informing and/or retraining current and new study personnel on SOPs, protocol requirements, informed consent process, etc.
- Changing the storage area for the investigational product and implementing stricter access controls
- Scheduling all follow-up visits as early as possible within the protocol required visit window
- Reassigning the task of patient scheduling to a different person

7

List and explain the preventative action(s). ISO 9000:2005(E) defines preventative action as an action to eliminate the cause of a potential nonconformity or other undesirable situation. What will minimize the potential for the problem to continue or be repeated?

Examples of preventative actions include:

- Adding research coordinators to the study to provide additional support and implementing procedures to ensure that each study has enough personnel assigned
- Adjusting the monitoring plan/strategy
- A sponsor or monitor providing additional remote support
- Modifying or updating an SOP to improve a process. For example, defining who is responsible for patient scheduling.

8

Describe the plan for implementing, verifying, and closing the CAPA.

9

Add the appropriate signature lines.