

Good Clinical Practice Professional Certification Scheme (GCPPCS)

SYSTEM FOR PROVISIONAL APPROVAL OF PERSONNEL CERTIFICATION BODIES

0. INTRODUCTION

0.1 The Good Clinical Practice Professional Certification Scheme (GCPPCS), hereinafter referred to as the Scheme, envisages that independent, competent personnel certification bodies (PrCBs) assess and certify GCP professionals against the Minimum Standard of Competence criteria set under the Scheme and certify them on behalf of CDSA-THSTI, the Scheme Owner.

0.2 The PrCBs, to operate under the Scheme, shall need to primarily comply with the requirements specified in ISO 17024 and the additional Scheme requirements.

0.3 The PrCBs would not get an applicant and would not be able to offer their process for witnessing as part of the accreditation process to the accreditation body to get accreditation or to get the relevant scope added in their accreditation if already accredited unless they are approved under the Scheme.

0.4 Further, to launch the Scheme, it is necessary that some PrCBs are available at the beginning.

0.5 Therefore, it is necessary to establish a procedure for Provisional Approval of PrCBs under the Scheme till such time they can get the scope added in their accreditation or get formally accredited from the National Accreditation Board for Certification Bodies (NABCB) as per ISO 17024.

0.6 This document sets out the requirements to be fulfilled by PrCBs desirous of operating under the Scheme pending formal accreditation and approval.

1. SCOPE

1.1 This document defines the criteria and process for PrCBs to obtain Provisional Approval to operate under the Good Clinical Practice Professionals Certification Scheme (GCPPCS), pending formal accreditation for the Scheme by NABCB as per the prescribed international standard(s) and approval by CDSA-THSTI.

1.2 This approval shall be valid for one year within which the approved PrCBs would have to obtain formal NABCB accreditation and approval of CDSA-THSTI.

2. CRITERIA FOR APPROVAL

The PrCBs desirous of certifying GCP professionals under this Scheme shall meet the criteria as prescribed in clauses 3 and 4 of this document.

3. ADMINISTRATIVE REQUIREMENTS

3.1 Legal entity: The PrCB shall be a legal entity in the economy in which it is located, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its certification activities. A governmental certification body is deemed to be a legal entity based on its governmental status. A PrCB, that is part of an organization involved in functions other than certification, shall be separate and identifiable within that organization.

3.2 Organizational structure: The PrCB shall define and document the duties, responsibilities and reporting structure of its personnel and any committee and its place within the organization. When the certification body is a defined part of a legal entity, the documentation of the organizational structure shall include the line of authority and the relationship to other parts within the same legal entity.

3.3 Integrity: The PrCB and its personnel shall maintain integrity at all times. The PrCB shall implement adequate measures to ensure integrity.

3.4 Impartiality:

3.4.1 The PrCB shall be impartial.

3.4.2 The PrCB shall be so structured and managed as to safeguard impartiality.

3.4.3 The PrCB and its staff shall not engage in any activities that may conflict with their impartiality.

3.4.4 The PrCB shall act impartially with its applicants, candidates and certified GCP professionals.

3.4.5 The PrCB shall have a process to identify, analyze, evaluate, monitor and document the threats to impartiality arising from its activities including any conflicts arising from its relationships on an ongoing basis.

a) This shall include those threats that may arise from its activities or its relationships or the relationships of its personnel. Where there are any threats to impartiality, the PrCB shall document and demonstrate how it eliminates or minimizes such threats and document any residual risk. The demonstration shall cover all potential threats that are identified, whether they arise from within the PrCB or from the activities of other persons, bodies or organizations.

b) Top management shall review any residual risk to determine if it is within the level of acceptable risk. When a relationship poses an unacceptable threat to impartiality, then certification shall not be provided.

c) The risk assessment process shall include identification of and consultation with appropriate interested parties to advice on matters affecting impartiality including openness and public perception.

NOTE 1 Sources of threats to the impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

NOTE 2 One way of fulfilling the consultation with the interested parties is by the use of an impartiality committee.

3.4.6 The PrCB shall not impart education and/or training for GCP professionals within the same legal entity.

3.4.7 The PrCB shall have a process to eliminate or minimize risk to impartiality if training/education of GCP professionals is carried out in a related body which is linked to the PrCB by common ownership etc.

3.4.8 The PrCB shall have a process to ensure that the examiners and invigilators are free of any conflict of interest with the applicant(s) by means of being a teacher or trainer in the recent past. A separation of 2 years is considered acceptable for the purpose.

3.5 Confidentiality: The PrCB shall ensure confidentiality of information unless required by law, obtained in the course of its certification activities by having a suitable system. Information gathered would not be used for any commercial or other purposes other than that to support certification of candidates.

3.6 Security: The PrCB shall develop and document policies and procedures to ensure security throughout the assessment and certification process.

3.7 Liability and Financing:

3.7.1 The PrCB shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

3.7.2 The PrCB shall evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

4. TECHNICAL REQUIREMENTS

4.1 Personnel:

4.1.1 The PrCB shall have, as part of its organization, personnel, either employed or on contract, having sufficient competence for managing process of certification of GCP professionals.

4.1.2 The PrCB shall have defined processes for selecting, training, and formally authorizing examiners and for selecting technical experts, if needed, used in this activity.

4.2 Competence

4.2.1 The competence for the examiners and question paper setters used by the PrCBs shall be:

- a) Post-graduate degree in medical sciences/nursing/pharmaceuticals/biological sciences/ biostatistics/ clinical data management.
- b) 5 years of work experience in clinical research after receiving a post-graduate degree.
- c) GCP trained.
- d) The team of personnel (examiners or trainers, or question paper setters) to have overall Collective competence for all 6 domains.

4.2.2 Personnel records: The PrCBs shall maintain up-to-date personnel records, as per requirements of the Scheme document of each of its personnel involved in its certification activities.

4.3 Certification process

4.3.1 The PrCB shall manage the process of certifying GCP professionals as per the documented 'Certification Process' prescribed under the Scheme.

4.3.2 The PrCB shall maintain records to demonstrate that the certification process is effectively implemented.

4.3.3 The PrCB shall ensure the requirements of the Scheme are met with at any point in time.

4.3.4 The PrCB shall certify GCP professionals only under the Scheme and shall use the logo of the Scheme in the certificates issued to the certified GCP professionals following the rules prescribed under the Scheme.

4.3.5 The PrCB shall have written agreement with the certified GCP professionals on the use of the certificate issued to them.

4.3.6 The PrCB shall have a process to handle appeals and shall be publicly available by the candidates against any of its decisions.

4.3.7 The PrCB shall have a process to handle complaints from the GCP professionals and shall be publicly available from the users of the services of the certified GCP professionals or any other stakeholder.

4.4 Certification agreement: The PrCBs shall have a legally enforceable agreement for the provision of certification activities to GCP professionals. Besides, the PrCBs shall ensure its certification agreement requires that the GCP professionals comply at least, with the specific requirements in the Scheme document.

4.5 RESPONSIBILITY FOR DECISION ON CERTIFICATION

4.5.1 The PrCBs shall be responsible for, shall retain authority for, and shall not delegate its decisions relating to certification, including the granting, maintaining, recertifying, expanding and reducing the scope of the certification, and suspending or withdrawing the certification and if required shall have an independent decision-maker for the purpose.

4.6 PUBLICLY AVAILABLE INFORMATION

4.6.1 The PrCB shall maintain a website for providing information about the Scheme and its certification activities under the Scheme.

4.6.2 The PrCB shall maintain and make publicly available information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification and about the certification activities and geographical areas in which it operates.

4.6.3 The PrCB shall make publicly available information about applications registered and certifications granted, suspended or withdrawn.

4.6.4 The PrCB shall make publicly available its processes for handling appeals and complaints.

5. APPROVAL PROCESS

5.1 Application

5.1.1 Any organization interested in approval as a PrCB for the Scheme may apply to CDSA-THSTI in the prescribed application form along with the prescribed application fee. The applicant shall also enclose the required information and documents as specified in the application form.

5.1.2 The filled in an application form for approval shall be duly signed by the CEO/authorized representative/s of the organization seeking approval.

5.1.3 On receipt of the application form, it will be scrutinized by the secretariat at CDSA-THSTI and those found complete in all respects will be processed further.

5.2 Assessment process

5.2.1 On review of the application for completeness, an assessment team comprising a team leader and member(s)/technical expert(s) will be nominated by CDSA-THSTI for assessment at applicant's office and other locations where critical activities are undertaken, if required. Under normal circumstances, the assessment at head office will be for a total of two mandays. In case the PrCB is already accredited to ISO 17024, the mandays may be reduced.

5.2.2 The names of the members of the assessment team along with their CVs will be communicated to the applicant giving it adequate time to raise any objection against the appointment of any of the team members, which will be dealt with by CDSA-THSTI on merits. All assessors/experts nominated by CDSA-THSTI shall have signed undertakings regarding confidentiality and conflict of interest.

5.2.3 If necessary, CDSA-THSTI may decide based on the report of office assessment or otherwise, to undertake witness assessment(s) of actual evaluation or any part of the certification process by the applicant.

5.2.4 The assessment team leader shall provide an assessment plan to the applicant in advance of the assessment.

5.2.5 The date(s) of assessment shall be mutually agreed to between the applicant and CDSA-THSTI/assessment team.

5.2.6 The Office assessment will begin with an opening meeting for explaining the purpose and scope of assessment and the methodology of the assessment. The actual assessment process shall cover a review of the documented system of the organization to assess its adequacy in line with the criteria as specified in this document. It will also involve verification of the implementation of the system including scrutiny of the records of examiners' competence and other relevant records and demonstration of examiners' competence through means like interviews, etc. In short, it will be an assessment for verifying technical competence of the applicant for operating under the Scheme.

5.2.7 At the end of the office assessment, through a formal closing meeting, all the nonconformities and concerns observed in the applicant's system as per the assessment criteria and the assessment team's recommendation to CDSA-THSTI shall be conveyed to the applicant.

5.2.8 Based on the report of the assessment, and the action taken by the applicant on the nonconformities/concerns if any, CDSA-THSTI shall decide on granting Provisional Approval to the applicant as PrCB under the Scheme.

6. VALIDITY OF APPROVAL

6.1 The approval shall be valid for a period of one year.

6.2 The PrCB shall obtain formal accreditation as per ISO 17024 from NABCB within one year of Provisional Approval by CDSA-THSTI to formalize its approval.

6.3 The Provisional Approval shall be subject to suspension/withdrawal with due notice of 15 days in the event of any noncompliance to the requirements of the Scheme and serious complaint from the market.

6.4 The approved PrCB shall inform CDSA-THSTI without delay about any changes relevant to its approval, in any aspect of its status or operation relating to:

- a)** Its legal, commercial, ownership or organizational status;
- b)** The organization, top management and key personnel;
- c)** Main policies, resources, premises and scope of approval;
- d)** Other such matters that may affect the ability of the PrCB to fulfil requirements for approval.

CDSA-THSTI shall examine such information and decide on the issue on merits with or without an on-site verification.

6.5 The PrCB shall send data of the candidates certified/rejected immediately within one week after the issue of the certificate/conclusion of assessment to CDSA-THSTI. The data shall be submitted in the specified format for maintaining the registry of the GCP professionals.

6.6 CDSA-THSTI shall witness the process of assessment/certification by an approved PrCB atleast within the period of validity.

6.7 Any extension of validity of Provisional Approval shall be based on a written request for justifiable reasons and shall involve office or witness assessment or both as decided by CDSA-THSTI.

7. FEE

7.1 The following fee structure shall apply:

Provisional Application Fee	Rs.10, 000/-
Annual Fee – (Provisional Approval by CDSA for 1 yr)	Rs.25, 000/-
Certification Fee per Certificate issued	20% of the Certification Fee Per candidate

7.3 CDSA-THSTI at its discretion may revise/ levy any other fee necessary with due notice to the PrCBs.

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