I. The Procedures is developed with the view to ensure the quality & efficiency of Discipline Review Meeting.

II. Discipline review meeting refers to the meetings proposed by the chief reviewer and participated by the same discipline reviewers, where, in the process of discipline review, the chief reviewer find some problems existed, cannot form a definite discipline review conclusion and need to have a future discussion after sufficiently collecting the research data submitted by the applicants, carrying out literature study, referring to guidance, technical standards and principles for solution of common problems and summarizing opinions of other reviewers.

III. The review offices are responsible for the specific management of discipline review meeting.

IV. Discipline review meeting, which is generally proposed by the chief reviewer, shall be organized and convened by the consent of the director of the office and directors of the review offices can also directly propose the discipline review meeting.

V. Generally discipline review meeting is held inside a review office, the participants include the chief reviewer, co-reviewers, director of this review office, as well as other personnel of the office as required by review.

The discipline review meeting invitation for reviewers from other review offices shall be agreed by the director of this office and the director of office whose personnel are invited.
VI. The review office shall propose the demand for invitation of external experts to participate discipline review meeting if necessary, and shall fill in the Approval Form for Invitation of External Experts for discipline review meeting, which is to be verified by the director of the review offices, instructed and agreed by the CDE leadership (Authorized Person) for concrete implementation. The office of management and communication shall provide assistance with related works.

Discipline review meeting is to be held, as far as possible, by ways of video or telephone meetings, and if necessary, round table meetings. The discipline review meeting-related affairs such as the experts’ conflict of interest, confidentiality etc. can be taken care of in reference to the requirements of the Procedures for Organizing the Expert Consultation Meeting (Interim).

VII. Under the following conditions, proposals can be made to invite external experts to participate in the discipline review meeting:

1. CDE is in want of internal reviewers with professional background related to the area of expertise involved in the issues to be discussed.
2. The issues to be discussed pertain to the prerequisite or key technical points for the subsequent conclusions or solutions.
3. Need to invite external experts to participate in the discussions.
4. For the application discussed in discipline review meeting attended by external expert, if the follow-up Expert Consultation Meetings for the application is necessary, the discipline issue that have been discussed in discipline review meeting shall no longer be discussed and the relevant discipline expert shall be no longer invited in principle.

VIII. When the discipline review meeting needs the participation of the office of management and communication or the CDE leadership (Authorized Person), it shall be proposed by the director of the review office.

IX. Discipline review meeting shall be convened under the following conditions:

1. Registration applications that are in line with the special approval procedures;
2. Discipline opinions are different among the co-reviewers;
3. Need to convene a consultation meeting for the review;
4. When meetings are to be convened to communicate with the applicants for registration;
5. Involving the discipline common problems that need to be discussed;
6. Discipline review meeting proposals made by director of the review office or CDE leadership (Authorized Person);
7. First-time review with task difficulty coefficients of "3" and above;
8. Other cases (for example, for consultation with the Registration Department, the need for verification, and third party verification etc.)

X. The chief reviewer is responsible to organize and preside the discipline review meeting, to inform the participants in advance of the meeting date, venue, issues to be discussed, related overview of the application, the collected data, and literature and materials etc. The attendees should get well prepared for the topics of the meeting to ensure the quality and efficiency of the meeting.

XI. Discipline review meeting discussions should focus on topics of the meeting. The chief reviewer is responsible for reporting the overview on the application (preferably in ppt), the issues to be discussed and the reasons for discussion, as well as associated study data, references, guidance and technical standards. The participants should fully express their views on the basis of preparations before the meeting and submit further supporting materials. The meeting shall ultimately form definite comment or suggestion.

XII. The comments or management suggestions formed by discipline review meeting should be clear and well defined, and representing the common understanding to this end up to date, pursuant to which follow-up comprehensive review can be made.

XIII. Disputable issues without a definite conclusion even after discipline review meeting shall be submitted to the Office Directors’ Joint Meeting for discussion in reference to the requirements of the Procedure for Review Decision Making Pathways (Interim). Issues that call for comprehensive discussion and review with other professions can also be submitted to the joint meeting of chief reviewer
for discussion.

XIV. Discipline review meeting should form the meeting minutes, which are to be drafted by the chief reviewer, and verified by the review office for concrete implementation. Discipline review meeting minutes can be recorded either in the form of "one case, one meeting", or "many cases, one meeting".

The meeting minutes should be timely uploaded to CDE Review Information System, and reflected in the discipline review report.

The meeting minutes must accurately and fully reflect the main contents of the discussions (including different views and opinions), and shall give details of the consensus or the rationale of the solution suggestions; the meeting minutes, once formed, shall be promptly informed to all attendees.

XV. Human resources and information office shall research in conjunction with the research and evaluation office and the office of management and communication to establish discipline review meeting management modules, perform quantitative assessment on the contents involved in the Procedures, and evaluate the effect of discipline review meeting on a regular basis.

XVI. All CDE review posts shall comply with and implement the Procedures.

XVII. This Procedures shall enter into force as of the date of promulgation.

**Annex:** Approval Form for Invitation of External Experts for Discipline Review Meeting.
Annex:

**Approval Form for Invitation of External Experts for Discipline Review Meeting**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Accepted Number</th>
</tr>
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<tbody>
<tr>
<td>The Applicant for Registration</td>
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<tr>
<td>Indications</td>
<td>Registration Category</td>
</tr>
<tr>
<td>Review Reporting Office</td>
<td>Review Office</td>
</tr>
<tr>
<td>Chief Reviewer Reporter,</td>
<td>Chief reviewer</td>
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<tr>
<td>Co-reviewers</td>
<td></td>
</tr>
<tr>
<td>Issues to be Discussed</td>
<td></td>
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<tr>
<td>Experts Intended to be Invited (Name, Professional and Units, Contact)</td>
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<tr>
<td>Person for Invitation Proposal (Signature)</td>
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<tr>
<td>Opinion of the director of the Review Office that proposed the invitation</td>
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<tr>
<td>Opinions of the Office of Management and Communication and Communication</td>
<td></td>
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<tr>
<td>Instructions &amp; Opinions of CDE leadership (Authorized Person)</td>
<td></td>
</tr>
<tr>
<td>Conditions confirmed by project manager (Meeting Date, Venue, etc.)</td>
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</tbody>
</table>

**Disclaimer:**
This document is for reference only. For any dispute, the Chinese version shall prevail.