Grant of License to act as Contract Research Organization, Clinical Trial Site, BA/BE Studies Center & Bioanalytical Lab.

### Performance of function as prescribed in the Bio-Study Rules 2017 by the Applicant

- Creation of application on Form-I of the Bio-Study Rules, 2017 for Licensing of CRO, Clinical Trial Site, BA/BE Studies Center or Bioanalytical Lab
- Submission of Application Dossier as per checklist
- Submission of Fee Challan
- Rectification of Shortcomings

### Actions to be taken by DRAP

- Receipt of application Dossier
- Preliminary Evaluation by Desk Officer (Within 30 working days)
- Constitution of inspection panel by CSC or by Chairman CSC
- Placement before Clinical Study Committee (CSC)
- Inspection report placed before Clinical Study Committee (Evaluation of report within 10 working days)
- Issuance of Rejection letter
- Issuance of Shortcoming letter (Within 10 working days after approval)
- Observation/Deficiencies

#### Actions

- Complete
- Deferred on the basis of shortcomings
- Incomplete due to shortcomings / clarifications
- Not Recommended
- Recommended

#### Issuance of License

- Issuance of License on positive inspection report, to act as BA/BE Studies Center on Form-IV and/or License to act as CRO, Clinical Trial Site or Bioanalytical Laboratory on Form-V of the Bio-Study Rules, 2017 issued to the applicant. (valid for 3 years) (Within 15 working days after finalization of CSC meeting minutes & approval)

Applicant can submit appeal against decision of CSC to the Authority within 30 days of receipt of decision.

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