## DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

|                   |   | Anne           | xure – 12   |               |          |                 |
|-------------------|---|----------------|-------------|---------------|----------|-----------------|
| 0                 | FORM Title: Checklist for NOC/Permission to Start<br>Clinical Study |                |             |               |          | Ø               |
| Form No.          | Version No.   | Effective Date | Review Date | Authorized by | Date     | Page No.        |
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| SI. | Content   | Submitted? | Remarks |
|-----|---|------------|---------|
| No. |   |            |         |
| 1.  | DGDA approval certificate for CRO                     |            |         |
| 2.  | Approved protocol by BMRC                             |            |         |
| 3.  | Investigator's Brochure                               |            |         |
| 4.  | Informed consent form                                 |            |         |
| 5.  | Copy of signed agreement with sponsor                 |            |         |
| 6.  | CV of principle investigator and his/her team members |            |         |
| 7.  | GCP training  |            |         |
| 8.  | List of SOPs  |            | 8° 0    |
| 9.  | GMP certificate of manufacturing plant                |            |         |
| 10. | Test samples, COA and Summary protocol                |            |         |

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