APPLICATION

For

ACCREDITATION OF CLINICAL TRIAL IN INDIA
(Ethics Committee, Investigator and Clinical Trial Site)

No.: 01
Date: January 2015

NATIONAL ACCREDITATION BOARD FOR HOSPITALS and HEALTHCARE PROVIDERS
NATIONAL ACCREDITATION BOARD FOR HOSPITALS and HEALTHCARE PROVIDERS

Activities and Fee structure

<table>
<thead>
<tr>
<th>Type of Facility</th>
<th>Activities</th>
<th>Accreditation Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assessment</td>
<td>Surveillance</td>
</tr>
<tr>
<td>Up to 2 sites of different specialities in any hospital/institution and 3 Investigators</td>
<td>2x1 man-days</td>
<td>1x1 man-days</td>
</tr>
<tr>
<td></td>
<td>2x2 man days</td>
<td>2x1 man-days</td>
</tr>
</tbody>
</table>

NOTE: Any additional site or investigator would be charged Rs. 5000/- per site or investigator
Service tax of 12.36% will be charged on all the above fees which is to be included in the fees accordingly while sending to NABH.

Guidance notes:

1. Fees to be paid through Demand Draft/ local cheque in favour of Quality Council of India payable at New Delhi. Fees is non-refundable.
2. Five copies of this application form duly filled in are to be submitted along with self-assessment tool kit, declarations (Annexure 1,2,3 as applicable), other relevant documents and fees.
3. The accreditation fee does not include expenses on travel, lodging/ boarding of assessors, which will be borne by the applicant on actual basis.
4. The accreditation, once granted will be valid for three years. The accredited entity may apply for renewal as per the NABH policy.
5. The surveillance visit will be planned during the 2\textsuperscript{nd} year of accreditation which is usually between 15-18 months.
6. NABH may call for an un-announced visit, which could be a Surprise Assessment or based on any concern/ feedback/ complaint reported by any individual or organization or media.
GENERAL INFORMATION:

1. Application for (please tick the relevant item)
   a. Accreditation* □
   b. Re-accreditation □
      Reaccreditation cycle number ...............  
      * (If initial accreditation, please select accreditation)

2. Applicant: (select all that apply)
   a. Ethics Committee □
   b. Investigator □
   c. Clinical Trial Site □
      *Separate certificate and accreditation number will be issued to Ethics Committees, Investigator and Clinical Trial Site

3. Name and other details of the applicant (the same shall appear on the accreditation certificate)
   a. Ethics Committee: NA □
      Name and contact details (address, email id, fax contact no.etc) of the Ethics Committee
      Number of Members
      Accreditation Number or Application acknowledgement Number
      Registration Number, if already registered with CDSCO
      *Add additional rows as required if more than one Ethics Committees associated with the Clinical Trial Site
      * Ethics Committee must provide a signed Ethics Committee declaration form

   b. Investigator(s): NA □
      Name and contact details (address, email id, fax contact no.etc ) of Investigator
      Details of the Site with Speciality
      *Add additional rows as required if multiple investigators associated with the Clinical Trial Site
      *Each investigator must provide a signed investigator declaration form

   c. Clinical Trial Site: NA □
      a. Name and contact details (address, email id, fax contact no.etc ) of the Clinical Trial Site
      Number of (operational) beds in the hospital/institution
      Location
      *Clinical Trial Site must provide a signed Clinical Trial Site declaration form
      *If the Clinical Trial Site has more than one subunit/hospitals in different locations, a separate application form is required for each of the units.
4. Name of Hospital (If applicant is individual Ethics Committee or investigator, mention the name of associated hospital/institution).

_______________________________________________________________________

*For Independent Ethics Committee please write Not Applicable

*Please update name of hospital in case of joint application as it is possible that clinical Trial Site mentioned in point 3.c is a Clinical Trial Organization within a hospital or Clinic attached to a hospital.

Contact details of the hospital/institution:

Street Address: ___________________________________________________________

City/Town: ________________________________________________________________

Locality/Village: __________________________________________________________

District: _________________________________________________________________

State: _________________________________________________________________

Website: ________________________________________________________________

4.1 Contact :

*Please indicate with whom correspondence to be made

- Top Management in the Hospital

  Mr. /Ms./Dr. : _____________________________________________________________

  Designation: ____________________________________________________________

  Tel: ___________________________________________________________________

  Mobile: __________________________________________________________________

  Fax: ___________________________________________________________________

  E-mail: __________________________________________________________________

5. Ethics Committee Chairperson (For Independent Ethics Committee)

  Mr./Ms./Dr.: _____________________________________________________________

  Designation: ____________________________________________________________

  Tel: ___________________________________________________________________

  Mobile: __________________________________________________________________

  Fax: ___________________________________________________________________

  E-mail: __________________________________________________________________
6. Accreditation Coordinator

Mr./Ms./Dr.: ________________________________________________________________

Designation: ________________________________________________________________

Tel: ______________________________________________________________________

Mobile: ___________________________________________________________________

Fax: ______________________________________________________________________

E-mail: ____________________________________________________________________

7. Declaration: We are familiar with and shall abide by the terms and conditions of maintaining NABH accreditation (NABH-T&C).

Date of Application:

__________________________________________________________________________

Authorized Signatory

Name: ______________________

Designation: ________________
# Ethics Committee Declaration Form

<table>
<thead>
<tr>
<th>Ethics Committee Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Number (if already registered with CDSCO)</td>
<td></td>
</tr>
<tr>
<td>Date of Registration and validity</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Number of Clinical Trial proposals reviewed till date</td>
<td></td>
</tr>
<tr>
<td>Number of Clinical Trial proposals reviewed annually (give figures for last two years)</td>
<td></td>
</tr>
<tr>
<td>Total number of ongoing protocols</td>
<td></td>
</tr>
</tbody>
</table>

**Declaration by the Chairperson:**

- I confirm that the information provided is accurate.
- Access will be provided to NABH assessors to areas necessary for conducting assessment of clinical trial at the site.
- If there are any changes in the above information these will be communicated to NABH within 30 calendar days
- We are familiar with and shall abide by the terms and conditions of maintaining NABH accreditation (NABH-T&C).

**Date of Application:**

**Signature of Chairperson:**

**Name:**

____________________________________________________________________________
List of Attached Reference documents

EC Membership list (NABH format to be used as per 3.a)

List of trial(s)

SOPs:

- Composition, procedures for new induction and resignation of members
- Frequency of ethics committee meetings
- Receipt, review and decision making of proposals
- Review of protocol amendments
- Procedure for deliberations and maintaining minutes
- Periodic review and oversight
- Procedure to be followed for vulnerable population
- Review of informed Consent Document (subject information sheet and informed consent form) and informed consent process
- Reporting, analysis of SAEs and making opinion on compensation
- Handling issues related to non-compliances, protocol violation, complaints by the participants and other stakeholders
- Declaration of conflict of interest and confidentiality agreement
- Financial declaration of payments received and disbursed
- Training for committee members
- Communication with different stakeholders
**Investigator Declaration Form**
(to be filled in separately by each investigator applying for accreditation)

<table>
<thead>
<tr>
<th>Investigator Name (First/Middle/Last)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth</td>
</tr>
<tr>
<td>Registration Number with Name of State Medical Council</td>
</tr>
<tr>
<td>Degrees/ years</td>
</tr>
<tr>
<td>Experience in Clinical Practice (years)</td>
</tr>
<tr>
<td>Experience in Clinical Trials (Years)</td>
</tr>
<tr>
<td>Total number of clinical trials conducted as Investigator</td>
</tr>
<tr>
<td>Total number of clinical trials conducted as Sub-Investigator</td>
</tr>
<tr>
<td>Current number of trials as Investigator and Sub-Investigator</td>
</tr>
<tr>
<td>Contact Number</td>
</tr>
<tr>
<td>Correspondence Address</td>
</tr>
<tr>
<td>Permanent Address</td>
</tr>
<tr>
<td>Name of Clinical Trial Site(s) where the trial is proposed to be conducted</td>
</tr>
<tr>
<td>Confirm whether the proposed Clinical Trial Site(s) are accredited under NABH CT Standards</td>
</tr>
<tr>
<td>Investigator Accreditation Number (Office to issue)</td>
</tr>
</tbody>
</table>
Declaration by investigator:

- I confirm that the information provided is accurate.
- Access will be provided to NABH assessors to areas necessary for conducting assessment of clinical trial by the investigator.
- If there are any changes in the above information these will be communicated to NABH within 30 calendar days.
- I am familiar with and shall abide by the terms and conditions of maintaining NABH accreditation (NABH-T&C).

Date Application Completed:

Signature of Investigator:

Name:

Designation:

List of Attached Reference documents

List of trials conducted as SI and PI
Copy of self-attested Medical Registration (including Post graduate degrees if any)
Copy of latest CV
SOP on Investigator role and responsibilities
# Clinical Trial Site Declaration form

<table>
<thead>
<tr>
<th>Clinical Trial Site name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency facility available at the Clinical Trial Site</td>
<td></td>
</tr>
<tr>
<td>If answer to above question is No, is there a MOU with another Hospital/Healthcare facility with access to emergency facility</td>
<td></td>
</tr>
<tr>
<td>Please provide name, address of the Hospital/Healthcare facility and its accessibility to the clinical trial site</td>
<td></td>
</tr>
<tr>
<td>Existing accreditation if any</td>
<td></td>
</tr>
<tr>
<td>Registered Ethics Committee associated with hospital</td>
<td></td>
</tr>
<tr>
<td>NOTE: Clinics need to be associated with an accredited Institutional Ethics Committee</td>
<td></td>
</tr>
<tr>
<td>Total number of protocols till date</td>
<td></td>
</tr>
<tr>
<td>Total number of ongoing clinical trials</td>
<td></td>
</tr>
<tr>
<td>Total number of clinical trial staff (List of coordinators/research nurses/investigators)</td>
<td></td>
</tr>
<tr>
<td>Hospital Ownership:</td>
<td></td>
</tr>
<tr>
<td>- Private-Corporate</td>
<td></td>
</tr>
<tr>
<td>- PSU</td>
<td></td>
</tr>
<tr>
<td>- Armed Forces</td>
<td></td>
</tr>
<tr>
<td>- Trust</td>
<td></td>
</tr>
<tr>
<td>- Government</td>
<td></td>
</tr>
<tr>
<td>- Charitable</td>
<td></td>
</tr>
<tr>
<td>- Others (Specify)</td>
<td></td>
</tr>
<tr>
<td>Year and month in which registered and under which authority (as per state and central requirements)</td>
<td></td>
</tr>
<tr>
<td>Year and month in which clinical functions started</td>
<td></td>
</tr>
<tr>
<td>Contact details: Telephone number and address</td>
<td></td>
</tr>
</tbody>
</table>
Declaration by the Hospital Administrator/Authorized Signatory:

- Access will be provided to NABH assessors to areas necessary for conducting assessment of clinical trial at the site.
- I confirm compliance to local regulatory requirements for conduct of clinical trials.
- The hospital/institute will provide the necessary support, infrastructure and human resources for conduct of clinical trials and ethics committee functioning.
- I confirm that the information provided is accurate.
- If there are any changes in the above information these will be communicated to NABH within 30 calendar days.
- We are familiar with and shall abide by the terms and conditions of maintaining NABH accreditation (NABH-T&C).

Date Application Completed:

Signature of Authorized Signatory:

Name:

Designation:

List of Attached Reference documents

Clinical Trial Staff details
List of Specialties and investigators for accreditation
SOPs:
- Subject Protection Policy (including transparent mechanism of enrolment)
- Informed Consent, including procedures for Audio-visual recording of consent
- Medical management of Adverse Events
- Adverse Events and Serious Adverse Events Reporting (including emergency care)
- Roles and responsibilities of study team
- Site Research Team training
- Research Pharmacy (Investigational Product Management)
- Protocol compliance and protocol deviations
- Documentation policy
- Storage and retention of trial related documents
- Conflict of interest Disclosure form
- Equipment Calibration and Maintenance
- Quality Management Plan (including quality control measures)