# ANNEX 2

**AF/02-012/01** **Study Assessment Form for Case Study and Case Series**

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| --- | --- | --- | --- | --- | --- |
| Protocol Number: | | | | | |
| Title : | | | | | |
| Version No... | | | | | |
| Principal Investigator(s): | | | Professional Registration No, if applicable: | | |
| Institute: | | | Contact No. | | |
| Co – investigator(s): | | | | | |
| Total No. of Cases: | | | | | |
| Funding Agency: | | | | | |
| Reviewer’s name : | | | | | |
| Review Status: ⬜ Full board ⬜ Expedited ⬜ Emergency | | | | | |
| Description of the Case Study in brief: | | | | | |
| **Mark and comment on whatever items applicable to the study.** | | | | | |
| Qualifications of Investigators and study sites | | | |
| 1 | Are Qualification and experience of the Participating Investigators appropriate?  ⬜ Yes ⬜ No  ⬜ CV not attached | |  |
| 2 | Disclosure or Declaration of Potential Conflict of Interests  ⬜ Yes ⬜ No  (**Note:** Refer serial number 11 and 12 of the “AF/05-008/05 APPLICATION FORM for Initial Review of CASE STUDY / CASE SERIES”) | |  |
| Privacy, Confidentiality and Consent | | | |
| 3 | Privacy & Confidentiality: Is the identifiers removed from study-related information or report?  ⬜ Yes ⬜ No | |  |
| 4 | Is there a written permission to use the patient information for research from the patient or their parent(s)/legal guardian?  ⬜ Yes ⬜ No | |  |

**Reviewer Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**