# ANNEX 5

**Form AF/05-008/01**

**APPLICATION FORM for Initial Review of CASE STUDY / CASE SERIES**

1. Protocol Number (*To be assigned by IRB Secretariat):*
2. Title: ……………………………………………………………………………………………………………
3. Version No.: …………
4. Total number of cases: …………
5. PARTICULARS OF THE PRINCIPAL INVESTIGATOR (PI)

 Name: …………………………………………………………………………………………

 Address: ………………………………………………………………………………………

Contact Number: …………………………… Fax(optional): …………………………………………. E-mail: ……………………………………………............................................................

1. CHARACTERISTICS of CASES:

Age Range (Specify):

Impaired: ☐ None ☐ Physically ☐ Cognitively ☐ Mentally

Limitation: ☐ Illiteracy ☐ Prisoners ☐ Hospitalized ☐ Nursing home

 ☐ Pregnancy ☐ Poor/uninsured ☐ Employees of study site

 ☐ Students or staff of the PI ☐ Military personnel

 ☐ Others vulnerable to coercion, specify…………………………………….......

1. Specify the site(s) of cases (Institution, Place and Country): ...............................................................
2. FINANCIAL DISCLOSURE: ☐ YES ☐ NO, why not? .......

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1. **CO-INVESTIGATOR(S)**:

|  |  |  |
| --- | --- | --- |
| **Name and Institution** | **Role in the study** | **Contact Number** |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 4. |  |  |
| 5. |  |  |
| 6. |  |  |
| 7. |  |  |
| 8. |  |  |

1. Has the Principal Investigator (PI) ever been involved in or convicted of a crime, disciplined by a public or private medical organization, or by a licensing authority?

☐ No ☐ Yes, explain……………………………………………….................................

1. Does the PI, the study colleagues or their families have any financial relationship with the sponsor other than payment for the conduct of the study?

☐ No ☐ Yes, If Yes describe the relationship…………………………………………………………..

1. Does the PI, the study colleagues or their families have any other personal considerations that may compromise, or have the appearance of compromising a researcher's professional judgment in reporting case(s)?

☐ No ☐ Yes, If Yes describe it ………………………………………………………………………….

1. How long will the research data be stored by the PI? …….years after closing the study.
2. Is there a written permission to use the patient information for research from the patient or their parent(s)/legal guardian?

 ☐ Yes ☐ No

1. Is the identifiers removed from study-related information or report? ⬜ Yes ⬜ No
2. Has the case study been disapproved or terminated by any other Research Board?

 ☐ No ☐ Yes, explain…………………………………………….......................................

**SIGNATURES:**

 Date: ………………..

 Principal Investigator

 Date:…………………

 Protocol Chairperson (if applicable)

**COMPLETION:**

 Date:…………………

 Member-Secretary, IRB