**Initial clinical investigation application – list of documents submitted**

1.

*NOTE*

*When an approval is issued this list of approved documents will be attached to the approval letter. It is thus important that the applicants keep this list of documents provided at the initial submission and* ***submit it at each change*** *(validation questions, response to RFI, etc.)* ***with a clear indication of which documents have been updated/added.***

*Non-applicable sections/rows may be deleted in the table below.*

|  |  |
| --- | --- |
| ***Documents*** | ***Version and/or date*** |
| **COVER LETTER** |  |
| Ex: Cover-Letter\_20210526.pdf | 26/05/2021 |
| *…* |  |
| **APPLICATION FORM** |  |
| Ex: Application-Form\_20210526.pdf | 26/05/2021 |
| *…* |  |
| **CIP** |  |
| Ex: CIP\_v1.1.pdf | *V1.1 – 26/05/2021* |
| *…* |  |
| **INVESTIGATOR’S BROCHURE (including any annexes)** |  |
| Ex: IB\_v1.2\_20210526pdf | V1.2 – 26/05/2021 |
| *…* |  |
| **MANUFACTURER’S INSTRUCTIONS FOR USE** |  |
| … |  |
| **LIST OF GENERAL SAFETY AND PERFORMANCE REQUIREMENTS** |  |
| *…* |  |
| **NOTIFIED BODY CERTIFICATES** |  |
| … |  |
| **PROOF OF INSURANCE** |  |
| *…* |  |
| **SUITABILITY OF SITES** |  |
| *…* |  |
| **EXAMPLE OF LABELS** |  |
| *…* |  |
| **DECISIONS FROM OTHER COUNTRIES** |  |
| *…* |  |
| **PATIENT RELATED DOCUMENTS** |  |
| *…* |  |
| **CV OF PRINCIPLE INVESTIGATOR(S)** |  |
| *…* |  |
| **PMCF PLAN** |  |
| *…* |  |
| **OTHER DOCUMENTS** |  |
| *…* |  |