**Instructions for Completing**

**The Investigator of Record Agreement (IoR)**

To be used for DMID studies not conducted under an IND

|  |  |
| --- | --- |
| General Guidelines | * All clinical sites must submit an Investigator of Record agreement for each new non-IND essential documents submission. * No section of the Investigator of Record Agreement should be left blank; all sections must be completed. * **There must be no significant *(may impact the interpretation or intended use of the information)* typographical errors and no “write-overs”.** * After the initial IoR is submitted, any correction or revision to information requires the submission of BOTH pages 1 and 2 of the IoR.   + If the required information does not fit within the form, please attach a separate sheet with this additional information, the appropriate section number, the protocol number, and name of the Investigator of Record listed in Box 2. * If the clinical site is outside of the United States and is affiliated with an administrative site, both the clinical site and administrative site must submit a separate IoR. All IRBs should be listed in section 6 for both sites. |

|  |  |
| --- | --- |
| Addenda | Addenda to the IoR must include the following information   * Name of the PI * Protocol Number * Section number to which addenda pertains |
| Section 1 | * The full protocol title as listed in the protocol and DMID protocol number must be listed. Protocol number only is not sufficient. |
| Section 2 | * The PI name must be spelled correctly and the complete mailing address must be present (physical address is preferred; PO Box is acceptable). * The facility listed in Section 2 of the IoR must have an OHRP Federal Wide Assurance number (FWA#) assigned. |
| Section 3 | * The appropriate box must be checked (usually the CV box). |
| Section 4 | * Name(s) and address (es) of all facilities where the clinical investigation will be conducted must be listed. * If the study is conducted at the address that is entered in Section 2, the name and address must also be entered in Section 4. |
| Section 5 | * Only clinical laboratory facilities need be included. Research laboratories must be identified in the protocol, not on the IoR. * Names and addresses of the clinical laboratories must be listed. * If no laboratories are used for the trial, “None” or “Not Applicable” is noted. |
| Section 6 | * Name(s) and address (es) of all of the IRBs utilized for the specific protocol must be listed. * The IRB listed in this section must be registered with OHRP and linked to the FWA number of the facility listed in Section 2. |
| Section 7 | * Names of all sub-investigators authorized by the PI to conduct significant subject assessments must be listed. (Sub-Investigators are usually physicians or other professionals responsible for making protocol decisions.) |
| Section 8 | * The Investigator of Record, listed in Section 2, must agree to the commitments listed in this section and hand sign and date accordingly. |

For additional questions or assistance with filling out the IoR Agreement, please contact:

DMID CROMS Essential Regulatory Documents Group (ERDG)

Technical Resources International, Inc.

6500 Rock Spring Drive, Suite 650

Bethesda, MD 20817

Fax: 301-897-7482

[ERDG@dmidcroms.com](mailto:ERDG@dmidcroms.com)