**Instructions for Completing**

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

To be used for DMID studies not conducted under an IND

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| 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.
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| Addenda | Addenda to the IoR must include the following information* Name of the PI
* Protocol Number
* Section number to which addenda pertains
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| Section 1 | * The full protocol title as listed in the protocol and DMID protocol number must be listed. Protocol number only is not sufficient.
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| 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.
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| Section 3 | * The appropriate box must be checked (usually the CV box).
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| 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.
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| 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.
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| 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.
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| 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.)
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| 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.
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For additional questions or assistance with filling out the IoR Agreement, please contact:

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