This is an image of an up and down arrow key.  **Only use arrow down/up keys to navigate. Do not use tab key.**

**dch-1277-A, IRB ABBREVIATED INITIAL Review Application**

Michigan Department of Health and Human Services (MDHHS)

(Revised 8-24)

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| --- | --- | --- |
| Email: [MDHHS-IRB@michigan.gov](mailto:MDHHS-IRB@michigan.gov) | Phone: 517-241-1928 | Fax: 517-241-1200 |

**section 1 – project identification**

|  |  |
| --- | --- |
| 1.1 | Project Title |

|  |  |
| --- | --- |
|  | Alternative Title |

|  |  |
| --- | --- |
| 1.2 | Responsible Department Employee |

|  |  |  |
| --- | --- | --- |
|  | Phone | Email |

|  |  |
| --- | --- |
|  | ID Mail Address |

|  |
| --- |
| **Note:** The Responsible Department Employee must have a michigan.gov email address, have completed Human Research Protections Training within the past 3 years, and have Bureau Director or equivalent approval to submit applications to the Institutional Review Board. Applications must be submitted from the email address of the Responsible Department Employee to [MDHHS-IRB@michigan.gov](mailto:MDHHS-IRB@michigan.gov). |

|  |  |
| --- | --- |
| 1.3 | MDHHS Administration |

|  |  |
| --- | --- |
|  | Bureau or Office |

|  |  |
| --- | --- |
|  | Authorizing Supervisor (Bureau or Office Director/Equivalent) |

|  |  |
| --- | --- |
|  | Email for Authorizing Supervisor |

|  |  |  |
| --- | --- | --- |
| 1.4 | Primary Investigator | Title |

|  |  |
| --- | --- |
|  | Organization |

|  |  |  |
| --- | --- | --- |
|  | Phone | Email |

|  |  |  |
| --- | --- | --- |
| 1.5 | Is this project federally funded? | Yes  No |

|  |  |  |
| --- | --- | --- |
|  | If yes, specify the federal agency | Grant or Contract Number |

|  |  |  |
| --- | --- | --- |
| 1.6 | Non-Federal funding source(s) if applicable | Grant or Contract Number |

|  |  |  |
| --- | --- | --- |
| 1.7 | Is this project subject to FDA regulations? | Yes  No |

|  |  |
| --- | --- |
|  | If yes, specify below which FDA-regulated test articles will be used. |

|  |  |
| --- | --- |
|  | No test article used |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Drug or biologic used | IND # |  | Trial Phase |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Device used | IDE # |  | Risk Level |  |

|  |  |  |
| --- | --- | --- |
| 1.8 | What date do you plan to begin this project? | What date do you plan to complete this project? |

|  |  |  |
| --- | --- | --- |
| 1.9 | Are you requesting an IRB Authorization Agreement allowing the Michigan Department of Health and Human Services to rely on the review provided by another organization’s IRB? | Yes  No |

|  |  |
| --- | --- |
|  | If yes, explain why it is appropriate for MDHHS to rely on the review provided by another institution’s IRB. |

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|  | If yes, include with your application a copy of the IRB Authorization Agreement used by the other institution listing that institution’s FWA #, IRB Registration #, and Institutional Official. |

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| 1.10 | List the other institution(s) with an Institutional Review Board reviewing this project here. |

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| 1.11 | Describe any conflicts of interest that could be perceived to compromise the integrity of the project. |

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**section 2 – project summary**

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| 2.1 | Provide a brief summary in lay terms describing the project. This should not be as detailed as a study protocol (which can be attached separately). Describe: the purpose of the project, how human subjects will participate, how data or biological specimens will be obtained, how records will be maintained securely, and your plans for distributing findings. |

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**(Do not type beyond this point)**

**section 3 – INSTRUCTIONS FOR SUBMITTING YOUR APPLICATION**

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| --- | --- |
| 1. | Verify all required elements of sections 1 and 2 are complete. |
| 2. | Attach all materials submitted to the other organization’s IRB (e.g., IRB application, study protocol, data collection tools, informed consent documents, etc.) with this abbreviated application. |
| 3. | If approval has already been granted by another IRB, attach the notice of approval. |
| 4. | Ensure approval by the Responsible Department Employee (note: Responsible Department Employees should perform a programmatic review to ensure MDHHS involvement in the project is appropriate, and should serve as the first line in identifying and addressing human research protection issues that may be pertinent to the project). |
| 5. | The Responsible Department Employee should indicate approval and submit the complete application by emailing all documents from his or her MDHHS email account to [MDHHS-IRB@michigan.gov](mailto:MDHHS-IRB@michigan.gov). |

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| Completion of the MDHHS IRB Initial Review Application (DCH-1277) is required for IRB Review at MDHHS when the MDHHS IRB is the only IRB reviewing the project, or when MDHHS has primary responsibility for the project. Do not submit this abbreviated application if no other IRB will review this protocol. |

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| The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group on the basis of race, national origin, color, sex, disability, religion, age, height, weight, familial status, partisan considerations, or genetic information. Sex-based discrimination includes, but is not limited to, discrimination based on sexual orientation, gender identity, gender expression, sex characteristics, and pregnancy. |
| **AUTHORITY:** Code of Federal Regulations Title 45 Part 45 |

**End of form**