**Contact Information**

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| **Principal Investigator:** |  | **Person Completing This Form:** |  |
| **Institutional Affiliation:** |  | **Anonymous: If Yes, please check** |[ ]
| **IRB Protocol Number:** |  | **Date Submitted:** |  |
| **May we reveal your name to the Investigator:**  [ ]  Yes [ ]  No |  |

**Complaint/Concern Information**

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| **Instructions:** Upon completion, please email this form to research@mayinstitute.org. This form may also be either faxed to the IRB at 781-440-0401 or sent by mail to: Human Research Protections Program, 41 Pacella Park Dr., Randolph, MA, 02368.  |
| 1. **If not anonymous, how was the information disclosed?**
 |
|  [ ]  Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Other Contact: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Is this report being made on behalf of someone else?**  [ ]  Yes [ ]  No  If “yes”, please provide a brief explanation:
 |
|  |
| 1. **Is this complaint associated with a study?**  [ ]  Yes [ ]  No

If “yes,” please tell us the title of the study or provide a summary. Any information will be helpful.  |
|   |
| 1. **Please describe your complaint or concern:**
 |
|  |
| 1. **How would you like this complaint or concern resolved?**
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|  |
| 1. **Have you contacted the Principal Investigator or study staff?** [ ]  Yes [ ]  No Name of the person contacted:
 |
|  |
| 1. **Are you or were you a participant in this study?**  [ ]  Yes [ ]  No
 |
| 1. **Did you receive a consent document?**  [ ]  Yes [ ]  No
 |
| 1. **Have you previously reported this complaint?** [ ]  Yes [ ]  No
 |
| 1. **Please provide any additional information:**
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|  |

**HRPP Use Only**

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| **Actions Taken:**  [ ]  Notified IO [ ]  Investigation Initiated [ ]  Referred to Convened Board [ ]  Notified other Sources **Level of Risk of the study:**  [ ]  Minimal Risk [ ]  More than Minimal Risk  **Unresolved Research Complaint**: [ ]  Yes [ ]  No |
| OHRP Staff Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |