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| Institutional Review BoardOffice of Research Compliance | MULOGO | DEVICE SAFETYV.1.3 |

**DEVICE SAFETY ADVISORY BOARD REVIEW FORM**

Under UPP 2-3, human subjects research or educational activities involving the physical interaction of human beings, other than exclusively faculty or enrolled students, with manufactured devices **(a)** that have not been commercially obtained by the University or **(b)** that have been modified by University personnel or students when the device may be tested on or transferred to non-Marquette personnel are subject to review and approval prior to the transferring of the device. The Vice Provost for Research has designated a subcommittee called the Device Safety Advisory Board (DSAB) of the Institutional Review Board (IRB) with the review and approval for devices falling under UPP 2-3.

A DSAB statement regarding significant risk of the device for testing or transfer is not a statement or guarantee of the safety or efficacy of the device. Device developers, groups working on a device, and faculty advisors are responsible for ensuring compliance with University Policy and Procedure UPP 2-3. Review by the DSAB only partially satisfies requirements of the policy. Specific requirements in addition to DSAB review apply prior to transfer of a device.

This form is not appropriate for research projects involving activities or devices that require IRB review under OHRP or FDA regulations. If you do not know whether your project requires IRB review under OHRP or FDA regulations please contact the Office of Research Compliance at (414) 288-7570 or orc@marquette.edu prior to submitting this form.

**DIRECTIONS:**

1. Approval **and** inspection is required before the transfer may occur. Allow 3-5 days after submission for contact from ORC regarding questions and scheduling of the inspection.
2. The faculty advisor **must** submit this completed Device Safety Advisory Board Review Form along with any additional supporting materials to benjamin.kennedy@mu.edu;
3. The “Submitter” should be cc’d in that email;
4. If available/applicable, attach the following:
	1. Project Definition Document (for Senior Design students)
	2. Detailed device information including photographs or drawings
	3. Manufacturer’s device electrical/mechanical safety documentation (for devices being modified)
	4. Electrical Safety Testing documentation
	5. Any other documentation that would assist the Device Safety Advisory Board to determine the level of risk posed by the device
5. Subject line **must** read “DSAB for [submitter’s name]”.

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| **I. GENERAL INFORMATION** |
| **Project Title:** | ***For Office Only*****MU DSAB#: DV** **-** |
| **Submitter/ Lead Contact:** | **Submitter Phone:** |
| **Submitter E-mail:** | **Faculty Advisor:** |
| **Students involved with project:** |
| **II. DESCRIPTION** |
| A. | This project is:[ ]  Student thesis/dissertation[ ]  Student class project[ ]  Non-student research proposal[ ]  Private consulting activity[ ]  OTHER (specify): |
| B. | This project is:[ ]  Not funded or self-funded[ ]  Federally funded[ ]  Non-federally funded[ ]  OTHER (specify): |
| C. | Check all that apply:[ ]  Faculty advisor is recommending review because testing on MU students or employees will occur with:a) a new device that was manufactured by MU; orb) a commercially bought device that was modified in some way.[ ]  A new device that was manufactured by MU or a commercially bought device that was modified in some way will be **transferred** to **someone** or **group external** to Marquette University, **Excludes** sponsoring companies like GE Healthcare, Medtronic USA Inc., Abbott Laboratories, DePuy Orthopedics, Inc., 3M, etc. **Includes** organizations for groups who will use the device directly on people like the Milwaukee Center for Independence, community centers and group homes.[ ]  Commercially market the device[ ]  NONE OF THE ABOVE |
| D. | Date you plan to transfer the device to non-Marquette personnel: |
| E. | Date and location of where the device will be available for inspection. DSAB approval/inspection must occur prior to any testing or transferring to non-Marquette personnel: |
| F. | Provide a brief description of **(a) the device**, **(b) its intended purpose**, and **(c) why it is needed**: |
| G. | Provide a description of the demographics of who the device is being transferred to. Include information such as age, mental or physical status, and any other relevant social factors (e.g., prisoners, pregnant women, homeless, family or other support mechanisms). |
| H. | Describe the setting in which the device will be used. For instance, possible locations, and any special considerations related to the environmental setting (flat surface, large room, another person to assist, quiet area, etc.): |
| I. | Describe any **(a) mechanical safety**, **(b) electric safety**, and **(c) other risks** associated with the device. Include how these **risks will be minimized**. |
| **II. DETERMINATION *(For office use only)*** |
| **A.** | **Inspected by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **B.** | **[ ]** Device is approved for testing or transferring**[ ]** Device is approved for testing or transferring with recommendations below**[ ]** Device is **NOT** approved for testing or transferring |
| **C.** | **Comments/Recommendations:** |