DESCISION TREE FOR MANUFACTURED & FABRICATED DEVICE PROJECTS

IRB REVIEW

1 Does your project involve "human subjects"?

YES ↓ NO (stop)

2 Is it "research"?

YES ↓ NO (stop)

3 IRB submission may be required. Contact the IRB office for consultation.

If IRB submission is needed, allow for approximately 4 weeks for review.

DEVICE SAFETY REVIEW

1 Are you manufacturing or fabricating a new device?

OR

Are you modifying a commercially available device?

YES ↓ NO (stop)

2 Will the device be **transferred** to non-Marquette individual (i.e., non-faculty, staff, student?

YES ↓ NO (stop)

3 Will the device be used for medical treatment under the supervision of a health care professional?

NO ↓ YES (stop)

4 Device Safety Review submission is required. Allow for 2 weeks for review/inspection.