



1. In order to determine that a project could reasonably be viewed as QA/QI and not human subjects research, the answer to all of the following questions should be "Yes":

- a) The activity is undertaken by or for JHM (to be conducted at JHH, and/or JHBMC, and/or HCGH), and
- b) The goal of the activity is immediate improvement in JHM patient safety or care, and
- c) The safety intervention to be adopted as a JHM system clinical protocol has been established in other settings, and
- d) The QA/QI clinical protocol will be adapted over time to accommodate JHM initiatives.

If the answer to one or more of these questions is "No", submit a "Research Determination Worksheet" to OHSR (<http://irb.jhmi.edu>) to obtain an opinion on a case-by-case basis.

2. For a project that is to be funded through a federal grant, or a commercial contract, and there is an identified Principal Investigator, the answer "yes" to any of the following questions will classify the activity as human subjects research and not a QA/QI activity:

- a) The activity is not intended to produce an immediate improvement in safety/care at JHM that will be sustained over time;
- b) The activity will use a fixed clinical protocol that may not be altered by staff, and
- c) The activity involves non-JHM sites;
- d) The activity involves an intervention and either (i) randomization or (ii) poses risks greater than those presented by routine clinical care.