## ARROWHEAD REGIONAL MEDICAL CENTER INSTITUTIONAL REVIEW BOARD FULL BOARD REVIEW CATEGORIES

The Chair or designee is responsible for final determination of type of review. The IRB retains the right to require full board review when warranted by the nature of the research and/or inclusion of vulnerable subject populations. IRB duties are described in the Federal Regulation for Protection of Human Subjects 45 CFR 46.

## **Criteria for Full Board Review**

Research activities that involve more than minimal risk to human subjects require review at a full board IRB meeting. The research requires approval from a majority of those members. *If you believe your project meets criteria for the full board review, please check all categories below that apply.* 

Research involving greater than minimal risk procedures and:

- Clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgical procedures
- Taking place internationally where subjects may be at physical, psychological, or legal risk.
- Disclosure of information that could require mandatory legal reporting (child/elder abuse, etc.)
- Deception
- Includes vulnerable populations (children, prisoner, pregnant women and neonates, per federal regulation)
- Any other research which the IRB chair or designee determines the risks are greater than minimal.