



### **Guideline on Residents, Interns, ACGME-Approved Fellowships as Study Coordinator**

Given the extremely demanding schedule associated with the education and training of a resident or intern and the extensive responsibilities associated with the role of a study coordinator, the RSRB has implemented restrictions on when a resident or intern can take on the role of Study Coordinator. In general, the Study Coordinator is responsible for the day-to-day management and oversight of the study and acts as the primary administrative point of contact for internal and external research staff and internal and external regulatory departments. At a minimum this includes managing:

- the enrollment and follow up of subjects
- the collection and analysis of research data
- regulatory documentation (RSRB, ORPA, ORACS, etc.)
- study documentation (informed consents, research charts, etc.)

A resident or intern **cannot be** the Study Coordinator in the following types of studies:

- Greater than minimal risk
- Minimal risk study with regular study visits or repeated follow up

There may be some minimal risk studies where a resident or intern can appropriately take on the role of Study Coordinator. A resident or intern **can be** the Study Coordinator in the following types of studies:

- Chart Review only
- Survey/Interview/Focus Group with no follow-up
- Telephone follow up
- Those that qualify for exemption
  - Please note that residents and interns can be the Principal Investigator on studies that qualify for exemption.

There may be times during training when a resident or intern is in a “research year”. Additional consideration may be given for a resident or intern to take on the role of Study Coordinator during this period.

If a Principal Investigator would like to propose that a resident or intern take on the role of Study Coordinator in any study, the protocol must provide written justification for why this individual should take on this role. In addition, the RSRB submission should include a letter of approval from the Residency Program Director or Fellowship Director, acknowledging the role the individual will have on the study and the time commitments involved.