**GUIDANCE FOR NEW MODIFICATION REQUEST FORM**

**All study changes will now fall under the term “Protocol Modification”, with the distinction being made between MAJOR and MINOR.**

**Breakdown and Examples for the guidance on top of page 2 of the Modification Request form**

**MAJOR MODIFICATION Examples:**

* **Change of Risk to subjects (increase or decrease to minimal)**
* **Addition of procedure that is independently greater than minimal risk**
* **Change to Inclusion/Exclusion criteria**
* **Change in research design (change in science that may affect participant/procedures)**
* **Increase to number of subjects enrolled greater than 10%**
* **Change of PI**
* **DSMB report with safety/risk findings**

**MINOR MODIFICATION Examples:**

* **Revisions to protocol that do not change risk level (addition of minimal risk procedure such as blood draws, questionnaires, letters/clarification of protocol)**
* **Minor wording changes for ICF (clarifications/changes to timeframes/slight changes in subject comp)**
* **Change of personnel (remember NJH COI form for new additions)**
* **Recruitment/Advertising material (submission for NJH website)**

**\*TIPS\***

**For submission that have both Major and Minor changes, please break up into 2 forms separate submission forms. For change of personnel, to aid in prompt processing, always use a separate form (don’t combine with other minor revisions such as advertisement)**

**When in doubt, call HRPP for advice, or select Major (and be pleasantly surprised if it ends up being Minor)**