**APPROVE CONTINGENT VS DEFERRAL OF APPROVAL**

When reviewing a study the IRB may opt to approve it contingent upon minor modifications or defer approval. A contingent approval means that only one member of the panel has to review the responses and can grant the final approval. A deferral of approval means that the changes required to secure final approval are substantive and the study must be brought back to the convened board for review. These categories of approval apply to initial review, continuing review and review of modifications.

**When do you grant a contingent approval?** When you can provide a clear directive to the Principal Investigator, or only need confirmation from the investigator, such that you can determine that the relevant regulatory criteria for approval can be satisfied you can grant a contingent approval. The IRB should provide the reason for each change that is required. For example:

* To ensure risks to subject are minimized, confirm that only women who have a confirmed negative pregnancy result will receive the investigational drug.
* To ensure risks are reasonable in relation to anticipated benefits, a contract must be fully executed and the provisions for subject injury in the contract must be consistent with the consent.
* To ensure subject selection is equitable, include both men and women as subjects since the disease is prevalent in both genders.
* To ensure consent will be appropriately obtained, confirm that the prospective subjects will be allowed to discuss the option of participation with their primary care physician should they wish to do so.
* To ensure the consent document contains all required elements, identify procedure X as an experimental procedure.
* To ensure that data monitoring is adequate to ensure subject safety, confirm that the data monitoring board is meeting at least annually and that a qualified statistician is a member of the board.
* To ensure privacy is adequately addressed, confirm that the consent process will be conducted in a private room.
* To ensure that confidentiality is protected, confirm that all research records are kept in a locked location accessible only to the research team.

**When do you defer approval?** When you are asking for clarification, requiring additional information or requiring substantive change to the research (i.e. you are unable to determine that one or more of the regulatory criteria for approval can be met) you must defer approval. For example:

* Clarify why you are using procedure A instead of procedure B to obtain your samples when procedure A is known to have a higher risk of…………
* Clarify why men are excluded from participation in this study; the condition under study is also prevalent in men.
* The consent must be re-written in lay language using an 8th grade reading level as a benchmark
* Clarify what information is to be reviewed by the data monitoring committee and how often they intend to meet.
* Provide the measure you will take to ensure confidentiality of the data.