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Update from the IRB: "Approved with Conditions" Determination Returns

The IRB has reinstated the use of the **Approved with Conditions** determination. This is distinct from the more familiar **Modifications Required** determination.

What's the difference?

- **Modifications Required**: The study **cannot proceed** until the requested changes have been submitted to the IRB and formally approved.
- **Approved with Conditions**: The study is **allowed to proceed**, but **specific conditions must be met** after approval has been granted.

What does this mean for your study team?

If your study is **Approved with Conditions**:

- Review the listed condition(s) carefully.
- Address all conditions before your next continuing review.
  Please note that some of the conditions may need to be resolved before the next continuing review.
- If a condition isn't met, include a clear explanation in your continuing review submission.
- Note: a study may not be eligible for continuing review approval if the conditions have not been met prior to submitting for continuing review.

Examples of possible conditions:

- A new study with an unaffiliated investigator may be approved on the condition that the Unaffiliated Investigator Agreement (UIA) is completed after approval.
- A continuing review may be approved on the condition that it returns to the IRB in six months instead of the standard twelve.

Where to find the details:

- All conditions will be outlined in your **IRB Approval Letter**.
- Administrative follow-ups (e.g., submitting a completed UIA) can be sent to the IRB as an **Administrative Report**.