



HUMAN RESEARCH PROTECTIONS PROGRAM (HRPP) TIP OF THE MONTH

Tips for IRB Protocol Modifications

**Please explain the specific changes
& have a clear rationale for the
change**



- A clear explanation of why the change is necessary
- The context that helps us understand what prompted the decision
- Is the rationale specific and tied to a triggering event or justification?
- It goes beyond stating what the change will support

● **Examples of Complete Rationale**

- “We are increasing the accrual goal because recruitment has exceeded expectations and we want to capture additional data.”
- “We have received new/additional funding that allows us to expand recruitment to additional sites, requiring a higher enrollment target.”
- “The protocol was amended to add a new study arm due to [reason]. This requires more subjects to maintain statistical power.”

● **Examples of Incomplete Rationale**

These statements describe what the change supports, but not why it was needed:

- “This change is being made to account for future screening and enrollment.”
- “We received additional funding.”
- “The protocol was amended.”



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