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How Can IRBs Help Investigators with their Applications?

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After an institutional review board (IRB) reviews a clinical study application, it can accept the application, accept the application with conditions, or reject the application. If it accepts the application with conditions, how much assistance should it give the investigator in preparing a resubmission?

There are three main issues:

- **Will the assistance enable the investigator to address the issues?** For example, saying "the eligibility criteria do not meet community standards" does not guide the investigator to a specific remedy.
- **Is the IRB qualified to provide the assistance?** For example, the IRB might know that the risk section of the consent form is hard to understand, but it might not have the necessary expertise in the therapeutic area to propose clarifications.
- **Does the assistance compromise the IRB's objectivity?** For example, if the IRB advises the investigator to obtain assistance from a respected member of the IRB, how will the interpersonal dynamics of the IRB be affected?

Continuum of Assistance

The IRB can assist the investigator in the following ways:

- Fix any problems, e.g., by rewriting the consent form or requiring a change to the eligibility criteria.
- Identify specific issues with the application.
- Identify areas of the application that need improvement.
- Develop guidance documents, e.g., examples of acceptable and unacceptable consent form language.
- Offer or recommend training that is relevant to the application but not specific to it.

The IRB can recommend that the investigator obtain assistance in revising the application from the following people:

- A specific member of the IRB.
- A specific person in the human subjects protection office.
- A specific third-party independent of the IRB, such as an experienced investigator or consultant.
- Someone on a list of recommended independent third-parties.
- Someone the investigator independently identifies.

Considerations

The following is a more complete list of issues the IRB should consider when developing its policies and procedures for offering assistance to investigators:

- What resources ("pockets of expertise") are available to investigators preparing study applications?
- When will the assistance be offered — before or after IRB review?

- Will the assistance enable the investigator to address the issues?
- Does the IRB have the necessary time and resources to lend assistance?
- Will the assistance be offered formally (in writing) or informally (verbally)?
- Is the person lending assistance qualified and available to provide the assistance, respected by the investigator, and in agreement with the IRB on the issues to be addressed?
- Will the person lending assistance provide insights in the proclivities of the IRB, e.g., say "this IRB won't accept that wording"?
- Will the IRB give the resubmission its standard rigorous review?
- Should the IRB be concerned that the investigator will not respond well if, after accepting the assistance, the study application is still unacceptable?
- If the IRB chairperson or other member would be the person lending assistance:
    - Do the other members ordinarily defer to that member?
    - Is the member open to criticism?
    - Would the member be able to attend and participate in the review discussion, rights not afforded to investigators?
    - Would the member abstain from voting on the application?
    - Does the work involved create a burden on the member beyond what he or she "signed up for"?
    - Would the member be able to participate in the review discussion, a right not afforded to investigators?
    - If the IRB still finds a problem, would it feel comfortable questioning the work of the member?
- If someone from the human subjects protection office lends assistance, do any of the above issues apply?

Conclusion

An IRB can view its role as preventing research that does not protect human safety and welfare, or it can view its role as helping investigators ensure that human safety and welfare are protected. While the former role is adversarial, the latter is more collaborative. A collaborative relationship seems preferable but requires IRBs to develop effective policies and procedures that do not compromise the IRB's responsibilities.

Authors

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