IRB Reviewer Worksheet for Reviews

This reviewer worksheet is copied with modifications from Khan and Kornetsky's "Overview of Initial Protocol Review" printed in IRB Management and Function (2006). The reviewer worksheet serves the purpose of a reminder checklist of the mandated criteria IRB members must consider before approving a protocol. It is also a convenient and organized way to assist reviewers in discussing their critique of the protocol during a meeting. The worksheet is also the basis for further discussion and dialogue between the IRB and investigators.

Introduction U ^ ‰] .] u • U l P^ŒP}µ]v. Unce v

Review of any research protocol must begin with the IRB member asking and answering these questions: "Why is this research important to conduct?" and "What will be learned from the proposed study?" IRB members should be provided with adequate data regarding earlier related studies and associated references. Applications must include a clear description of the objectives of the research, a statement of the study hypothesis (if any), and should adequately address how data will be obtained.

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Appropriate inclusion and exclusion criteria for research participants are essential in order to justify human subjects research ethically. The selection of subjects must be equitable. Criteria

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economically/educationally disadvantaged, employees)?

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IRB members must consider how, when, and by whom participants will] v š] . v approached for recruitment. Reviewers must consider methods for recruiting subjects (traditional paper or internet advertisements, databases, newsletters, recruitment by sending letters, physician referrals, medical record reviews, etc.). It is important to consider what study staff member is best suited to approach potential research subjects, when and where subjects should be contacted, and the amount of time provided for potential subjects to consider participation. All recruitment materials and practices must be reviewed and approved by the IRB. The IRB must be assured that the recruitment process promotes voluntary participation and is not coercive in any way.

Worksheet Questions

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2. Are the location and timing of the recruitment process acceptable?

subject during the research must also be evaluated. When questionnaires and behavioral or

10. Additional elements such as alternative procedures, when applicable, as outlined under 45 CFR 46.116(c)

2) • • v Š X Like the consent document, no federal regulations exist for assent documents. However, many institutions still require separate assent documentation. For protocols that involve children, each IRB must determine whether the obtainment of assent is required and, if so, an appropriate mechanism for obtaining and documenting assent. The IRB must also determine whether the permission of one or both parents should be obtained. Assent obtainment and documentation requirements need to be considered on a protocol basis. The following questions prompt the IRB members to make this special determination when required.

Worksheet Questions

1. Is assent required?
2. If yes, is a separate assent form required? Is a witness signature or an attestation to the assent required?
3. For parental consent, if the subject is unable to consent, is the signature of one or both parents/guardians required?

3) W Œ } • } • š } ( ] v] v P] v (} Œ u sse } t v X Although the regulations require the inclusion of certain elements in the informed consent document, they do not provide rules or requirements for the process of obtaining informed consent. Investigators and reviewers are urged to consider the following general recommendations and suggestions when proposing or reviewing a method of obtaining consent.

- Who?
  It is important to consider what type of relationship exists between the subject and the

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3. Does the consent process minimize the possibility of coercion or undue
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4. Is t