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Forecasting Regulatory Requirements: Case Study Worksheet

This worksheet for in-person case studies includes paired down questions from the online tool for Identifying Regulations in Investigator-Initiated Research. If you are off-site you may want to use the online tool that includes links to guidance and built-in advice. For these case study discussions, assume the study is non-exempt human subjects research where the institution is engaged in the research activity.

OHRP Regulations at 45 CFR 46

1. What level of IRB approval is needed for the study? Review expedited categories and minimal risk definition
    a. Expedited All procedures must meet OHRP expedited review categories & be no greater than minimal risk to qualify
    b. Full IRB review

2. Are there protected populations in this study?
    a. No
    b. Yes If yes, what might be issues t think about r requirements for a study involving a protected population?
        i. Pregnant women
        ii. Prisoners
        iii. Children

3. How will you document informed consent?
    a. Waiver of consent Review waiver of consent criteria
    b. Waiver of written documentation of consent Review waiver of written documentation of consent criteria
    c. Written consent

4. Are there any special consent considerations for the study? (children, legal guardian consent, non-English speakers)

FDA Regulations at 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812

1. Is this study a clinical investigation as defined by the FDA? Review definition
    a. No Study is not subject to the FDA regulations
    b. Yes Study is subject to the FDA regulations

If YES,

2. Does the study involve a drug?
    a. No
    b. Yes
        i. Does the study need an IND? Review IND flowchart and IND exempt criteria
            1. No
            2. Yes

3. Does the study involve a device? Review FDA device definition
    a. No
    b. Yes
        i. Is it an investigational device subject to the IDE regulations? Review IDE decisions
            1. Non-significant risk device; abbreviated IDE. IRB approval only
            2. Significant risk device; submit IDE to the FDA
            3. Exempt; not subject to IDE regulations

The HIPAA Privacy Rule at 45 CFR 164

1. Does the study involve the collection or use of PHI? Review HIPAA guidance
    a. No Study is not subject to the HIPAA Privacy Rule
    b. Yes

If YES,

2. How will you document permission for the use of PHI? Review HIPAA guidance
    a. Waiver of HIPAA Authorization
    b. Individual Authorization from participants