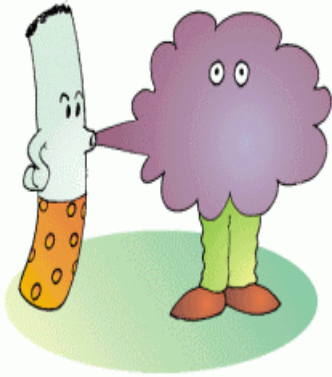


Conundrums of Adolescent Research and Treatment

Problem: Substance abuse and mental health interventions with adolescents raise regulatory barriers to conducting valid experimental research.

- **Parental permission** and **mandatory reporting** requirements compromise confidentiality.
- **Differing state laws** defining *minor* and *emancipated minor* complicate national sampling.
- IRB's interpretations of **risk** and **consent** requirements may differ from the investigator's.



These problems were studied in the context of smoking cessation research. Typical situation: Students caught smoking in school were given the option of participating in smoking cessation research program. Most were interested in participating. However, most are minors whose parents do not know they smoke, and would not participate if parental permission were required. The counseling involved in the treatment program might reveal child abuse and trigger mandated reporting requirements. Identified subjects might be subpoenaed in an effort to identify merchants who sell cigarettes to minors. Any compromises of confidentiality with adolescents destroy cooperation with the intervention program. Researchers who found solutions to such obstacles often found that their IRB would not accept those solutions.

Hypotheses or Expectations

- Some erroneous solutions are employed by IRBs and researchers.
- Experts in sensitive adolescent research and regulations could reach consensus on protocols for sensitive adolescent research and treatment.

Method: Surveys of IRBs and researchers asked about how they handle smoking cessation research with adolescents. A workshop of experts then responded to the survey findings with recommendations.

Results of IRB survey:

- 57% waive parental permission **ONLY** for older children, normal educational activities & non-sensitive research.
- 13% **NEVER** grant waivers.
- 42% allow **PASSIVE CONSENT** (which the Common Rule does not recognize!)

Results of researcher survey:

- ✓ Researchers considered parental permission the most serious obstacle for conducting important studies of high risk behaviors and treatment among youth.
- ✓ 47% sought a waiver of parental consent, as permitted by the Common Rule:
- ✓ Teen participation *per se* involves minimal risk and significant benefit.
- ✓ Recruitment of most teens would be impossible if parental permission were required.
- ✓ The only significant risk of participation would be breach of confidentiality.
- Researchers reported **IRB objections to waiver:**
 - ✓ **Teens are vulnerable**; just participating in a survey and treatment program could affect some individuals adversely.
 - ✓ **A parent might complain** that their child participated in research without their knowledge.

Researcher solutions: Avoid seeking parental permission for their smoking teen.

- Create a "tobacco prevention and cessation" program with intervention targeting non-smokers as well.
- Obtain parental permission for whole school to participate in smoking cessation for those teens later found smoking.
- Seek IRB approval only for program evaluation; treat smoking cessation intervention as normal school program.
- Collect anonymous data only, permitting immediate follow-up, but preventing study of relapse behavior.

Expert Solutions: Experts endorsed the above researcher solutions, and added...

- Obtain a **waiver of parental permission**.
- Obtain a **certificate of confidentiality** in states where selling cigarettes to minors is illegal.
- **Avoid intense counseling** that could evoke information about child abuse.
- **Obtain no signed assent forms** or other written record of participation.
- Consult with the IRB early in the process of research planning.

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