Ethics

Lecture 10 – Part II

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EPS Lectures

Expected Benefits and Costs in Experiments

Expected Benefis from Experimental Research

- Types of Expected benefits:

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- Types of Expected benefits:
  1. Societal Benefits

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  2. Therapeutic Benefits (to Subjects)

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  3. Collateral Benefits (to Subjects)

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- We may not learn anything – our research may end up being impossible to interpret.
- We may learn only confirmation of facts we already know.
- Or we may actually make our knowledge more confused by learning something that does not make sense given facts we already know.

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- Of course, it is not always true that biomedical or psychological experiments involve therapeutic benefits.
- Sometimes these experiments use normal, healthy individuals who will not necessarily benefit directly from the treatment investigated.
- Or in some cases the subject pool may include patients who are terminally ill and there is none to little possibility that the therapeutic benefit would matter in their lives.

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- Consider Oken's field experiment conducted in Indonesia on direct democracy.

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  3. educational benefits.

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- In some sense there is a logical difficulty in saying that someone receives a private benefit from altruism since by definition altruism refers to actions that solely help others, yet it is normal in social science circles to think of altruism as providing individuals with some intrinsic benefit in terms of feelings or warm glow effects.

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- Subjects may also simply find participating in some experiments fun in the case of some of the computer interactive games (although many of course find them boring).

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- Furthermore, knowledge provided to subjects through debriefing can also cause harm to subjects.
- As the IRB guidebook points out: "Some subjects may not benefit from being told that the research found them to be willing to inflict serious harm to others, have homosexual tendencies, or possess a borderline personality."

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- As political scientists increase their interest in the relationship between political behavior and biology as some advocate (see Hibbing and Smith (2007)), the potential for physical harm in political science experiments can increase.
- Nevertheless, even with such an expansion, the possible physical harms from social science experiments are significantly less than those that can occur in biomedical experiments which might involve invasive medical procedures and drugs with unknown side-effects.

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Psychological Harms

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- Many risks in political science experiments are psychological – a subject may experience regret or loss or embarrassment because of the choices he or she makes in the experiment.

Expected Costs to Human Subjects

Psychological Harms

- Invasions of privacy & violations of confidentiality can cause psychological harms.

Definition (Invasion of Privacy)

When an experimenter learns private information about a subject without the subject's permission.

Definition (Violation of Confidentiality)

When an experimenter reveals private information freely given to him or her by a subject without the subject's permission.

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- Some field experiments may result in subjects committing illegal acts (bribery field experiment).
- Opportunity costs of participating in experiment.

Expected Costs to Human Subjects

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- Subjects might go into a spending frenzy and make unwise choices if they are unused to having large sums of money or if they missed out on the "jackpot" they might experience some type of depression.

Expected Costs to Non-Subjects

Two types of Risks to Non-Subjects

1. Harms to Confederates and Researchers

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2. Harms to Third Parties or Societal Risks

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Harms to Confederates

Definition (Confederates)

Individuals who participate in an experiment not as subjects but as part of the experimental treatment administered to subjects. Confederates generally have no choices to make in the experiment, but behave according to a script provided to them by the researcher.

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- In bribery experiment, confederates faced the potential of physical harm since they were asked to commit traffic violations (illegal left turns) that presumably were illegal because they might cause an accident.
- Researchers have an ethical responsibility to all humans who participated in the research and the risks to confederates should also be considered.

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Harms to Third Parties

Definition (Third Parties)

Individuals who are affected by an experiment but are not subjects, researchers, or confederates of researchers.

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- For example, a laboratory experiment that negatively affects a subject's health or pyschological well being also affects his or her family and colleagues.
- Bribery experiment caused risks for third parties as well in that the families of the police officers would have suffered if the officers who were bribed had been caught and the traffic offenses committed by the confederates could have potentially led to accidents, injuring

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- For example, researchers who conduct field experiments that study voter turnout in elections often vary turnout mechanisms, such as giving to some voters more information than others are provided or calling one group of voters to remind them to vote and not another group of voters.

IRB Assessment of Benefits and Risks

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- If the expected benefits outweighed the expected harms, then according to this approach, the research is ethical.
- Essentially this evaluation is what IRBs are supposed to do. According to the IRB Guidebook, "Evaluation of the risk/benefit ratio is the major ethical judgment that IRBs must make in reviewing research proposals."

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- Although surveys certainly have the potential to cause psychological harms, in general these risks are not significant enough to outweigh the benefits that can be gained from the research.

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- Specifically, IRBs are told not to consider collateral benefits or long-term societal risks.

Rules that Exclude Benefits or Risks

Long-term Societal Risks

- The Common Rule in 45CFR 46.111 states that IRBs "should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility."

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- I agree – ultimately greater knowledge is our goal & although it is possible that this greater knowledge may make society worse off in some cases or instances, the maintained belief is that the ultimate good of greater knowledge outweighs these negative possibilities (otherwise, why be a social scientist?).

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- An intervention of a random controlled experiment that biases an election qualifies as denying a benefit to a political candidate who would have won the election if it had not been for the intervention & a significant harm to a third party.

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- Example if a laboratory experiment has a small risk of affecting a subject's health, then it also has a minimal risk of affecting that subject's family and colleagues as a consequence.

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- However, as field experiments increase in social science we expect that more and more researchers will use confederates & the potential harms they are confronted with will increase.

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- However, as field experiments increase in social science we expect that more and more researchers will use confederates & the potential harms they are confronted with will increase.
- When confederates are recruited specifically to participate in an experiment, even though they are not the subjects of the experiment, the possible harms that may be inflicted on them as a consequence of their participation should be considered in the risk assessment of the research.

Rules that Exclude Benefits or Risks

On Collateral Benefits

- According to the Common Rule, collateral benefits, in contrast to therapeutic benefits, do not count toward the benefit-cost analysis of the research, and societal risks. The IRB Guidebook states:

Direct payments or other forms of remuneration offered to potential subjects as an incentive or reward for participation should not be considered a "benefit" to be gained from research. ... Although participation in research may be a personally rewarding activity or a humanitarian contribution, these subjective benefits should not enter into the IRB's analysis of benefits and risks.

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- Suppose that compensation is sizeable & expected costs are sizeable as well.
- If compensation is used in benefit-cost comparisons, then the research might be undertaken even when the other expected benefits (therapeutic and societal) are much smaller than the expected costs to the subjects.
- Such research, which does not provide enough expected therapeutic or societal benefit to offset the expected costs to the subjects should not be undertaken, even if subjects are compensated sufficiently to offset these expected costs.

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- If we think of participation as purely voluntarily, then if subjects are willing to accept payments to participate or altruistically desire to participate, and these payments or altruistic feelings are sufficient to offset the difference between the expected costs to the subjects & the therapeutic and societal benefits, why should that experiment be unethical?

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- If we think of participation as purely voluntarily, then if subjects are willing to accept payments to participate or altruistically desire to participate, and these payments or altruistic feelings are sufficient to offset the difference between the expected costs to the subjects & the therapeutic and societal benefits, why should that experiment be unethical?
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- This is an issue that has been oft debated in the ethics of biomedical research, particularly research with terminally ill patients.
- In the case where the experiment has no expected social value or benefit, it seems fairly simple that conducting the research is not ethical since the researcher is basically paying subjects to participate in a costly activity without any demonstrable social value.

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- But what about experiments that do have some social value albeit not sufficient to offset the expected costs to subjects of the research?

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- But what about experiments that do have some social value albeit not sufficient to offset the expected costs to subjects of the research?
- Given the inherent difficulty in measuring societal benefits, it might be the case that the estimated social value is insufficient for justifying the research for experiments in which the costs are greater than minimal. In this case, what is the problem with counting the compensation to subjects as a benefit given that in biomedical experiments therapeutic benefits to subjects are counted?

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- In contrast, it is possible for the compensation of subjects to be larger than the expected social benefits of the research making compensatory benefits distinctive.

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- Such a statement suggests that IRBs should not allow any sizeable compensation for subjects to participate in research.
- IRBs may also worry about the harms of wealth effects.

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- IRB Guidebook recommends that decisions on whether compensations provided to subjects either monetary or nonmonetary are problematic is left to individual IRBs to decide on a case-by-case basis.
- Two positions on how to view compensation to subjects are inconsistent.
- If deciding on the size of compensation should be done on a case-by-case basis, then deciding on how to evaluate compensation to subjects as expected benefits should also be decided on a case-by-case basis as well.

Rules on Assessing Benefits & Risks that Count

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- Making sure that these knowledge benefits are clear involves evaluating the research design and the expected validity of the research.

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- Nevertheless, the regulations do require that IRBs determine whether '[r]isks to subjects are reasonable in relation to ... the importance of the knowledge that may reasonably be expected to result.' "

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- The Guidebook states that most IRBs use the following strategy:
- If the research is funded by an agency that engages in peer review, then the IRB assumes that the agency has undertaken a rigorous review of the science and that the science does have the societal benefits claimed by the researcher.

- However, if the proposed human subjects research has not undergone such an external peer review, the IRB itself reviews "the research design with much more care, perhaps with the assistance of consultants, if the IRB itself does not possess sufficient expertise to perform such a review."

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- We only have anecdotal evidence on how IRBs review societal benefits from research as no comprehensive study of the substantive nature of IRB decision making has been conducted to our knowledge.

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- The fact that IRBs see it as their responsibility to evaluate research design and the societal benefits of research in a number of cases has led to some of the criticisms of IRBs by humanities and social science scholars.

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- There are many cases where social science experiments are distinctive from those typical in biomedical research.
- As a result social science experimentalists sometimes face difficulties in justifying their research designs with IRB boards dominated by biomedical researchers as well.
- Many of these hurdles result because the norms of informed consent, anonymity, and voluntaryism fit well within standard research designs for most biomedical experiments but in many cases do not fit well within the standard research designs for social science experiments.

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- One of the requirements for expedited review by IRBs is that only minimal risks exist in the research.
- The implication is that if risks can be shown to be minimal then the research has merit even if the benefits from the research are minimal as well.
- Given the fact that few social science experiments have therapeutic benefits and that there are difficulties in assessing societal benefits, assessing whether the risks of the experiments are minimal becomes more important for social scientists, probably more so than for biomedical experiments with possible therapeutic benefits.

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- Recall that "minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

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- (2) the standards for comparison.

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- An experiment may have an extremely low probability of harm but the magnitude of that harm could be sizeable or the experiment may have a high probability of harm but the possible magnitude is extremely low. (example the fMRI experiments) – Rare harmful events can certainly take place during any experiment.

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- Alternatively, in Clinton and Lapinski one of the potential harms is the opportunity cost to the subjects of spending the time watching the ads and responding to the questions. The probability of this harm is high, although it varies with subjects (some subjects may prefer to spend their time this way, but let's assume that most would rather do something else either on the internet or off), but the harm itself is likely small. Clearly, then all experiments have almost 100% probability of harm in terms of these opportunity costs.

Defining Minimal Risk

Standards for Comparison

- Given that expected risk is always positive, that there is always at least a small probability of a sizeable harm occurring to subjects during an experiment and a near 100% probability of minor harms to the subjects, what does it mean for risk to be minimized? How low is minimal? What matters then is the standard for comparison.

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- Using this standard, many laboratory experiments conducted by political scientists are designated by the OHRP as eligible for expedited review according to category 7

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- If we consult the list of types of research that the OHRP allows for expedited review, presented in Appendix C, such experiments are eligible under categories 1-4.

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- What is the appropriate standard for daily life in a field experiment?
- Is it whether an event occurs in daily life or whether it occurs frequently & under the same conditions as in the experiment?
- The second comparison leads to the conclusion of greater than minimal risks because if event occurred in daily life under the same conditions – then no point to experiment?

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- Sometimes, use an "uniform standard," that is, comparing the subjects to a population of 'normal' healthy individuals.
- Why is this important?
- It may be that the use of a relative standard takes unfair advantage of a population of subjects who are already vulnerable in some fashion.

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- Important that experimentalists consider explicitly these harms & how they might be minimized.

Other Criteria in the Common Rule

Subject Selection: Vulnerable Subjects & IRB Review

- The Common Rule states in 45CPR 46.111(b) that IRBs must ensure that "[w]hen some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects."

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- There are three primary implications ...

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- Research with more than minimal risks & no therapeutic benefit might be permitted, but only if of vital importance for understanding or eventually alleviating the subjects' disorder or condition.

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- Presumably, the restriction is for survey experiments where the focus is on pregnant women and only pregnant women are surveyed and since this does not apply to NSF funded grants, is not a large concern for many political scientists.

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- Although surveys are not exempt for these populations when subparts B, C, and D apply, if they have minimal risks, they are likely to be approved.

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- If the research involves more than minimal risks, then the Secretary of HHS (or his or her representative on these matters) must approve the research for it to receive federal funding.
- Of course, research that is not federally funded and involves more than minimal risk would not go to the Secretary presumably, but then whether local IRBs are willing to approve such research appears to depend on the institutions' rules.

Other Criteria in the Common Rule

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Subject Selection: More on Research with Prisoners

- Real problems with "freedom of choice" & incentives, experimental effects ...
- If political scientists wish to use prison populations for experiments in order to study these questions, in Subpart C the Common Rule requires that IRBs include at least one prisoner representative to evaluate the research proposal, that the incentives used in the research not be so sizeable as for subjects to ignore possible risks (which in a contained environment is likely to mean that even small incentives might be viewed as sizeable), & that the selection of who participates from the prison population is equitable.

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  - 2) children may feel that decisions on how the money is spent will be made by their parents or adult guardians and thus not care much about the size of their prizes.

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- Harbaugh and Krause (2000), who pioneered game theoretic and decision theoretic experiments with children, gave their child subjects tokens as rewards, which the children could redeem for toys & other prizes after the experiment.

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- As with prisoners, if an experimenter uses children in a school setting the experimenter should be careful that participation is open on an equitable basis to the children and that the children who participate are not unduly influenced by the incentives from participation.

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- Is it fair for children who participate in an experiment to be able to go to a special party with cake and ice cream during school time but the children who do not cannot enjoy the treats and must have a study hall instead?
- Believe experiments should take place outside of school hours & the incentives for participation to be child specific rather than social events during periods where nonparticipants would feel especially excluded.

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- A further challenge for experimenters using children is that state laws vary over the age of maturity.
- Moreover, identifying the legal guardians of children may not be as clear cut as it seems if a researcher is unaware of court rulings that affect the children studied.
- Finally, if the children are institutionalized, then it is important that the researcher is not simply using these children, who may be more vulnerable to coercion to participate because the sample is convenient, but because the subjects are particularly suited for the research question.

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- Ideally, a researcher should only use employees who work in departments or institutes that are outside of his or her own.
- Furthermore, as with students, in a university setting it may be more difficult for researchers to maintain data confidentiality and thus we recommend, when possible, that researchers use only experiment specific random identification numbers to store data as recommended with students above.

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- The requirement of informed consent leads to some of the most vigorous complaints from social scientists about the Common Rule and IRB research regulation. Why? ...

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- Second, qualitative researchers argue that informed consent is not possible in soak and poke activities since it is not possible to predict when the research will end or the extent of the involvement of possible subjects in advance.
- Third, providing full information to subjects in a social science experiment about the purpose of the research may invalidate the results in experiments.

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- The risks to subjects when they act in an experiment without informed consent should be included when evaluating the possible harms that can be a consequence of the research.

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- Certainly exempt research such as survey experiments do not require that researchers secure informed consent.
- For nonexempt research, the Common Rule allows for IRBs to waive informed consent under certain conditions.

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    - (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
  - (2) The research could not practicably be carried out without the waiver or alteration."

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  - (3) The research could not practicably be carried out without the waiver or alteration; and
  - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation."