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Section D

Application of Framework Part 2

Framework: Tension/Conflict

- Consider which, if any, of the ethical principles/requirements are in tension or in conflict with each other

Framework: Tension/Conflict

Beneficence vs. Beneficence	
Best interest of individual patient	Best interest of future patients
	Scientific validity
	Favorable risk benefit ratio

Respect for Autonomy vs. Beneficence	
Threats to voluntariness	Best interest of future patients

Framework: Key Facts

- What are the key facts relevant to the principles/requirements identified in the case?
 - Are there facts missing that would assist in the case analysis?
 - ▶ If yes, what assumptions will you make in order to proceed?
 - Are there contextual issues relevant to the case analysis?
 - ▶ If yes, are these contextual issues relevant to the ethical analysis of this case?

Framework: Key Facts

- For this exercise we are going to presume we have all the facts we need, but, for example, we may want to know exactly how much Dr. Patel will be reimbursed for participating in the trial to be assured that the amount is unlikely to have undue influence over her behavior

Framework: Options

- What options (or alternatives) are *possible* for how to proceed?

Framework: Options

- Which options are there? Which of these options are the most realistic in this context?

Threats to voluntariness	Conflicts of interest	Study design
Consent by third party	<ul style="list-style-type: none">▪ Disclosure▪ Consent by third party	Consider alternative designs

- What are the pros and cons of adopting each option?
- What concerns remain regarding the most realistic options?

Framework: Options

- Can any additional actions be taken to further minimize these concerns?
- How would each of the options address the moral concerns, tensions identified?

Threats to voluntariness	Conflicts of interest	Study design
Consent by third party	<ul style="list-style-type: none">▪ Disclosure▪ Consent by third party	Consider alternative designs

Framework: Recommend Option

- Which option would you *recommend* (or what is your assessment of what happened?)
 - Provide the ethical reasoning behind (or ethical justification for) your choice

Threats to voluntariness	Conflicts of interest	Study design
Consent by third party	<ul style="list-style-type: none">▪ Disclosure▪ Consent by third party	Consider alternative designs

Summary

- Take apart a case and put it back together