

A Case For Treating Clinical Trial Participation As Labour

Andrew D. Ross, Ph.D.

Jr. Clinical Ethicist, Central Zone

AHS Clinical Ethics Service

AndrewD.Ross@albertahealthservices.ca





Disclaimer

This presentation is based on a paper written prior to the author's employment with Alberta Health Services. The views expressed are entirely the author's and should not be taken to represent the views or policies of Alberta Health Services or the Clinical Ethics Service.





Session Objectives

- 1. Review the background to the problem of exploitation of participants in clinical drug trials.
- 2. Discuss a series of possible objections to treating clinical trial participation as a form of labour.
- Discuss a series of possible reasons to prohibit or minimize monetary offers as a means of compensating participants in clinical drug trials.





Outline

1. Background

- Situation of clinical trial participants in the current system
- Exploitation concerns

2. Participation as Labour

- Prima facie case
- Potential objections
- Implications

3. Competing Concerns

Reasons to prohibit, limit or minimize monetary compensation





1. Background





Clinical Trials





Dual Purpose of Clinical Trials

- Scientific: provide evidence of efficacy and safety of the investigational intervention
- 2. Pragmatic: satisfy prerequisite for regulatory approval to bring the new intervention to market





An Uncomfortable Situation

Participants in clinical trials are generally supposed to be acting altruistically...

...but this "altruism" feeds the extremely lucrative global pharmaceutical industry.





Exploitation Concerns







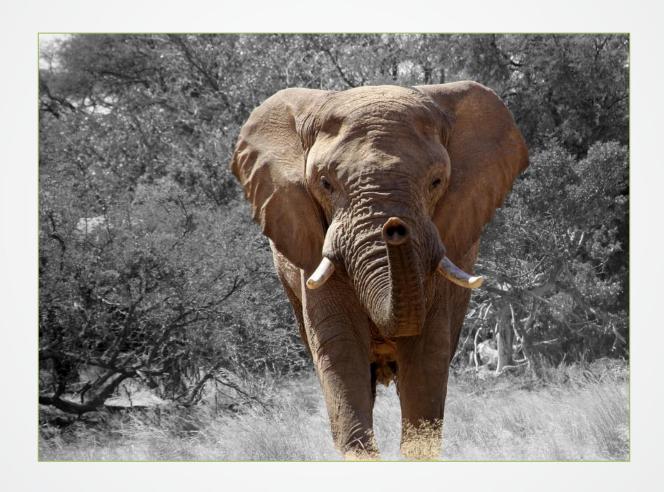
Exploitation - Definition

To exploit someone is to take unfair advantage of them. Exploitation can be consensual, and even a mutually-beneficial interaction can be exploitative.





How to Determine "Fairness"?







2. Participation as Labour





What is Labour?







What is Labour?

Labour is the use of human resources as a factor in the production (or attempted production) of something of value.





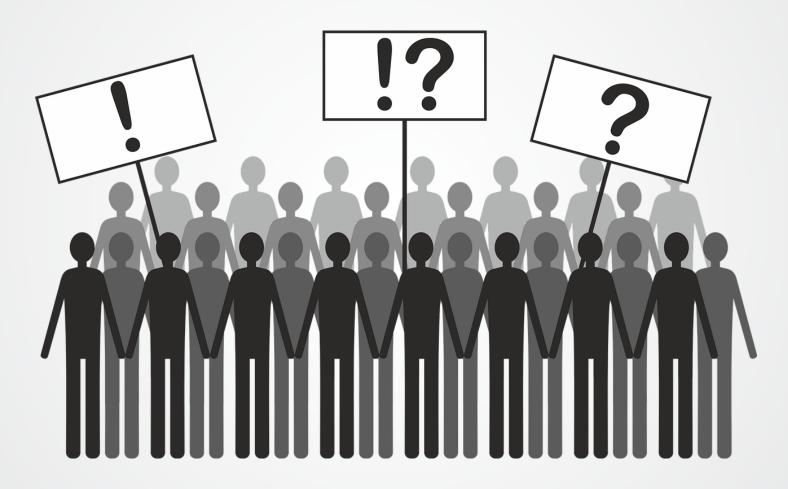
Prima Facie Case







Objections







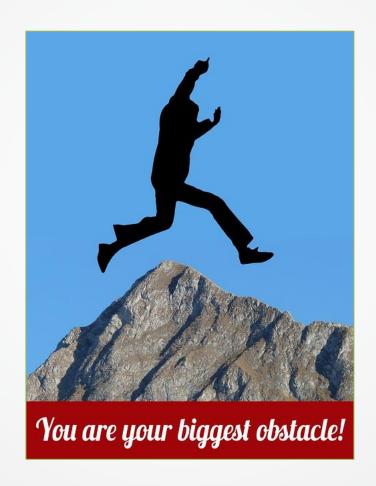
Objection: Direct Health Benefit







Objection: Motivation







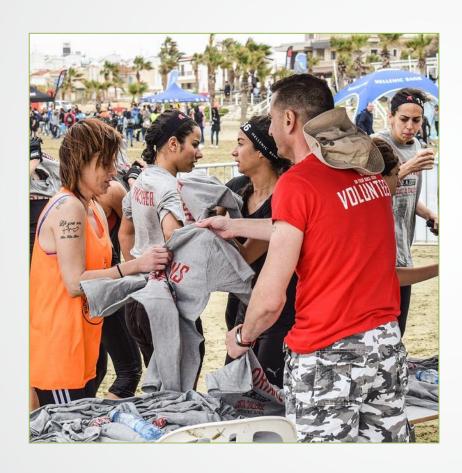
Objection: Passivity





Objection: No Free (Un-Coerced) Labour









Objection: Medical Research is Unique!







Implications

- It may be appropriate to use existing standards of fairness in labour exchange to judge the fairness of clinical trials towards participants
- It does not (yet) follow that clinical trial participants should be paid



An Important Distinction



Commercial

V.

Non-Commercial







Exploitation & Compensation

"Healthy Subjects" v. "Patient Subjects"



Commercial v. Non-Commercial Research





3. Competing Concerns





Exploitation & Compensation





Money, Labour and Exploitation

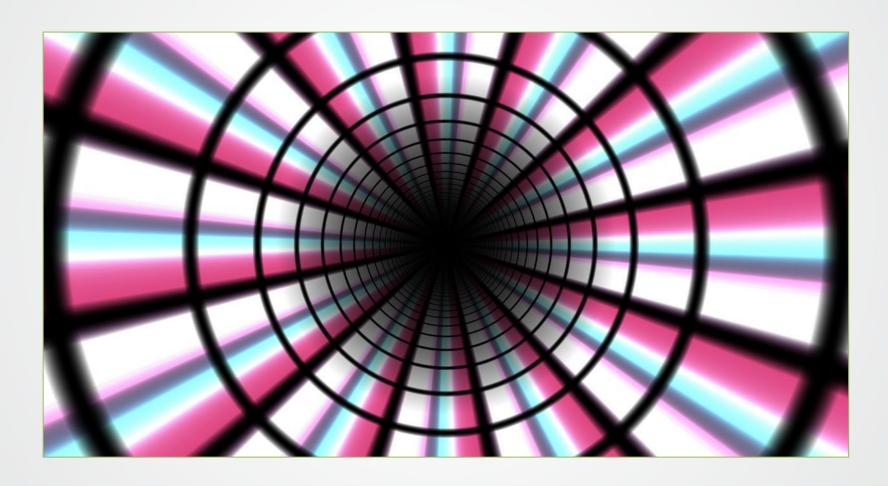








Undue Inducement







Undue Inducement (continued)







Bad Incentive







"Crowding Out"







Compensation Model Desiderata







Thank you for listening!

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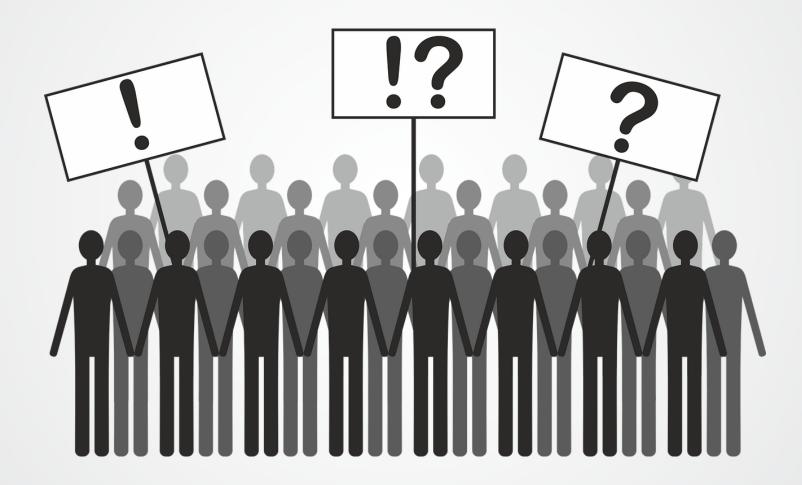
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AndrewD.Ross@albertahealthservices.ca





Questions?







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