

# Open versus restricted access to full academic trial protocols: advantages and disadvantages

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# Objective

- To examine the approaches to protection of intellectual property (IP) in two multi-centre trials currently being conducted in Canada.

# What is/is not an “academic trial”?

- **IS NOT:**
  - industry initiated
- **IS:**
  - initiated by the principal investigator
- **COULD BE:**
  - clinical
  - health technology assessment
  - compare treatments or treatment policies
- Funded or not
- Peer-reviewed or not

# What is IP?

- Legal rights that result from intellectual activity in the industrial, scientific, literary and artistic fields.
- Outcome of creative work
- Trade marks and patents
- What is the IP in academic trials?

# IP in academic trials

- Sample selection
- Recruitment/consent
- Baseline data
- Randomisation
- Intervention
- Outcome measurement
- Analysis
- Interpretation

The art of trial  
design

Standardised  
elements

IP associated with  
the package

# Two examples

- **CHIPS (Control of Hypertension in Pregnancy Study, ISRCTN71416914)**
  - women with hypertension - randomised to tight or less tight control of hypertension.
  - primary outcome: composite of pregnancy loss/neonatal intensive care.
  - recruiting 1028 pregnant women in 14 countries.
- **FACT (Folic Acid Clinical Trial, ISRCTN23781770)**
  - pregnant women - randomised to receive either 4 mg folic acid or placebo daily.
  - primary outcome: development of pre-eclampsia.
  - recruiting 3656 pregnant women in 4 countries.

# Approaches to protecting IP

- CHIPS – “open access”
  - publish protocol
  - [http://sunnybrook.ca/research/content/?page=sri\\_proj\\_cmicr\\_trial\\_chips\\_home](http://sunnybrook.ca/research/content/?page=sri_proj_cmicr_trial_chips_home)
  - Lancet
- FACT – “restricted access”
  - non-disclosure agreements (NDAs)
  - local investigators/institutions must sign NDA before full protocol is provided

# Open access

- **Positive consequences**
  - possible/actual sites have easy access to full study design;
  - potential for open discussion between collaborators;
  - study investigators held to high standards of reporting.
- **Negative consequences**
  - details are available with potential for plagiarism.

# Restricted access

- **Positive consequences**
  - details of study only available if legal agreement is signed.
- **Negative consequences**
  - may restrict academic openness and collegiality;
  - provide additional barriers to site recruitment;
  - investigators may select the results they wish to present (even if trial is registered).

# Discussion

- **Academic institutions**
  - reputation and wealth depends on IP
  - need to protect their IP and that of investigators
  - risk management approach
- **NDA's**
  - the legal way to “protect” IP
  - may suggest lack of trust in co-investigators
- **IP in academic trials is difficult to pinpoint**

# Discussion

- Selective reporting of outcomes from RCTs
  - half of registered trials not published
  - inadequate description in registries
  - description of outcomes
    - vague description
    - unreported substantive changes between registration/publication
    - outcomes not reported
    - significant outcomes more likely to be reported than non-significant

# Discussion

- **Open access** to trial protocols will not prevent bias in reporting
- **But** investigators will be held to higher standards of reporting
- **NDA**s are becoming more common in Canada
  - could be unstoppable trend
  - delaying recruitment of sites
  - potential for bias in reporting

# Conflict of interest/ bias

- **Laura Magee** – PI for CHIPS
- **Sue Ross** – Steering/working committee member for CHIPS
- **Stephen Wood** – Calgary site investigator for FACT

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