Clinical Trial Data and Safety Monitoring Board

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DSMB Objective

Ensure that all clinical research involving drugs used by living human subjects conducted at C&W meets the highest safety and acceptable scientific standards, in accordance with the Tri-Council Policy Statement.

Who needs DSMB ?

- Primary Investigator asked to have a DSMB
- Sponsor of the study asked to have a DSMB
- C&W REB or the UBC REB asked to have a DSMB
- RCT with medications for children that need monitoring

Who is DSMB ?

Chair –

Serving under Vice President for Academic Affairs PHSA

in consultation with the C&W REB chair

Members of the DSMB will normally serve for a term of two years with possible extension

Who is DSMB ?

Four or more members :

- At least 1 with broad expertise in the scientific methodology or areas of Research
- At least 1 statistician
- At least 1 member is knowledgeable in ethics,
- At least 1 member has no affiliation with the institution and, preferably, is recruited from the community served by C&W.

DSMB will :

- Approval for continuation of a study
- Approval for continuation of a study with specific terms
- Temporarily discontinue a study with specific terms for continuation of the study
- Terminate of a study

Current Experience

- Reviewed 2 studies
- Both are opioid related
- Both due to REB request

Challenges

- ‘Why do we need DSMB ?’
- ‘The new Police force in town’
- ‘This is more paperwork’
- ‘Every drug-related study needs DSMB’

Plan

- Continue to communicate
- Find additional members
- Smooth process (service)
- Save one child from one study

The Big Picture

- Safety data across trials
- Provincial or National framework for DSMB
- Will eventually all drug studies need DSMB