UNIVERSITY OF MANITOBA | Faculty of Medicine

REPEAT FINDINGS

Bannatyne Campus Research Ethics Boards

Declaration of Acronyms

- Research Ethics Board – REB
- Informed Consent Form – ICF
- Health Research Ethics Board - HREB
- Biomedical Research Ethics Board – BREB
- Health Canada- HC
- Clinical Trial – CT
- Personal Health Information Number- PHIN
- Personal Health Information Act- PHIA
- Freedom of Information and Protection of Privacy Act- FIPPA
- Information- Info
- Data and Safety Monitoring Board (DSMB)

RESEARCHERS?

FREQUENT FLYER

THOSE Less Travelled

REPEAT FINDINGS
The GOOD , The BAD and (the UGLY)….

Good

Prefer to say "NOT so Good"

The GOOD

- CORE Requirements embraced
- Placebo and Standard of Care Justifications
- General Process Submission Requirements
- Increased Understanding of Institutional Requirements
- Frequent Flyers- generally better designed protocols

NOT SO GOOD……

PROCESS

- Failure to answer questions
- **Inconsistent responses**
- Confusing submission with explanatory gaps
- Consent form language that is too **technical/jargon**
- Failure to follow consent form template
- Sloppy submission (grammar, spelling errors, etc.)

LACK of UNDERSTANDING

- PHIA and FIPPA
- Privacy Issues
- Recruitment
- Clinical Trial Registration
- Health Canada Requirements
- Safety Plans/Monitoring
- First Nations Research
- ETC.

Failure to Answer Questions

Issues

- Failure to answer relevant questions
- If not applicable, failure to provide rational why not when it is not obvious?
- Cutting and pasting from previous submission by researchers???
- NB for audit purposes.

Examples

- Blood samples and genetics involved but failed to provide response(yes or no)
- 27 relevant questions not answered
- No contact information provided(or address on letterhead of cover letter)

Inconsistent Responses

Issues

- Inconsistent responses within submission form
- REB is unclear as to what is being done at this centre?
- Cutting and pasting from previous submission of irrelevant processes, etc. by researchers???

Examples

- "NO" to including participants under 18 years of age yet inclusion criteria include14-25 years olds with no provisions outlined for guardian consent
- State "Standard of Care" not withdrawn yet procedures section do not include the Standard of Care.

Inconsistent Responses
Sub Form vs. Protocol vs. Consent Form

Issues

- Inconsistent Responses
- REB uncertain what is being done
- Cutting and pasting from previous submission by researchers???

Examples

- Sample size- different in all 3 locations
- Inclusion criteria: No guardian signature section on main consent form, protocol inclusion 10-14 years olds and submission form states no to minors with no consent provision outlined
- PHIN collection inconsistent

Confusing

Issues

- Confusing – poor explanations with no rational/background
- Data collection much more comprehensive than outlined study objectives
- REB does not know what research entails!!

Examples

- Acronyms never spelled out in whole submission
- Explanatory gaps in research methods section with poor explanation or rational
- True purpose of study not disclosed in ICF
- Missing processes (e.g. control group briefly mentioned in protocol but no procedures outlined, etc.)

Consent Form Language

Issues

- Too technical- sometimes even for REB members
- Acronyms not spelled out
- Too many acronyms or abbreviations not familiar to participants
- Too long

Examples

- Extreme Case – CPS section inserted into Risk Section
- Procedures section written as a protocol- section taken directly from protocol
- Medical terminology not explained
- Risks – no percentages or definitions of terms such as common, less common, etc.

Consent Form Templates not followed

Issues

- Elements of Informed Consent missing
- Incorrect contact information for researcher and REB
- Failure to review and remove irrelevant sections
- Different Consent forms not labeled(e.g. Control, Focus group, etc.)

Examples

- Relevant sections missing (e.g. risks, legal waiver clauses, etc.)
- Providing Lead Investigator/REB site information only or incorrect info as copied from previous consent
- Stating medical care will not be affected when irrelevant

Sloppy Submissions

Issues

- Extensive grammatical and formatting errors- incomprehensible for REB and participants
- Using or submitting non REB approved documents for Annual approval- auditing compliance issue
- Not dating documents

Examples

- Extreme Case- incomprehensible and potentially embarrassing for University. Signed by Department head.
- No headings in consent form with run on sentences
- Failure to update version dates in documents. Different version dates on each page.

Privacy Issues

Issues

- Poor understanding of definitions of type of data(e.g. anonymous vs. de-identified)
- Protection of data records – clinical and electronic not sufficiently outlined.

Examples

- Indicate data is anonymous but intend to link data by code
- Response states reviewing anonymous or de-identified data when looking at clinical charts which are identifiable
- Records not appropriately coded with unique ID code and link to Master list

Types of Information

- **Identifiable information** - information that clearly identifies specific individuals
- **De-identified information** - information about specific individuals that has been coded
- **Anonymized information** – information from which the identifying codes have been deleted
- **Anonymous information** - information that has **never** been linked to specific individuals

Recruitment

Issues

- Confidentiality of clinical or personal records- recruitment procedures fail to account for this PIHA/FIPPA aspect of study.
- Insufficient explanations

Examples

- Researchers contacting participants without permission to approach first sought by “circle of care” or custodian of records?
- Researchers do not separate recruitment from consent process
- “Word of Mouth”- fails to explain, who, where, when , etc.
- Control recruitment not outlined.

Clinical Trial Registration

Issues

"All clinical trials shall be registered before recruitment of the first trial participant in a recognized and easily web-accessible public registry."

Article 11.3

Examples

- Recognize it is a Clinical Trial but indicate will not register because will not publish in one of major journals. TSCP 2 requires this regardless of publication.

Clinical Trial Registration

Issues

- Diversity of definition not understood:

"*A form of clinical research….. Interventions include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process-of-care changes, preventive care, manual therapies and psychotherapies….. "*

- Registry requirements not followed

Examples

- State there is no control group therefore not a clinical trial
- State does not involve a drug or device therefore not a clinical trial
- Enrolling before registered, not updating registry every 6 months

Health Canada Requirements

Issues

- Approved drugs being researched for new indications, etc.
- Lack of monitoring procedures outlined in submission/and or protocol.
- ICF-approval status not identified.

Examples

- Researchers indicate HC application not required because drug is used clinically or use has been documented in literature.
- Poor or non-existent protocols for monitoring. Have not used HC templates.
- ICF- identifies approval status by FDA but fails to identify approval status in Canada.

Safety Monitoring Plans

Issues

- Lack of appreciation of the definition of independent DSMBs
- Safety monitoring procedures not outlined
- Failure to appreciate non-biomedical potential risks
- No safety plan follow up relating to administration of questionnaires eliciting signs of severe depression

Examples

- State there is an independent board when it is internal
- Failure to answer this question on form or provide sufficient details
- No data safety plan or adverse event definitions outlined
- Conducting research with identifying hot spots of sexual workers and not appreciating these significant risks

Aboriginal Research

Issues

- Lack of appropriate Aboriginal consultation
- Lack of appreciation of three distinct Aboriginal populations

Examples

- Answer "NO" to submission form question but data collection sheet collects ethnicity and study objectives outline analysis specific to one of the distinct Aboriginal peoples
- No – to consultation yet significant proportion of population is expected to be one of the Aboriginal populations

Manitoba Perspective

- Manitoba Assembly of Chiefs
  - Distinct populations
  - OCAP principles
    - Ownership
    - Control
    - Access
    - Possession
  - Enigok
  - Health Information Research Governance Committee(HIRGC)
- Manitoba Metis Federation
- Advisory groups

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Thank you.

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