- Tips and Reminders for Reviewing:
  - Link to RISe tutorial for initial review
  - Review all relevant documents attached to the study i.e. protocol, IB,
  - Check for consistency
  - Look at the hypothesis, methodology, selection & recruitment methods, risk vs. benefit, privacy & confidentiality etc.,
  - Methodology (John Cairns will elaborate on this further later)
    - Poorly designed research that provides no potential benefit to participants or society at large is not necessarily ethical
    - TCPS2 Article 2.7 *As part of research ethics review, the REB shall review the ethical implications of the methods & design of the research.*
    - Is the methodology appropriate in relation to the objectives?
    - Is the study statistically sound?
    - Is there clinical equipoise? TCPS 2 definition: *The existence of a genuine uncertainty on the part of the relevant expert community about what therapy or therapies are most effective for a given condition*.
    - Has the Phase of the study been identified in application, protocol and ICF?
    - Is there use of Placebo? *TCPS2 It is the responsibility of the researcher or sponsor to provide justification to the REB for the choice of a placebo control group, as opposed to the other possible choices of control group.* See Article 11.2
  - Selection and Recruitment
    - Are the inclusion / exclusion criteria appropriate given the purpose of the study?
    - Who is recruiting and how?
    - Who is being recruited? (captive populations such as students, employees, colleagues, OR vulnerable populations such as terminally ill, mentally incompetent)
  - Risks/Benefits
    - Risk should be minimized and be reasonable in relation to the anticipated benefits to the participant and the importance of resulting knowledge.
    - Foreseeable harms should not outweigh anticipated benefits
  - Informed Consent / Consent Form
    - This is a process continuing throughout the study
    - Participants must be competent in relation to what their study participation involves
    - Full disclosure of the purpose, anticipated outcomes, risks & benefits is imperative
    - Voluntary participation
  - Right to Withdraw
    - Must be clearly stated without consequence or reason provided
    - Clear explanation of what will happen to data already collected (destroyed, retained etc.)
  - Privacy / Confidentiality
    - Transparency about the degree of confidentiality
  - PI & Study team
    - Are they qualified? Who are they?
  - Project title
    - What is being done?
  - Study dates and funding
    - What is the length of the study – is it reasonable?
    - Any COI identified
  - Where is the study taking place?
  - Are approvals from other institutions / health authorities necessary or provided?
  - What other forms of Peer Review are attached or required? (are these reliable and or independent?)

- Should the study be approved as is (never happened?), provisos issued, deferred and returned to board?
- Please use the Pre-Review document: not only to prevent duplication of comments, but to answer the questions posed (these are highlighted in YELLOW)
- When posting your comments please draft them as you would like them to be read by the researchers. If issues are identified that require a discussion, mark them as such and them post clear PROVISOS that need to be sent to the research team.