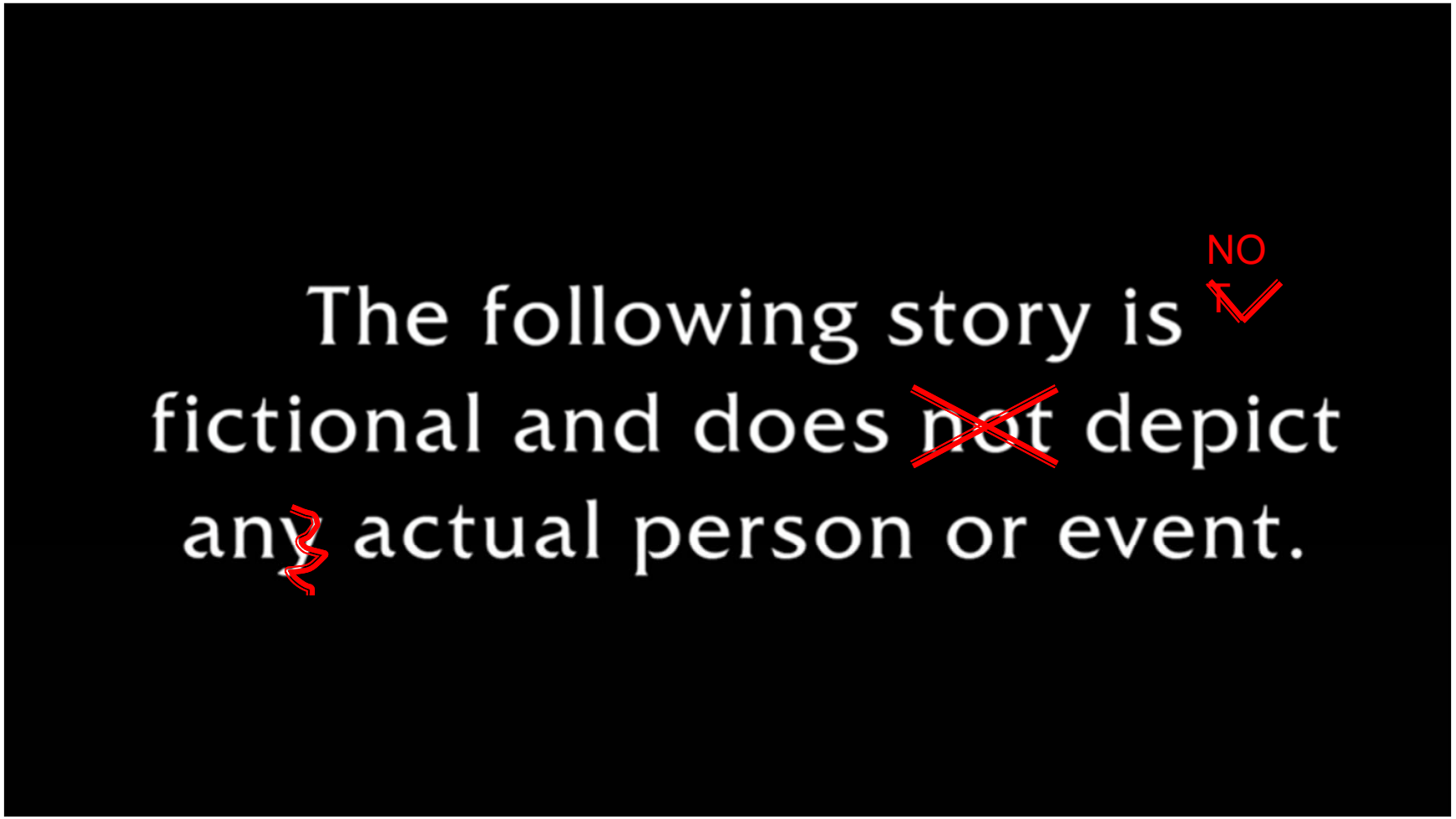
Weird Things

Interesting things this year



Depression/Anesthesia

- The use of anesthesia (isoflurane and propofol) to induce burst suppression on EEG to reduce/treat severe depression. Current treatment is Electroconvulsive therapy.
- The study will therefore test doses of both anesthetics at levels above and below the threshold to induce BS. In addition to these tests the study will look at leukocyte expression of depression-related genes.
- Ad hoc reviewer for expertise

Depression/Anesthesia (cont'd)

- Significant discussion of risks of anesthesia
- Small pilot study, need more information about it
- Due to the severity of depression, can the participants provide consent?
- Impact on pts with cardiovascular issues
- Do pts stay on current anti-depressants?
- DSMB is two study team members

Depression/Anesthesia (cont'd)

- Local, single site study. Response to revision requests – improved protocol and consent
- Only participants who can provide consent will be included, PI will be one making determination – recommendation
- More detailed eligibility relating to cardiovascular status
- Pts remain on any current medication
- Created Independent DSMB

Placebo and Deception

- NIH-funding, investigate treatment responses in patients with major depression, randomized, blinded, placebo-controlled
- Pts cannot be on medication for depression
- 8 weeks of drug (placebo or anti-depressant), before and after the 8 weeks they receive 2 i.v.s an "active" and an "inactive", so half believe they are getting drug via i.v.
- Deception – Both i.v.s are placebo

Placebo and Depression (cont'd)

- One group will be receiving placebo/placebo and other will be receiving placebo/drug
- Issue: Deception cannot be used when greater than minimal risk
- Separate out groups based on risks to that group (similar to Children's determinations when placebo)
  - Placebo/drug arm – GTM, no Deception
  - Placebo/placebo – saline – Minimal risk, Deception

Placebo and Depression (cont'd)

Concerns:

- Are we putting placebo/placebo group at increased risk?
  - Not on active treatment
  - Early treatment is important – but study follow-up provides more frequent counseling/visits than SOC
- Debriefing required - OK
- Tabled: Coordinator unblinded, patient interaction and DSMB prep

Fetuses and Neonates

- Regulations call out:
  - Neonates
    - Viable
    - Nonviable
    - Undetermined viability
  - Living Fetuses
  - Dead Fetuses

Neonates (Newborns up to 28 days old)

- Viable – being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration
  - Regular Children's Determinations
- Nonviable – after delivery that, although living, is not viable
  - Specific conditions, Both parents consent
- Uncertain viability – not determined in study
  - Specific conditions, Either parent

How we differentiate

- Living fetuses – Fetus regulations, even if fetus dies during the study, if purpose is to study living fetuses
- Dead fetuses – NHSR, unless mother is identifiable in research records (adult)
- Nonviable neonates – Neonate regulations, even if it dies, if purpose is to study nonviable neonates
- Dead people – includes babies, NHSR, unless mother is identifiable in research records (adult), if purpose to study dead baby

Weird Device Things

Investigational – Not Research

- Devices can be investigational but not be research
  - Require FDA approval
  - Then IRB approval
  - Protocol, for review, not research
- Compassionate Use (Single pt, small group)
- Treatment IDE (pt population)
- Continued Access

IRB Approval – Not Research

- Humanitarian Use Device
  - FDA Approved device
  - Proven safe and probably benefits pt
  - Consent is not an FDA requirement, UU IRB
  - Protocol is often surgical procedure
  - Not collecting data (would require separate study protocol)
  - Manufacturer annual report to FDA – events are not reviewed like they are in research