

A Day in the Life of an IRB Administrator: Still More From the Other Side

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Headaches

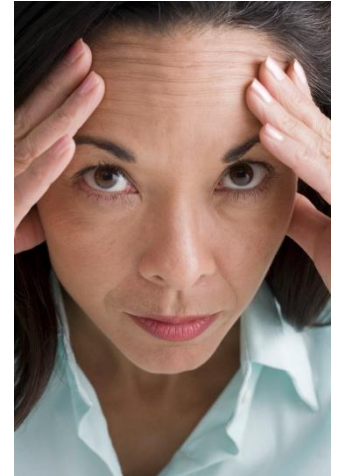
OR: Why the IRB isn't crazy for asking so many questions Part I

- ▶ Exclusion criteria not specific enough
 - Created confounding factors identified in annual progress report



Headaches

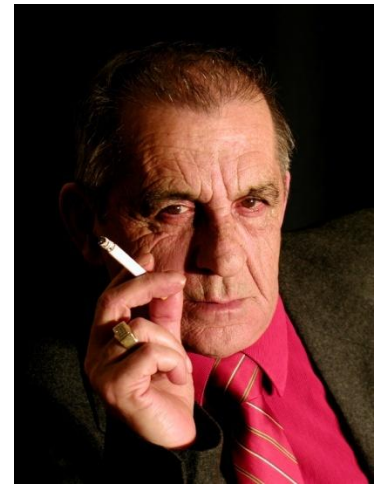
OR: Why the IRB isn't crazy for asking so many questions Part II



- ▶ Mix of deductive and inductive reasoning
 - Deductive: Moves from a general statement or theory to the specific.
 - Inductive: Moves from one's experience or observations to a theory.
- ▶ “Pasta” and “onions”

Headaches

OR: Don't make me come over there!



- ▶ Feds require progress reports for all studies with informed consent
 - PI responsibility to submit
 - Optional for institution to remind
 - Info should be organized and readily accessible to PI at all times
 - **Shutdown** and possible reporting if not received
 - Must be reviewed at convened meeting

Nightmares

OR: Infractions that can get you and the institution in the news for all the wrong reasons



- ▶ Failure to report an adverse event
- ▶ “Bending” inclusion criteria
- ▶ Changing procedures

Pleasant Dreams



OR: Easy-to-do, low-risk studies where everybody (including the attending and the resident) is happy

- ▶ Cell phone use and cognitive performance
- ▶ Measuring patient satisfaction
- ▶ Teaching effective compression-only CPR using a short internet-based video
- ▶ Patient attitudes about pain management