What I Wish I Would Have Known
My First Year as a Coordinator

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Background

- UR Life Science and Learning Center (LSLC) Research Assistant
- Canisius College, (ABEC) Canisius Canine Behavior Lab, Research Assistant
- UR Office of Research and Program Administration (ORPA) Office Assistant
Start February 2018

- 3 new coordinators, no coordinator experience
  - 2 with some research experience
  - 2 with Ortho experience
- Supervisor/Trainer <1 week
- 200+ Studies
Clinical Research Alphabet Soup

- PI
- Sub-I
- Co-PI
- HPC
- HURC
- IRB
- RSRB
- OHSP
- DOA
- DUA
- HSPP
- GCP
- AMA
- CRO
- (e)CRF
- NTF
- WIRB
- COV
- CR
- SOP
- QA
- SAE
- AE
Understanding Basic Study Information

- Exempt vs Expedited vs Full Board Study
- What is the line? How are they different?
- How to extract important information from a study approval letter
Binder Basics...

- What goes into a Regulatory Binder?
- FDA regulated?
- Departmental?
- When to make a Note to File?
- What goes in a NTF?
- How to QA your own study
Protocol Deviations, AEs, and SAEs

• What is the definition of a Protocol Deviation and an Adverse Event vs a Serious Adverse Event?

• Who do you report to?

• How quickly do you need to report each?
Study Coordinator Education

- "CCRP" Certified Clinical Research Professionals
- "ACRP" Association of Clinical Research Professionals
- "SCORE" Study Coordinators Organization for Research & Education

- What is this?
- How do I join?
- Do I need to join?
- Are there benefits to membership?
- Are there fees or dues?
Budgets, Finances, and More

- How to make a budget
  - What should be included?
  - Direct/Indirect costs, CPT Codes, etc.

- How to make and maintain a Post Award Workbook (PAW)

- Who/What determines percent effort

- F4s and subject payments
The “Other” IRB

- Western Institutional Review Board (WIRB)
  - What is it?
  - Why is this the IRB for a study?
  - How to navigate the site
  - How to submit Continuing Reviews and Amendments
When does a study need “other” reviews

Ie. HURC, IBC, RCBI, PRC

How to make eRecord work for you

How to determine HURC review dosing estimates

Dose-Risk SmartCard

Fig 1. The University of Colorado Adult Dose-Risk Smartcard. This page can be cut out or photocopied and folded to use as a two-sided, pocket-sized Smartcard.