What are Open Access Databases?

- Research databanks that do not contain any Protected Health Information (PHI).

- Submitted to the IRB as a databank protocol

- IRB confirms there is no PHI, and confirms procedures for the release of information for future research

- IRB approves the bank under the "Expedited" approval category

- Any subsequent research conducted using only this database is coded but otherwise totally de-identified and thus approved as "Non-human" research (investigator must agree to not re-identify)

So what?

- If conducting this type of research, no additional regulatory approval is necessary.

- Just do it!

- So far there are 3 "Open Access Databases" approved:
  - Patients with Cancer Deidentified Clinical Databank (IRB202101341)
  - COVID-19 De-identified Clinical Databank (IRB202000836)
  - UF Health Deidentified Clinical Databank (IRB202201755) = OMOP database

FY22 IRB-01 Metrics
Total New Protocols = 1,104

- Full Board: 87 (8%)*

- Ceded: 79 (7%)

- Expedited: 293 (26%)
  - 59 (5%) Data/Chart review

- Exempt: 496 (45%)
  - 439 (40%) Data/Chart Review

- Non-human: 149 (13%)

*Percent of total protocols

Questions?