

CDC/ATSDR  
Multi-Site PFAS Health Study

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# Study Overview

- New 5-year study with 7 sites; all have PFAS in water supplies
  - El Paso County, CO
  - Parchment/Cooper Township, MI, and North Kent County, MI
  - Montgomery and Bucks Counties, PA
  - Gloucester County, NJ
  - Hyannis, MA, and Ayer, MA
  - Hoosick Falls, NY, and Newburgh, NY
  - **Orange County, CA**
- each site will recruit 1000 adults and 300 children for clinical measurements
- shared core protocol, common IRB, and centralized data management
- each site performs local groundwater modeling and historical exposure reconstruction (Shin et al., 2011ab)
- additional site-specific community engagement and research activities

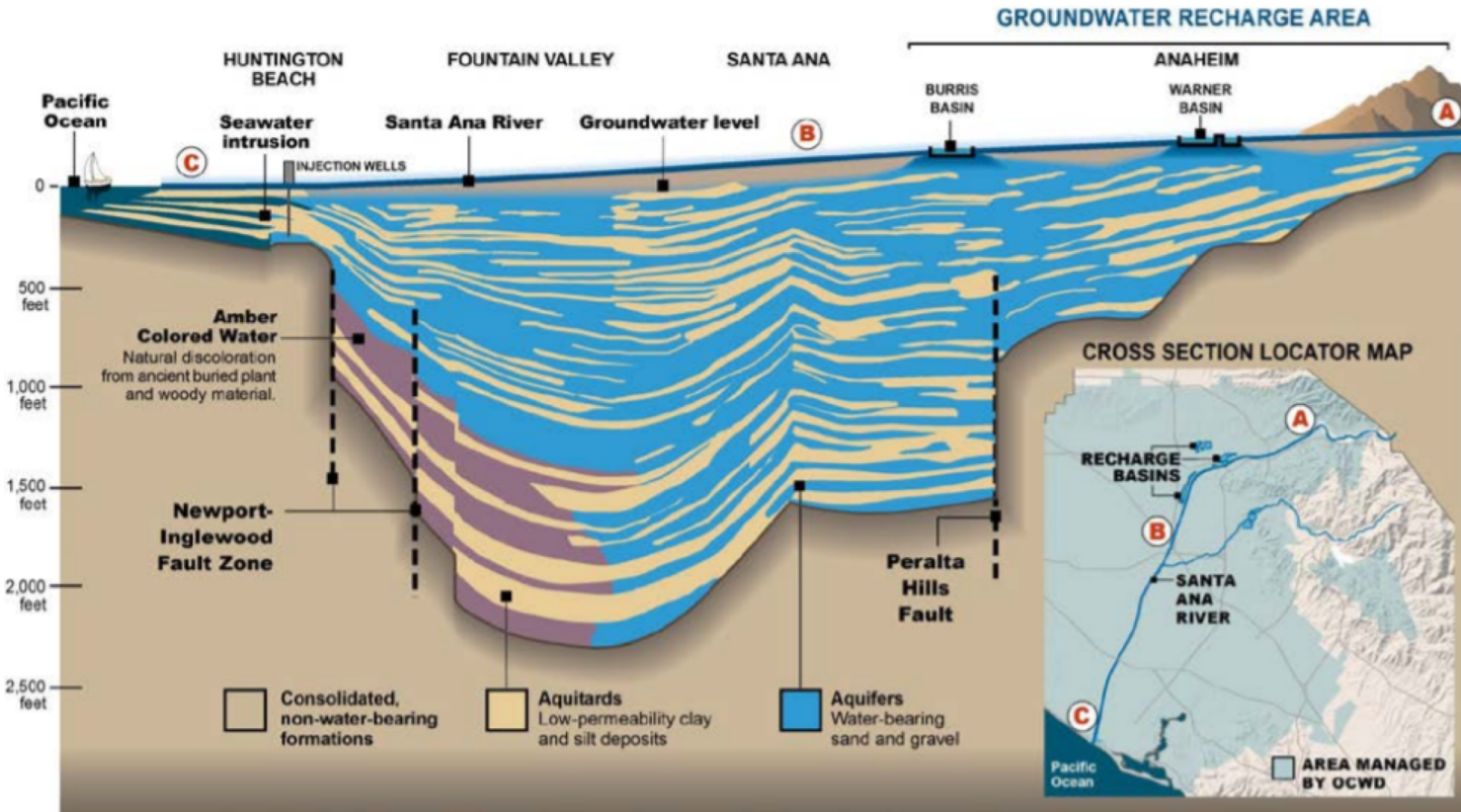
# Core Protocol Measurements

- Questionnaire
  - Including residential histories and water consumption
  - self-reported disease histories, validated by medical records
- Fasting blood and urine samples, shipped to CDC
  - PFAS concentrations
  - Biomarkers of immune response, lipid metabolism, kidney function, thyroid function, liver function, and glycemic parameters
- Body measurements and blood pressure
- Neurobehavioral testing
- Educational records
- Medication list
- Draft protocol: <https://www.atsdr.cdc.gov/pfas/PFAS-Research-NOFO.html>

# Orange County, CA

- Over **500,000 people** are served by water systems within 10 miles of UC Irvine Medical Center that had at least one water measurement exceeding 70 ppt PFOA+PFOS in UCMR3
  - Anaheim, Orange, Yorba Linda
- Local water utilities use seasonally varying combinations of groundwater, surface water, and/or imported water
- Groundwater supply and quality carefully managed by Orange County Water District (OCWD), but discovered to have PFAS during UCMR3 monitoring

# Orange County Groundwater Basin



Recharge from Santa Ana River (mostly **WWTP effluent**), advanced treatment local recycled water, and imported surface water from northern California and the Colorado River.

# Triangulation: External vs. Internal Exposure

- Measured exposure biomarkers often viewed as gold standard
  - **but** may be subject to physiological confounding or reverse causation in some health association studies--especially for PFAS (Longnecker, 2010; Watkins et al., 2013; Steenland et al., 2018)
- External exposure estimates have more measurement error
  - but error is likely to be non-differential, and associations unlikely to be affected by physiological confounding or reverse causation (Weisskopf and Webster, 2017)
- Both approaches have threats of bias, but of different types
  - Ideally, do epidemiology using both metrics, and compare results
  - Can put epidemiological effect estimates on same scale using pharmacokinetic models

# Other Site-Specific Activities at UC Irvine

- Additional water, soil, and/or stored blood PFAS measurements
- Developing pharmacokinetic models for PFAS in humans
  - Literature-based, validated by linkage of UCMR3 with NHANES biomonitoring data
  - Simplified web-based models (e.g., <https://www.ics.uci.edu/~sbartell/pfascalc.html>)
  - An R package for PFAS pharmacokinetics allowing time-varying exposures
- Further development of formal Bayesian statistical methods for pharmacokinetic calibration of individual historical exposure estimates using measured biomarkers (e.g., Bartell, 2003; Shin et al., 2014)
- Prospective follow-up of children (cut from budget in Year 1)

# Projected Timeline for California Site

- Groundwater modeling and pharmacokinetic modeling underway
- Participant recruitment and clinical measurements on hold for all sites until approval of core protocol by OMB and CDC IRB
  - randomized study invitations vs. targeted recruitment?
- Clinical visits in Years 2-3
- Complete exposure reconstruction and epidemiological analyses in Years 4-5

*Epidemiological analyses using pooled data from all sites at study end*



# PFAS Research Funding and Disclosure

- CDC/ATSDR Cooperative Agreement (U01-TS000308)
- National Institutes of Health (R21-ES023120)
- Research and Education in Green Materials Program at University of California, Irvine (UC-44157)
- C8 Class Action Settlement Agreement (Circuit Court of Wood County, WV)

Dr. Bartell has served as an expert witness for plaintiffs in two medical monitoring lawsuits for PFAS in New Hampshire.