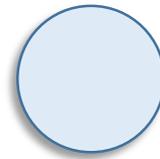
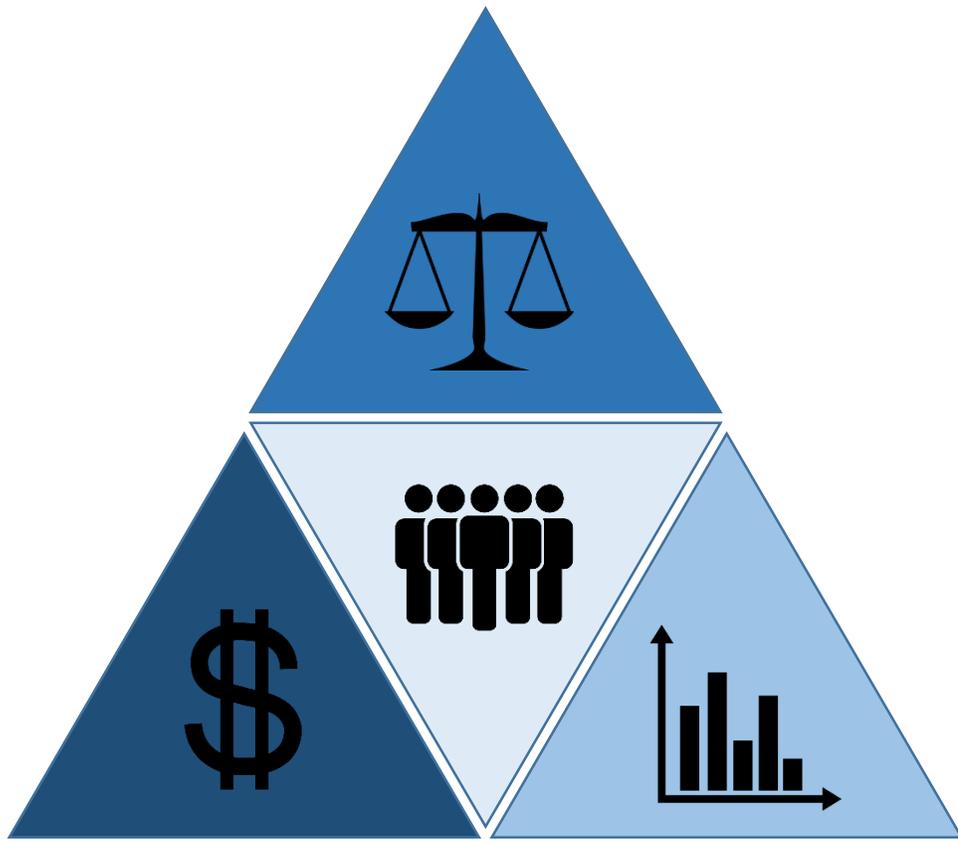


Experiences Coordinating Large Prospective Research Studies: a Researcher Perspective on Report-back

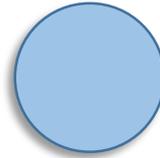
Partnerships for Environmental Public Health Conference
NIEHS December 13th 2018



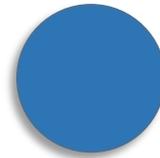
Linda A. McCauley, PhD, RN



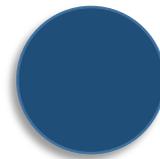
Participant



Investigator



IRB



Funder

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

CONSENSUS STUDY REPORT

Returning Individual Research Results to Participants

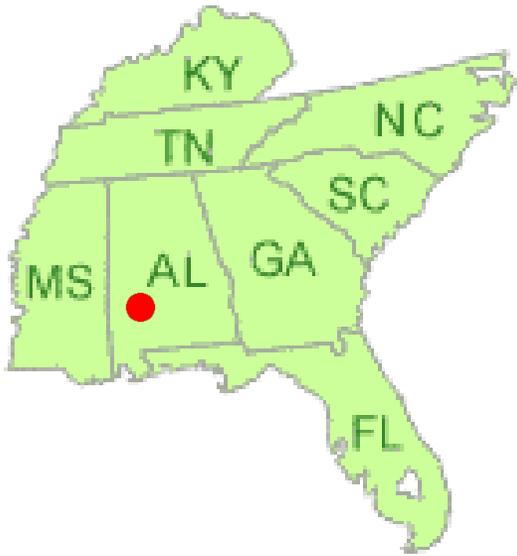
GUIDANCE FOR A NEW RESEARCH PARADIGM



Health and Environmental Data Belong to the Community



- Tuskegee syphilis experiment
- 600 black men treated for “bad blood”



- Researchers need to consider what matters most to participants
- Results could have legal implications for participants



30-DAY NOTICE

Peoplestown resident Cokethia Goodman shares her 'Renting in Atlanta' horror story *Page 2*

Cokethia Goodman was given a 30-day notice to vacate her rental home after the owners decided not to renew her lease. JEREMIAH LONG / THE ATLANTA VOICE

Bidirectional Community Input



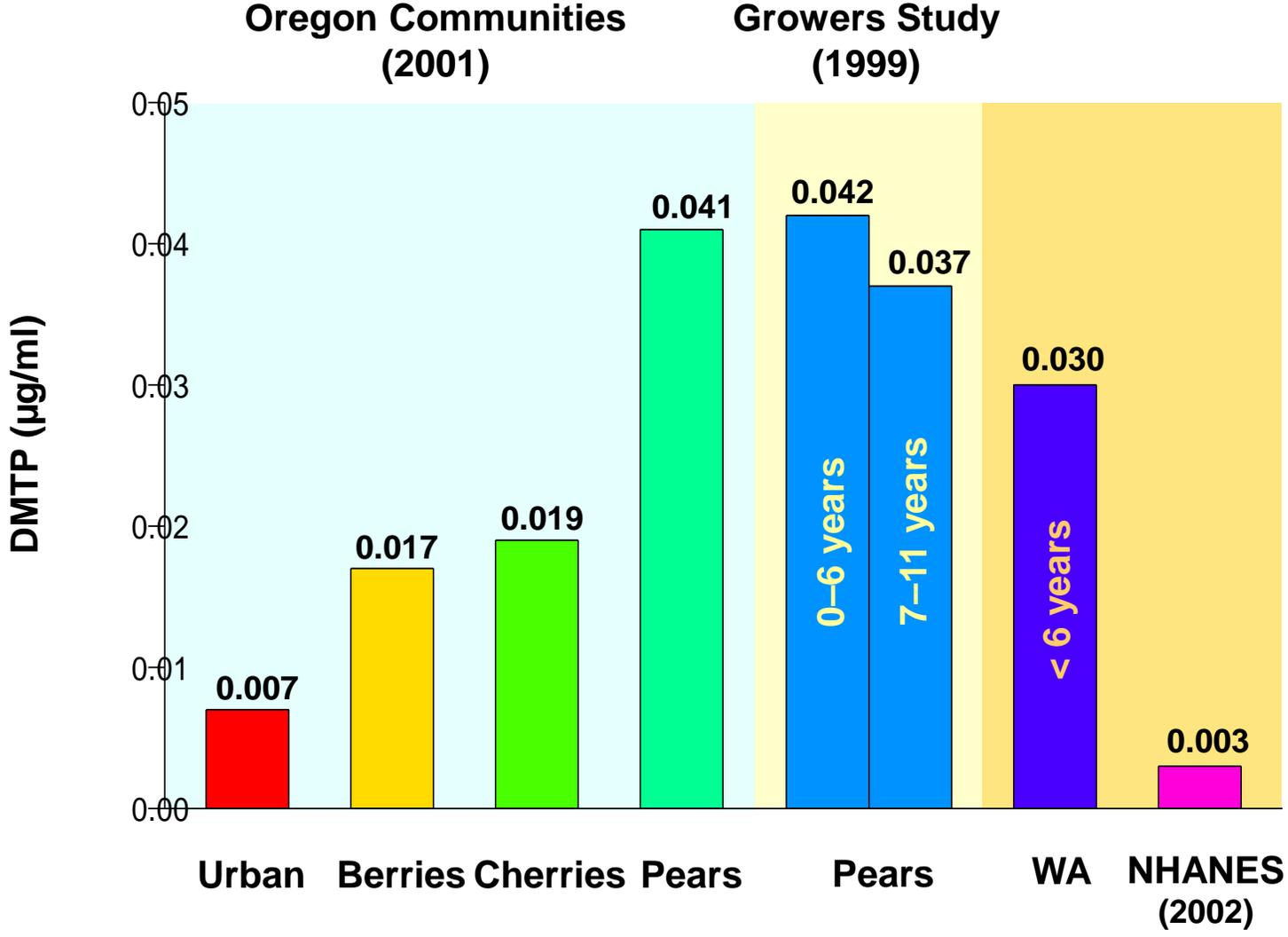
Participants are not our patients

- They may be someone's patient, but we are conducting research, not providing treatment
- Individual research data are never disclosed to groups/other individuals
- Communities grow stronger if they can see information about their health status or environmental threats in their community



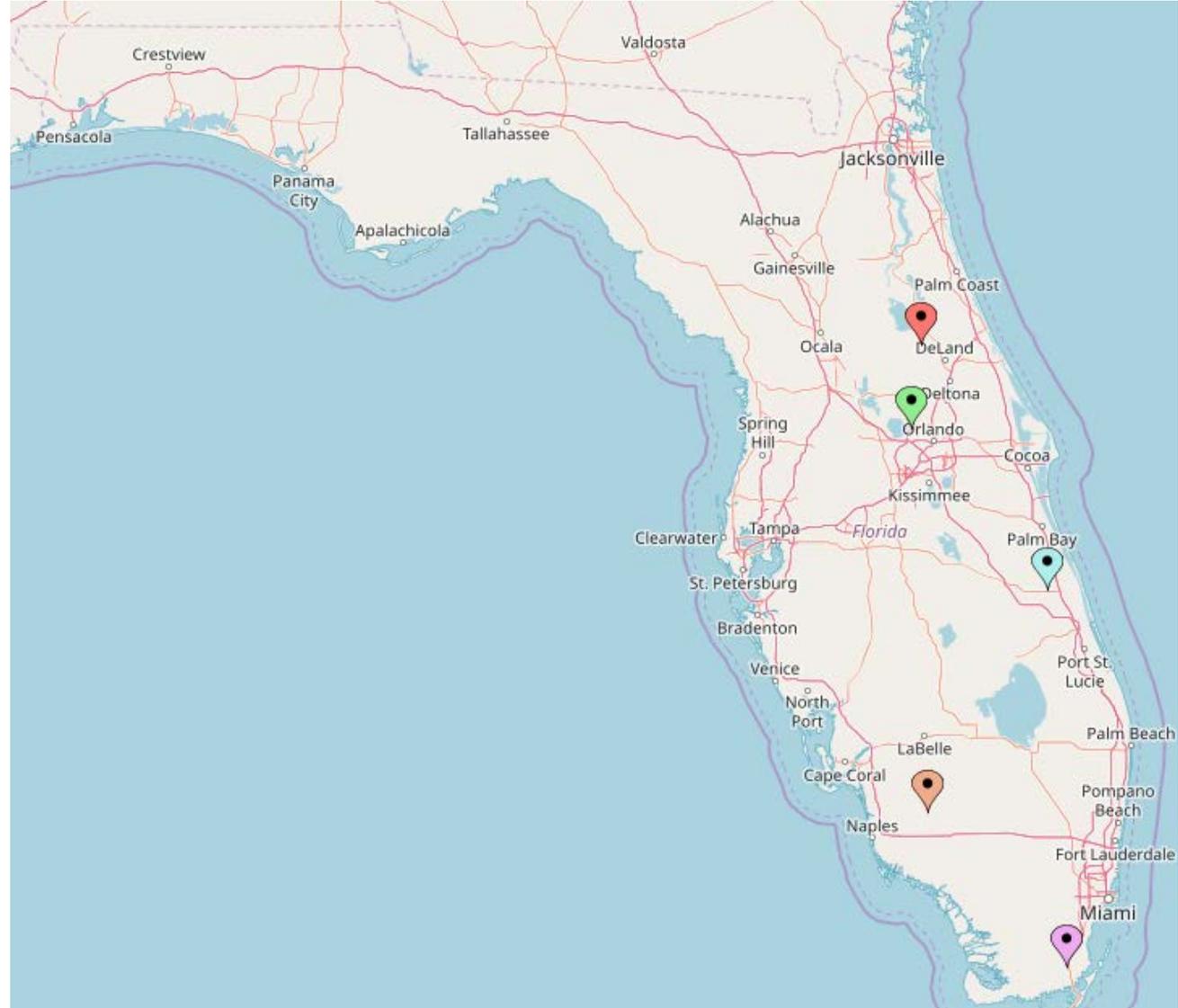
If grouped results are being published, the community should see the results also in a format they understand

Pesticide	% Detect	Median
Diazinon	77	0.31
Methyl Parathion	62	0.06
Chlorpyrifos	92	0.13
Malathion	81	0.18
Phosmet	96	4.40
AZM	69	5.53
Combined OP Total		9.40

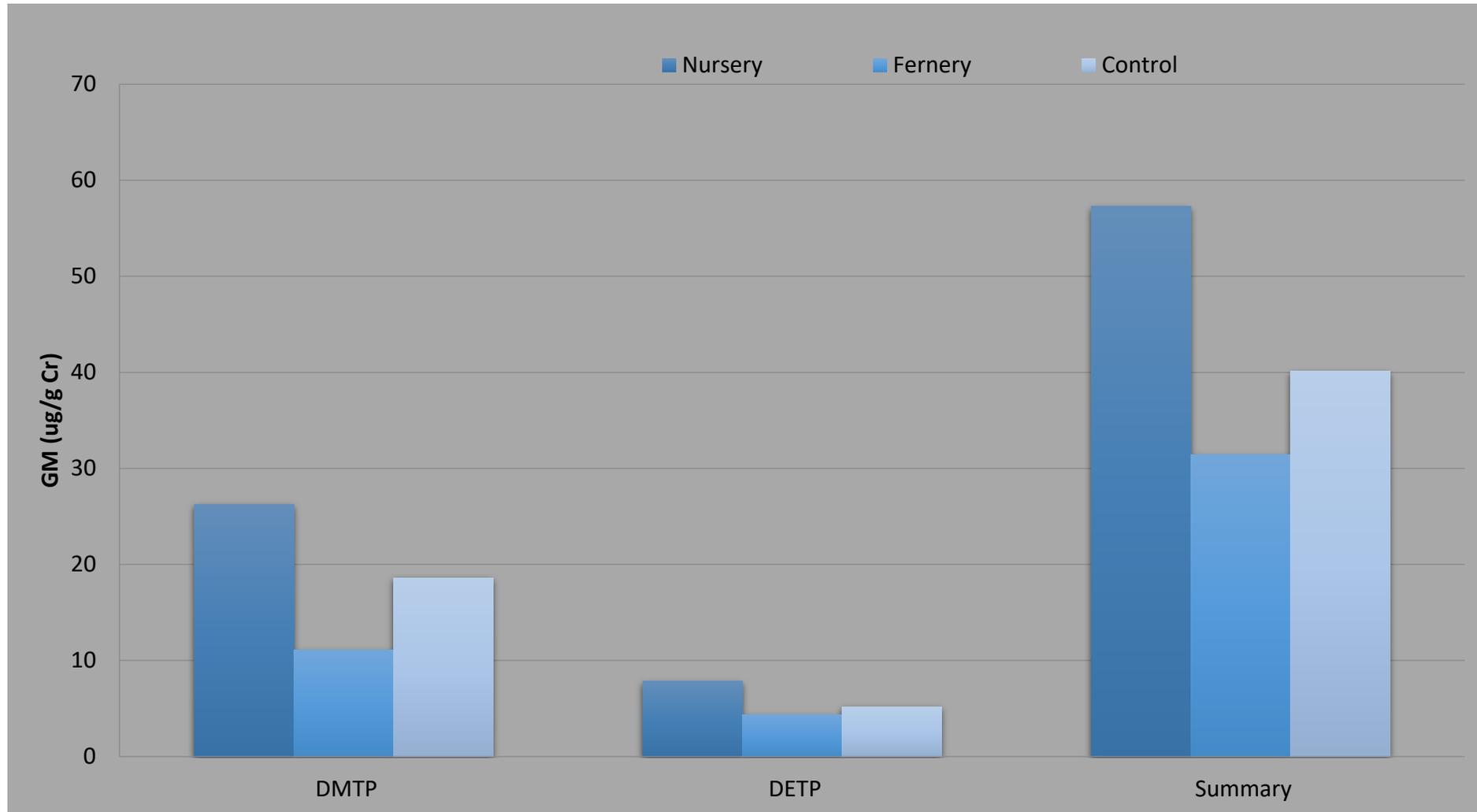


Girasoles Study Recruitment Locations

-  Pierson
-  Apopka
-  Fellsmere
-  Immokalee
-  Homestead



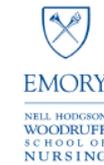
Grouped Results Can Improve Risk Perception



Individual Data

Health Screening Information provided to participants:

- Blood pressure
- Body mass index (BMI)
- Urine analysis
- Maximum core body temperature
- Basic metabolic panel
 - Creatinine
 - Hemoglobin
 - Blood glucose



Mi SALUD
La grasa corporal _____ La presión arterial _____
Alta temperatura _____ Índice de masa corporal _____



Índice de masa corporal

<18.5	Bajo de peso
18.5-24.9	Normal
25-29.9	Sobrepeso
30+	Obesidad

La diabetes es una enfermedad en la que el exceso de azúcar en el cuerpo conduce a problemas de salud.

Azúcar en la sangre recomendada <200

El estrés por calor señales de advertencia:

- Sudor excesivo
- Respiración rápida
- Debilidad
- Mareos
- Fatiga
- Náuseas
- Vómitos
- Calambres

Control y Prevención

- Mantenga un peso (IMC) normal
- Perder 7% del peso corporal (For BMI > 25)
- Evitar los alimentos azucarados
- Ejercitar 30 minutos 5 días a la semana
- Consulte a su médico si experimenta síntomas de insolación

Qué hacer

- Trasladarse a una zona más fresca o con sombra
- Sentarse
- Beber agua o bebidas deportivas
- Ventile y aplique agua fría al cuerpo



Health Screening Snapshot: PIERSON 2015

Study population

68 participants

100% Hispanic

Gender:

Women- 44

Men- 24

Average age:

37 years

(19-54)

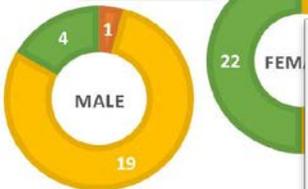
Dehydration

Urine osmolality:
1.003-1.038
(Normal <1.020)

Blood osmolality:
270-316
(Normal <295)

50% of participants begin
the workday dehydrated

Blood pressure



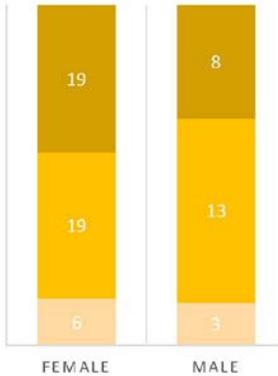
Participants referred for follow-up

14 cases of
high fasting
glucose (>120)

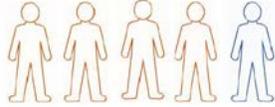
12 cases
high blood
pressure

Body Mass Index

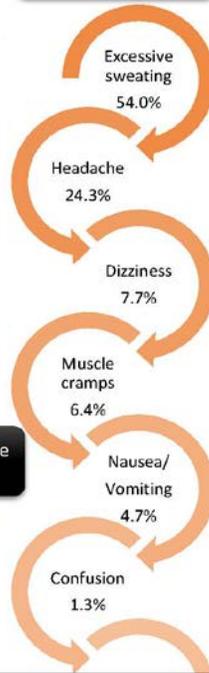
Normal Overweight Obese



4 of 5 had at least one day above core
temperature threshold (100.4°F)



Commonly reported Heat-Related Illness symptoms



Community Level Data

Referrals made:

- Elevated blood pressure: 26
- Elevated fasting blood glucose: 49
- Abnormal urine readings: 8
- Maximum core body temperature
- Out of range metabolic labs or blood in urine: 11
- Low hemoglobin: 4

Participants who were already under care were encouraged to share their screening results with their health care provider at their next visit



Social Impact Campaign



**KNOW
BETTER
LIVE
BETTER**



Toxic chemicals can settle in dust



SMALL CHANGES.
BIG
DIFFERENCE.



KNOW
BETTER
LIVE
BETTER

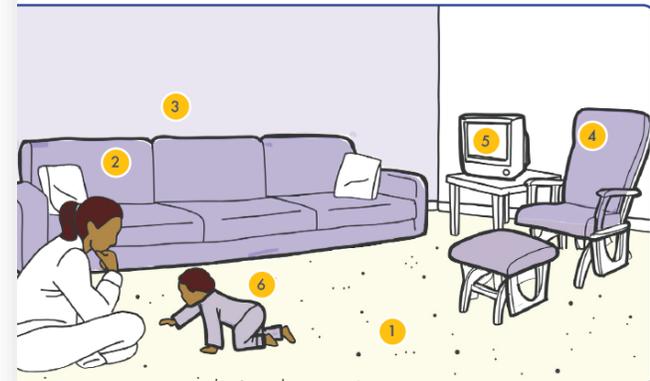
Flame Retardants

What are they?

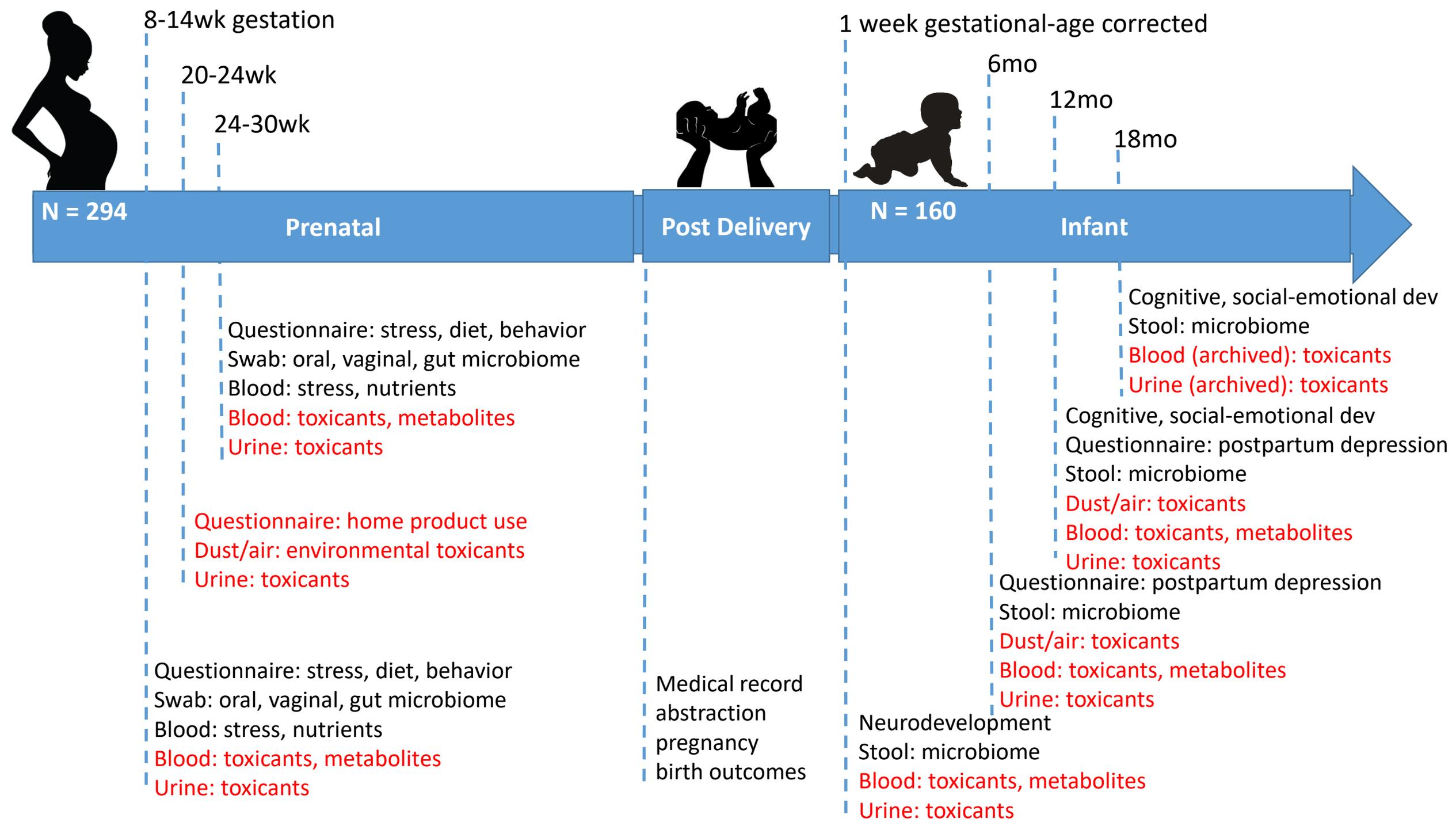
Flame retardants are chemicals that are added or applied to materials in order to slow or prevent the start or growth of fire. These chemicals can migrate from products into our bodies and disrupt normal hormone function.

Where are they found?

1. In dust and some carpet padding.
2. Furnishings: In many older products containing polyurethane foam, including highchairs, car seats, mattresses, and changing pads.



3. Building & construction materials: electrical wires and cables, and insulation materials, such as polystyrene and polyurethane insulation foams.
4. Transportation products: seats, seat covers and fillings, bumpers, overhead compartments, and other parts of automobiles, airplanes, and trains
5. Polybrominated diphenyl ethers (PBDEs) found in some electronics.
6. Clothing: specifically, in children's loose fitting pajamas ages 9 months–14 years.





HERCULES
May 2013

Maternal R01
September 2013

Epigenetic R01
July 2014

Infant R01
June 2015

Maternal Supplement
September 2015

C-CHEM²
September 2015

CHEAR
September 2015

ECHO
September 2016



Conclusions

- Longitudinal studies present distinct challenges
- Community perspective may or may not have been incorporated in initial recruitment/consent
- Pooled analysis of data from multiple cohorts with different IRB specifications: How is report back handled?
- Pilots that are funded as part of the original cohort, do investigators understand the report back principles?