



Maternal and Infant Environmental
Exposure Project (MIEEP)
a.k.a.
Chemicals in Our Bodies Project

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California Department of Public Health

Scientific Guidance Panel Meeting

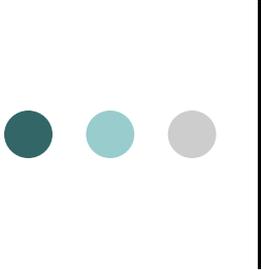
February 9, 2010

Sacramento, California



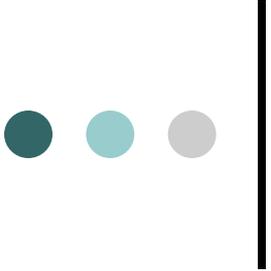
Overview

- Current project status
- Project design
- Questionnaires and other materials
- Project timeline



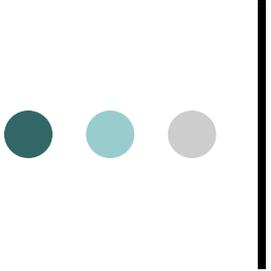
Chemicals in Our Bodies Project

- Collaborators
 - Biomonitoring California (CECBP)
 - UC San Francisco, Program for Reproductive Health and the Environment
 - Tracey Woodruff/Jackie Schwartz
 - UC Berkeley School of Public Health, Health Research for Action
 - Rachel Morello-Frosch, Holly Brown-Williams
- Funding
 - CDC Cooperative Agreement
 - CA Wellness Foundation
 - State CECBP resources



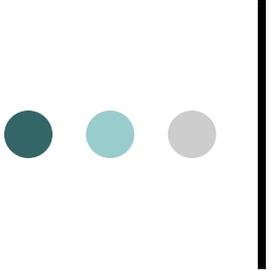
Project Aims

- Measure and compare levels of ~100 chemicals in blood and urine collected from ~100 maternal-infant pairs
- Identify leading sources of exposure to a subset of these chemicals
- Develop and test results communication/report back methods and materials
- Conduct exploratory analyses of the association between chemical exposure and pregnancy and birth outcomes



Project Aims (cont.)

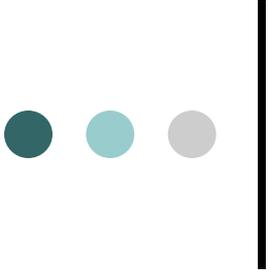
- Develop and test protocols and procedures applicable to larger, more representative study
 - Recruitment/enrollment
 - Data collection
 - Biospecimen collection/processing
 - Laboratory analyses
 - Report back results to participants



Chemicals of Interest

- Metals (Pb, Hg, Cd, As, etc.)
- Environmental Phenols – Bisphenol A, parabens, triclosan
- Organophosphate pesticides
- Pyrethroid pesticides
- Phthalates
- Polycyclic aromatic hydrocarbons (PAHs)
- Perchlorate

To be analyzed by Environmental Health Lab/CDPH



Chemicals of Interest (cont.)

- Perfluorinated chemicals (PFCs)
- Brominated flame retardants (PBDEs, etc.)
- Polychlorinated biphenyls (PCBs)
- Organochlorine pesticides (DDT, hexachlorocyclohexane, hexachlorobenzene)

To be analyzed by Environmental Chemistry Lab/DTSC



Project Design Components

- Recruitment/Informed Consent/Enrollment
- Exposure Questionnaire administration
 - In-person Exposure Assessment Interview
 - At-Home Questionnaire
- Medical Records Data Abstraction
- Biospecimen collection (maternal urine and blood, fetal cord blood)

Green = CDC coop agreement

Purple = CA Wellness Foundation

Black = In-kind support



Project Components (cont.)

- Chemical analyses - CECBP labs
- Data Analyses /Report Generation
- Report back
 - Preliminary Interview
 - Feedback Session (a.k.a. usability tests)
 - Results Communication Interview

Green = CDC coop agreement

Purple = CA Wellness Foundation

Black = In-kind support



UCSF General Hospital (SFGH) Prenatal Population

- Race/Ethnicity
 - 60% Latina
 - 20% African-American
 - 12% Caucasian
 - 8% Asian/Pacific Islander
- Low income, tend to be uninsured
 - Medi-Cal eligible during pregnancy
- Tend to be lower literacy
- >50% are primary Spanish speakers



28-34 weeks gestation

34-38 weeks gestation

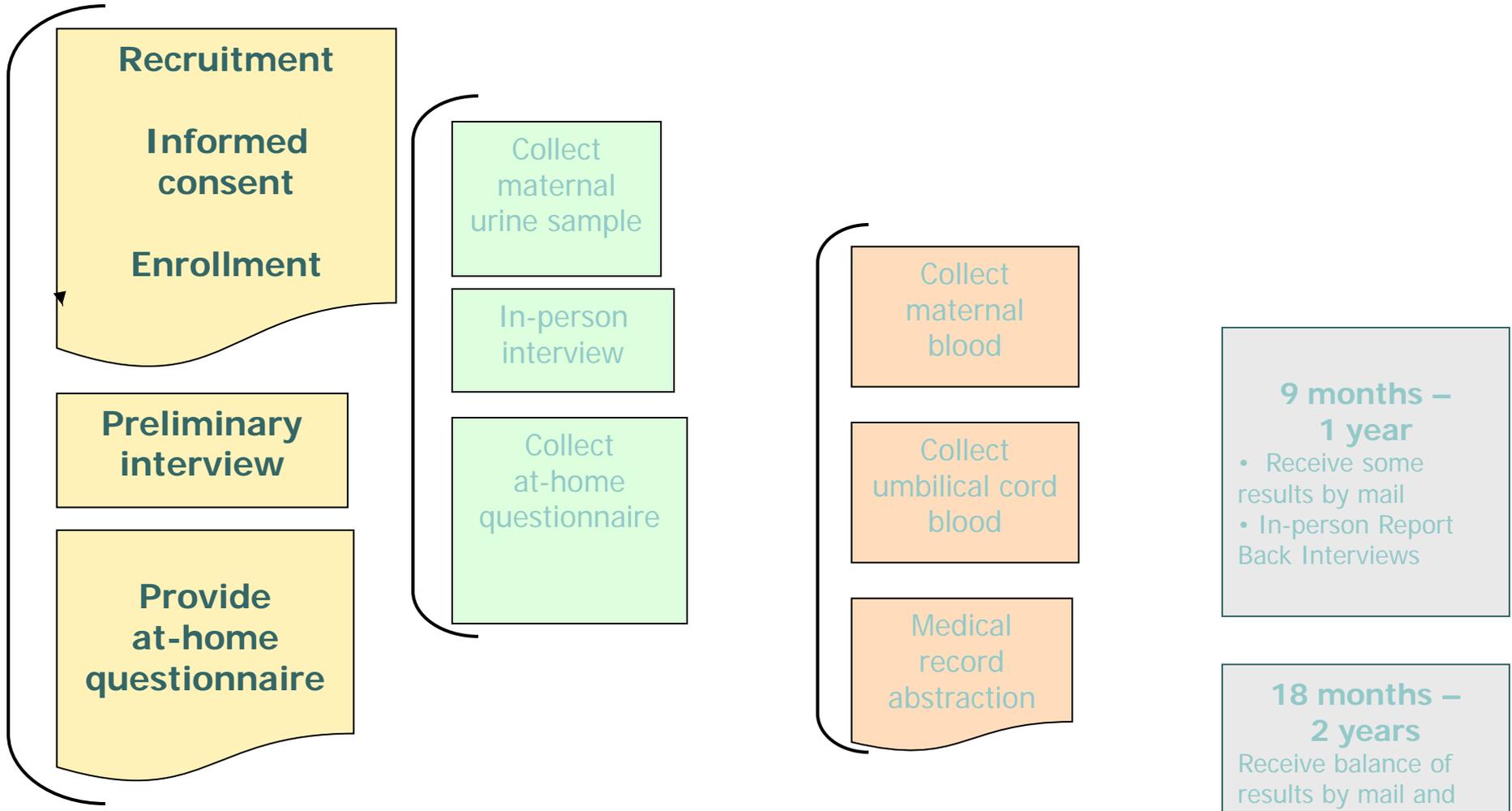
At delivery

After delivery

First Encounter

Second Encounter

Third Encounter



Chemicals in Our Bodies Project Design



28-34 weeks gestation

34-38 weeks gestation

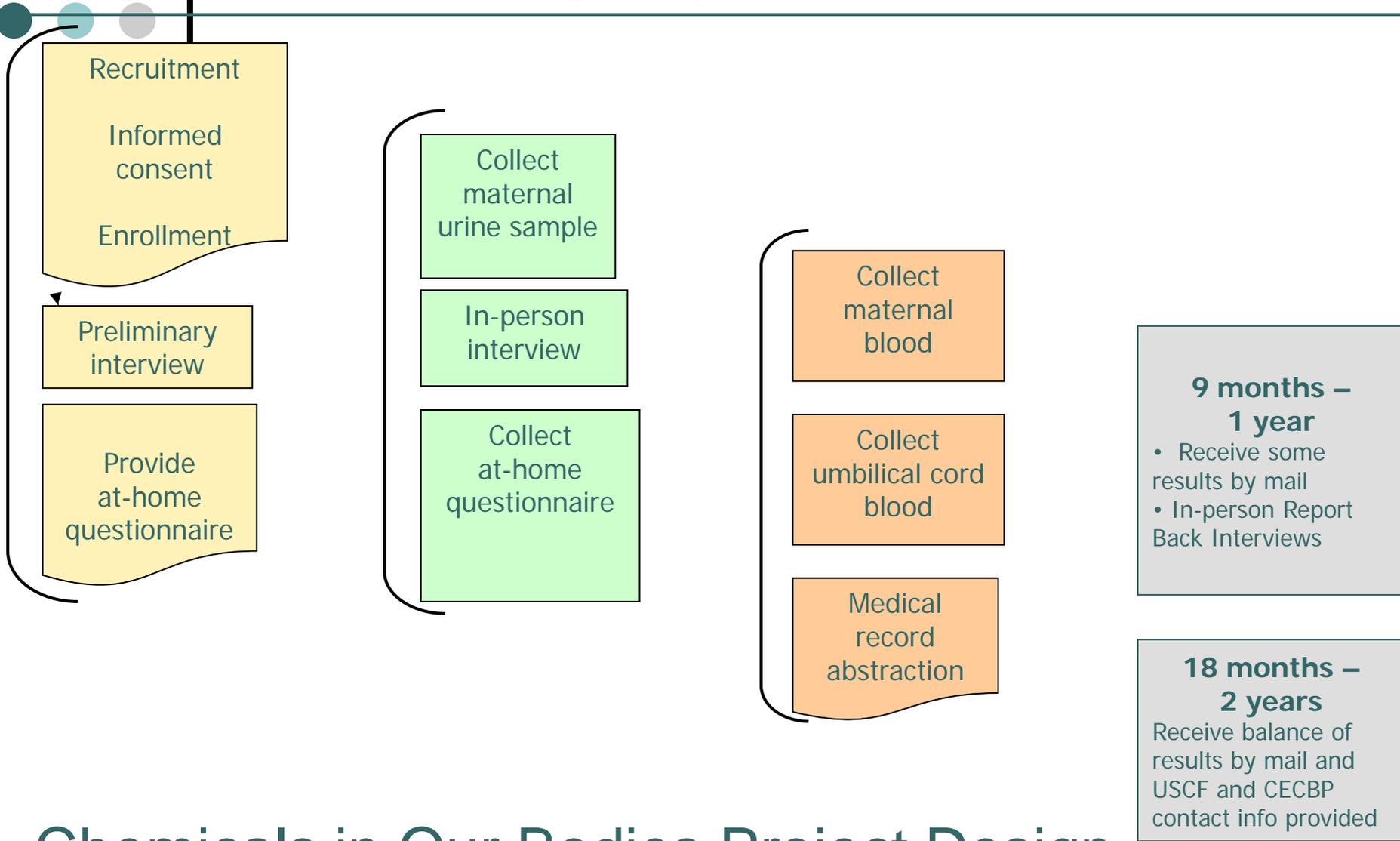
At delivery

After delivery

First Encounter

Second Encounter

Third Encounter



Recruitment

Informed consent

Enrollment

Preliminary interview

Provide at-home questionnaire

Collect maternal urine sample

In-person interview

Collect at-home questionnaire

Collect maternal blood

Collect umbilical cord blood

Medical record abstraction

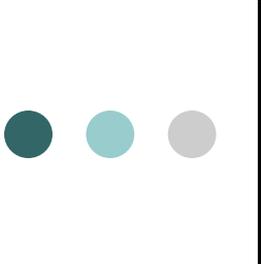
9 months – 1 year

- Receive some results by mail
- In-person Report Back Interviews

18 months – 2 years

Receive balance of results by mail and USCF and CECBP contact info provided

Chemicals in Our Bodies Project Design



Project Design – 1st Encounter

1. Recruit/Consent/Enroll

- Inclusion criteria
 - Receive prenatal care at Women's Health Center
 - Plan to deliver at SFGH
 - Low medical/ob risk
 - Spanish or English speaking
 - ≥ 18 years of age
- Res Asst (RA, Spanish speaking) to review medical charts, appointment logs, approach women in waiting area
- Participant Enrollment Packet



● ● ● | Project design: Informed Consent

- **Purpose of Project:**

- “learn if certain kinds of chemicals in our environment are present in the bodies of pregnant women and their newborn babies”
- “understand where these chemicals come from and how to reduce exposure to them”
- “look at the ways pregnant women come into contact with these chemicals”
- “find the best way to tell women about the types and amounts of chemicals we find in their bodies”



Project Design: Informed Consent

○ **What Participant can learn**

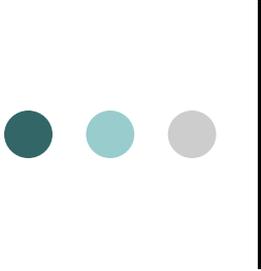
- “expect to find at least some chemicals in everyone’s blood and urine”
- “able to learn and receive info about types and amounts of chemicals found in your body”
- “how to reduce exposures”



Project Design: Informed Consent

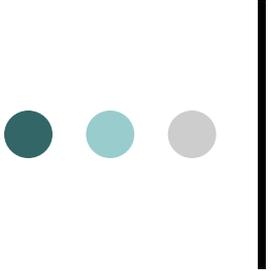
○ **What Participant can't learn**

- “We will not be able to tell you if the amounts of chemicals in your body are harmful for your health.”
- “We also will not be able to tell you whether any health problems you have may be caused by the chemicals we find in your body.”



Project Design: Informed Consent

- “Participating or not does not change any procedures or care during pregnancy or delivery.”
- Taking part in this project is entirely your choice.
 - “You do not have to answer all the questions we ask you.”
 - “You can change your mind and stop participating ...any time.”
- “We will never use your name or other identifying information in any meetings, reports, or articles.”



Project Design: Informed Consent - Stipends

- \$25 – urine sample and in-person interview
- \$20 – completed At-Home Survey
- \$20 – blood samples



● ● ● | Project Design: Informed Consent

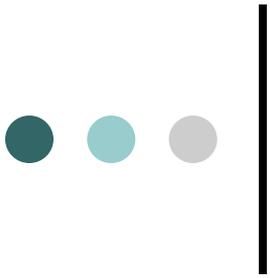
○ Participant is asked to indicate yes or no:

- “I want to participate in the Chemicals in Our Bodies Project”
- “I want to know my personal biomonitoring results” which may not be available for up to two years
- “I want to donate leftover blood and urine and personal information for use in future studies”



Project Design: Informed Consent

- If the participant indicates she would like to know her personal biomonitoring results, she is also asked to indicate her willingness to be contacted later for:
 - Feedback Session interview
 - Results Communication Interview



Questions regarding Informed Consent?



Project Design (1st Encounter)

2. Preliminary interview

- Baseline knowledge and expectations regarding participating in biomonitoring project (audio recorded)
- Example:
 - Why did you decide to participate in this project?
 - What do you hope to learn?
 - What might information about your exposure to chemicals mean for you or your family?
 - Where do you get information about environmental health issues or chemical exposures?



Questionnaire Development

- Purpose – identify potential sources and personal behaviors
 - Pesticides*
 - Perfluorinated chemicals*
 - Metals
 - Flame retardants
 - Phthalates
 - Environmental phenols



● ● ● | Questionnaire Development (Cont.)

- Administered in-person
- Self-administered at-home
- Minimize participant burden
 - Limit to 1 hour for each questionnaire
 - Translate documents into Spanish
- Timing of exposure to biospecimen collection (e.g., non-persistent vs. persistent chemical analyte)



Questionnaire Development (cont.)

- Scientific literature
- Sample questionnaires (examples)
 - CHAMACOS
 - National Children's Study
 - Occupational Health Branch/CDPH
 - NHANES
 - MIREC (Health Canada)
 - CHirP (Canada)
- Data from prenatal and newborn medical records
- Preliminary data analysis plans
- Compiled selected questions
- Field test/Revise



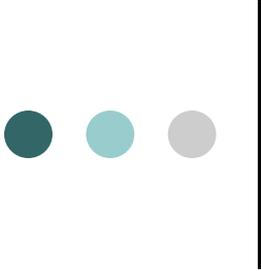
Questions regarding
Questionnaire Development
Process or Considerations??



Project Design – 1st Encounter

3. At-Home Questionnaire & instructions

- Chemicals targeted:
 - Perfluorinated chemicals
 - Flame retardants
 - Parabens
 - Phthalates
- Information on potential exposure sources
 - Home environment
 - Cleaning and personal care products during pregnancy
- Mail back (postage provided) or return at next visit



At-Home Questionnaire Personal Care Products (example)

“We would like to know about the products that you have used since you became pregnant.”

- “1. Gather your hair care products, makeup, and body and face products.
2. In the chart below, write the name and brand of each type of personal care product that you use. Include additional information on the label if you can.”
3. If you don't use a product..., check “I don't use”.
4. If you use a product not listed in the chart, write....at end of chart.
5. Please give as much information as possible. ...write as much information as you can remember about it.”

At-Home Questionnaire

Personal Care Products (example)

Hair Care Products



Product	Brand/ Company	Name of Product	Other Information		
Shampoo	<i>Dove</i>	<i>Go Fresh Therapy</i>	<i>Cool Moisture Cucumber & green tea scent</i>	<input type="checkbox"/> I use this but don't have all the information.	<input type="checkbox"/> I don't use
Conditioner				<input type="checkbox"/> I use this but don't have all the information	<input checked="" type="checkbox"/> I don't use



At-Home Questionnaire (example)

- Is any of your furniture treated to be stain or water resistant?
 - Yes
 - No
 - I don't know
 - I don't want to answer

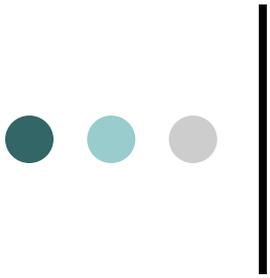
At-Home Questionnaire (example)

Have you had any furniture in your house like a sofa or chair that had exposed or crumbling foam?

- Yes
- No
- I don't know
- I don't want to answer

Examples of exposed foam:





Questions regarding At-Home Questionnaire?



28-34 weeks gestation

34-38 weeks gestation

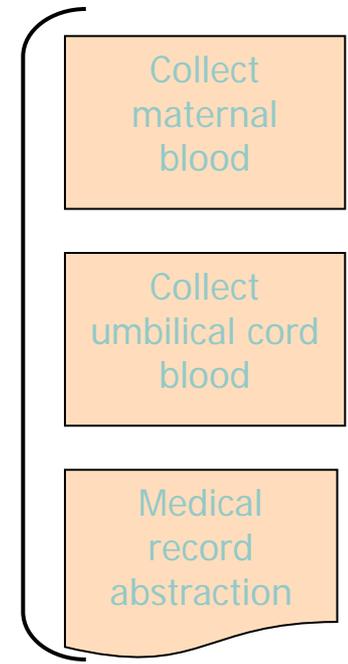
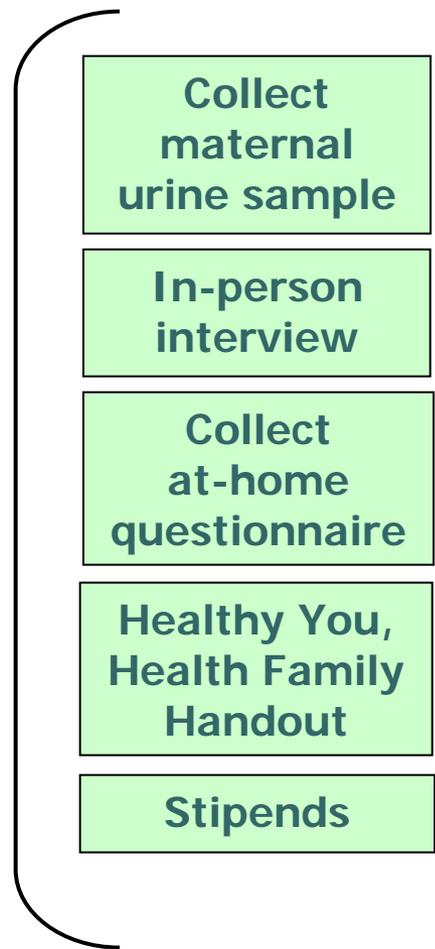
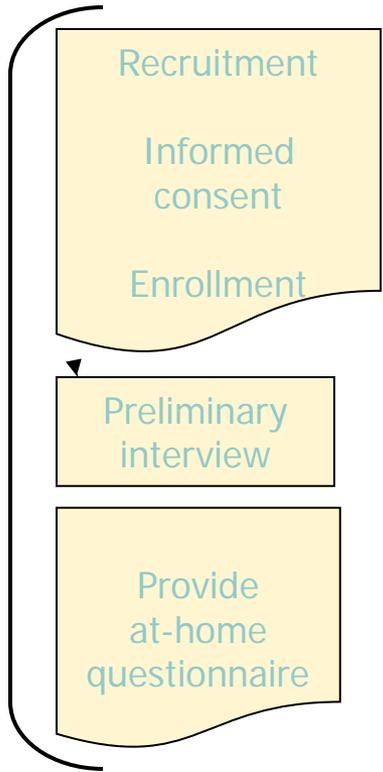
At delivery

After delivery

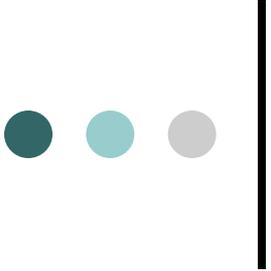
First Encounter

Second Encounter

Third Encounter



Chemicals in Our Bodies Project Design



Project Design – 2nd Encounter

Clinic visit - 34-36 wks gestation

2. In-person Exposure Assessment Interview

- Occupational history
- Hobbies and home activities
- Diet
- Behaviors/Use of certain items
- Demographic information

Exposure Assessment Interview

1. Since you became pregnant, have you [Activity] at any of your job(s)? If yes, how many hours each week or each month?

Activity	Yes	No	DK	Refused	Hrs/wk	Hrs/mo
Upholstered furniture (cover with fabric, replace foam/cushion filling)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Used, made or handled pesticides (bug spray) or weed killers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Removed paint by scraping, sanding, using a heat gun or using chemicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Refinished furniture or cabinets	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Welded or soldered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Installed carpet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

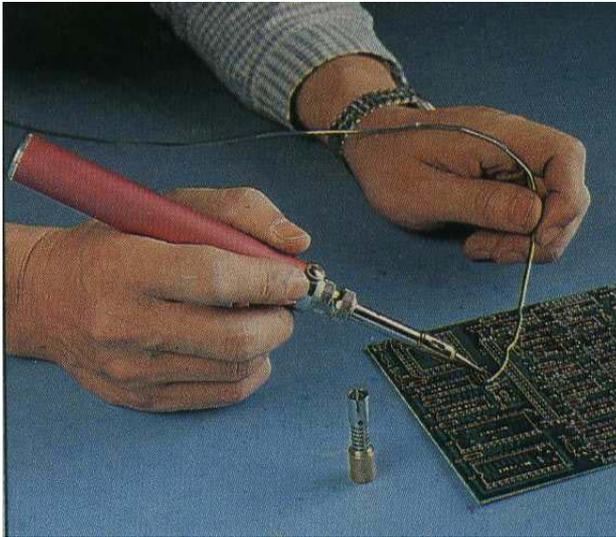


Since you became pregnant, have you or anyone in your home done any [Hobby]?

[IF YES] How many hours per week or month?

[Show hobby cue card]

Hobby	You						Someone else living in your home					
	Yes	No	D K	Ref	Hrs/wk or Hrs/mo		Yes	No	D K	Ref	Hrs/wk or Hrs/mo	
Repainting or refinishing furniture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Upholstering furniture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Ceramics or pottery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Welding or soldering	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
Other activity/hobby (describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____



In the past 30 days, did you or anyone else in your home use chemicals to [Purpose]?

[If Yes] How many times in the past 30 days did you (anyone else) use these chemicals to [Purpose]?

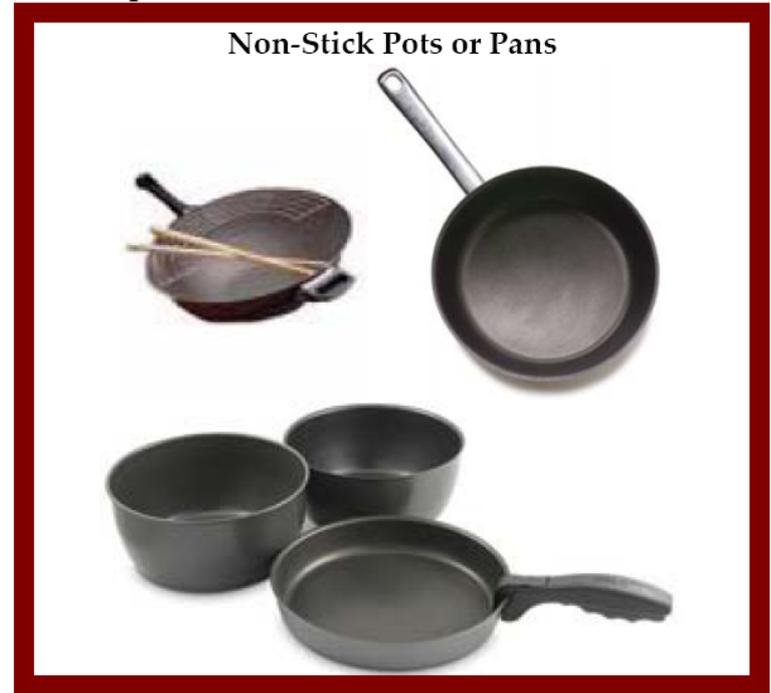
[If Yes] Did you (anyone else) use these chemicals in the past 24 hours?

	You		Anyone else	
Purpose	Last 30 days	Last 24 hrs?	Last 30 days?	Last 24 hrs?
Control fleas, cockroaches, ants, termites, flies, or other insects in your home like bug bombs, ant killing chalk)	<input type="checkbox"/> Yes _____ <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused ___ How many times?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused	<input type="checkbox"/> Yes _____ <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused ___ How many times?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused
Control fleas on pets (flea powder, flea collar, liquid drops)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused ___ How many times?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused ___ How many times?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused
Kill weeds, insects or other pests in your yard or outside your home	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused ___ How many times?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused ___ How many times?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> Refused



Questions about types of pots, pans, and appliances that you use for cooking and whether or not they are non-stick. Non-stick coatings are smooth and usually black or gray. Here are some pictures of non-stick or Teflon cookware.

Examples of Non-Stick/ Teflon cookware



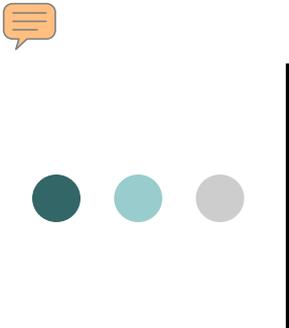
Do you use a non-stick [Item]? [If YES] How old is it?
 Does it have any scratches? How often do you use
 it? Do you wash it by hand or in the dishwasher?

Item	Use	How old	Scratches	Freq of use	Washed
Rice cooker	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	_yrs_mos_ wks <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	_yrs_mos_ wks <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	<input type="checkbox"/> Hand <input type="checkbox"/> Dishwasher <input type="checkbox"/> Don't know <input type="checkbox"/> Refused
Electric grill or frypan (ex - Foreman grill)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	yrs_mos_ wks <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	_yrs_mos_ wks <input type="checkbox"/> Don't know <input type="checkbox"/> Refused	<input type="checkbox"/> Hand <input type="checkbox"/> Dishwasher <input type="checkbox"/> Don't know <input type="checkbox"/> Refused



● ● ● | Since you became pregnant, how often do you eat [food item]?

- Meat
- Poultry
- Fish or shellfish from stores, markets or restaurants
- Fish or shellfish caught by you or someone you know
- Milk and dairy products
- Rice
- Pasta/noodles
- Fruit
- Vegetables
- Canned foods
- Canned drinks



Healthy You | Healthy Family | Healthy Home

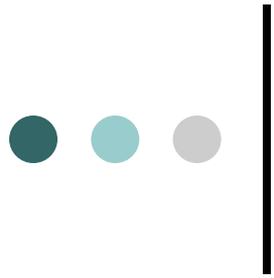
Protecting Your Family from Chemicals In and Around Your Home

Taking Care of Your Child



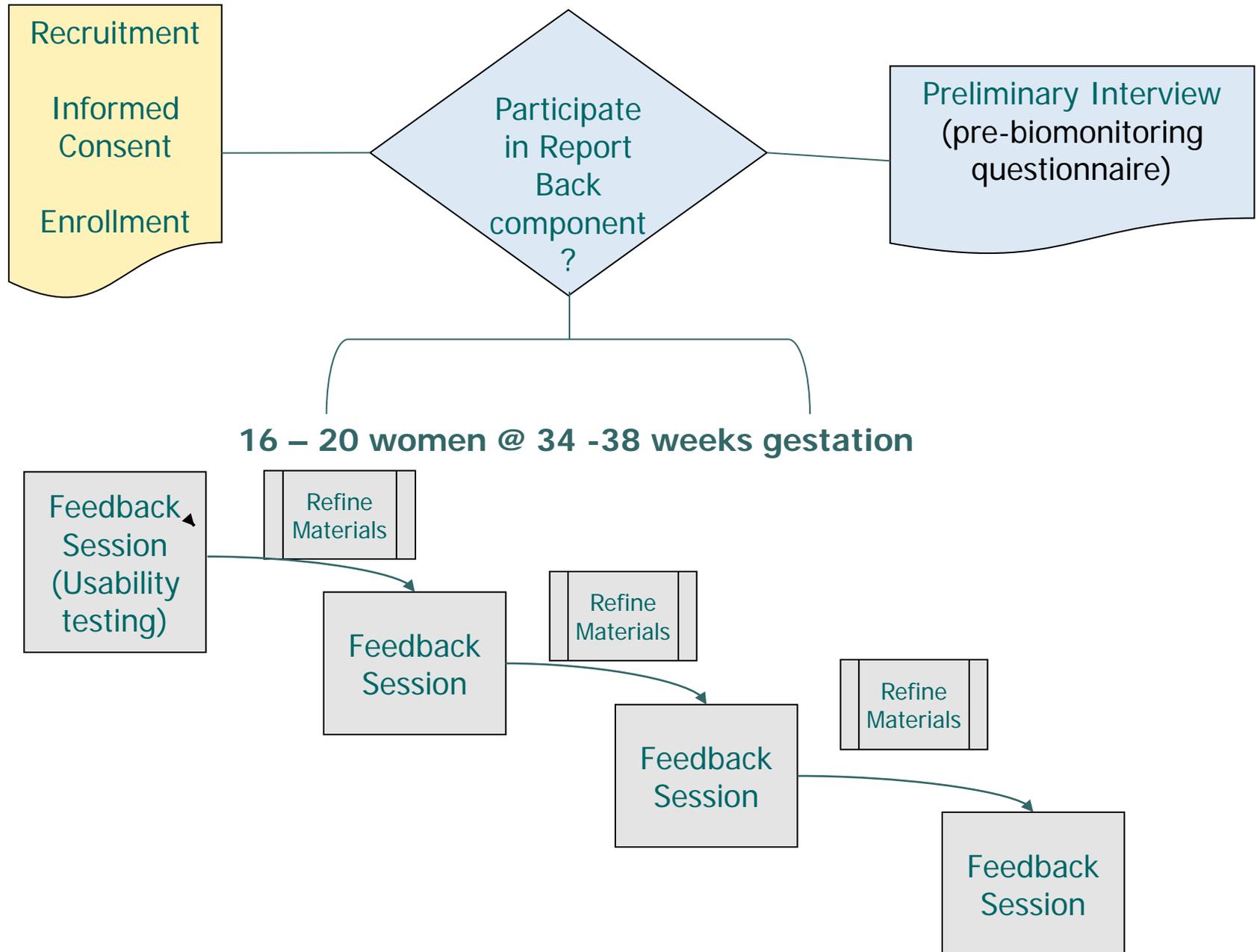
Wash your child's hands and toys often. Regular hand washing with soap and water helps prevent illness.

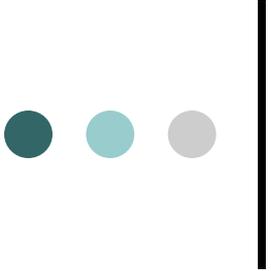
Mom's milk is best! Breastfeed as long as you can. If you use formula, use powdered formula. For baby bottles, use glass and avoid plastic ones.



Questions regarding
Exposure Assessment Interview
or educational handout?

Chemical in Our bodies – Feedback Session





Project Design – Feedback Session 34-38 wks gestation

- Four rounds of usability testing (English & Spanish)
 - 16-20 women
 - Example:
 - Show hypothetical test results in different formats
 - “Tell us in your own words what this ____ figure tells you.”
 - “What did you like or not like about how these results were presented?”
 - “Is there anything you would like to know about your test results that this example doesn’t tell you?”



28-34 weeks gestation

34-38 weeks gestation

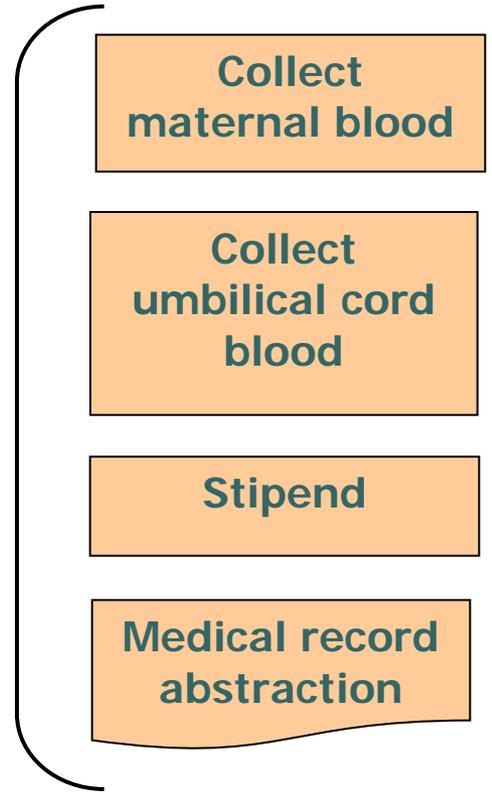
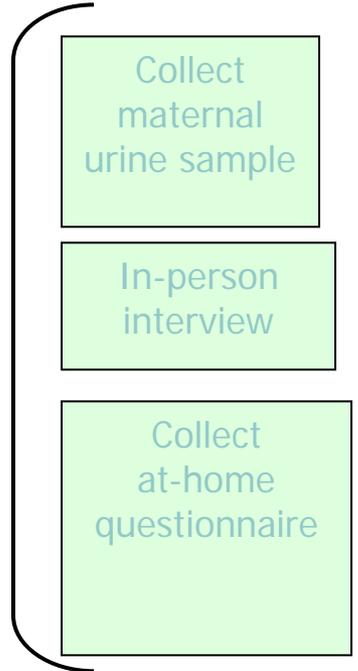
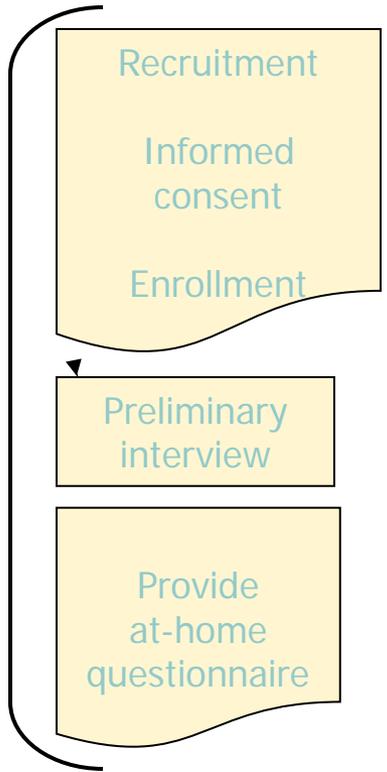
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After delivery

First Encounter

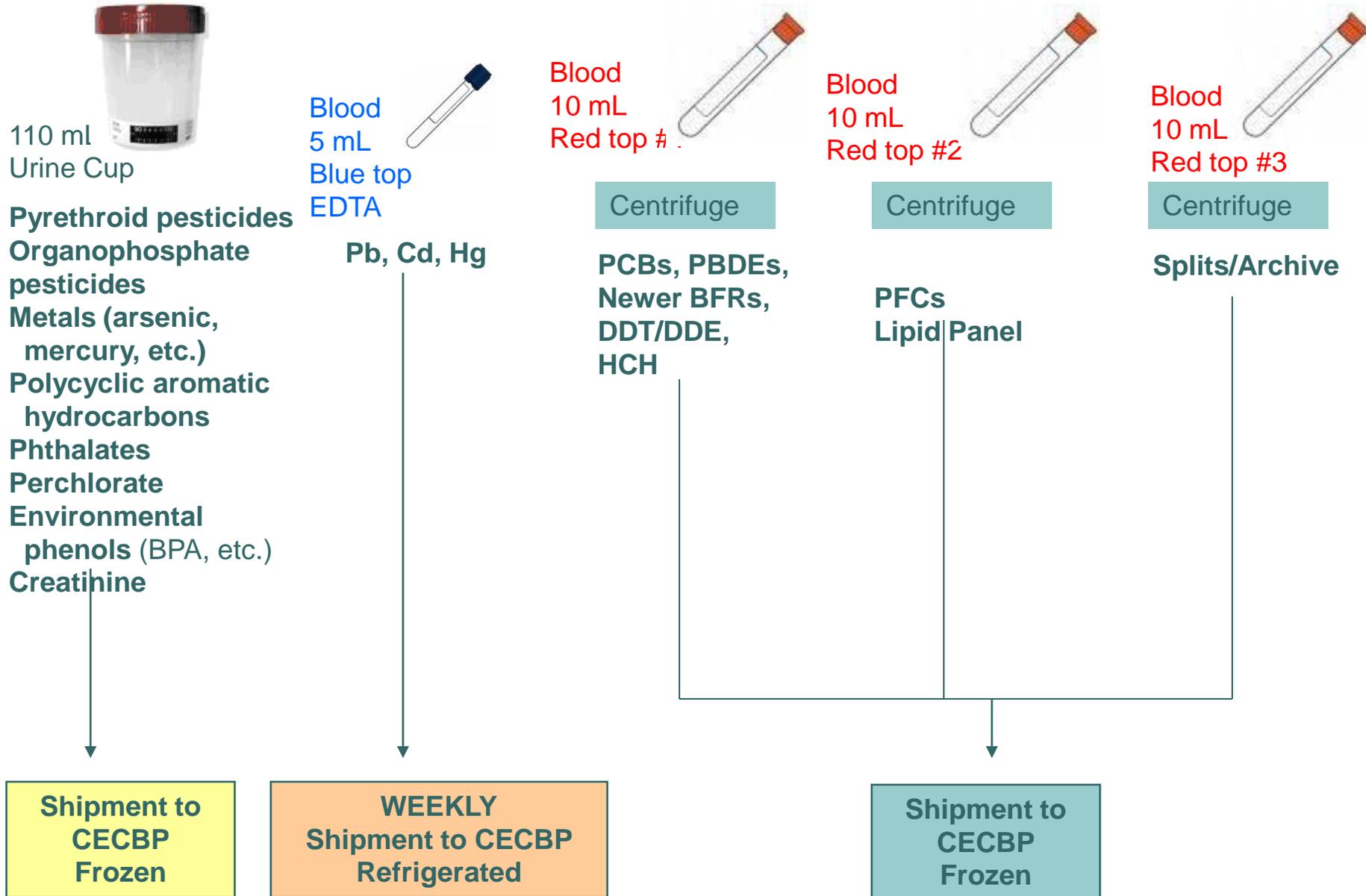
Second Encounter

Third Encounter

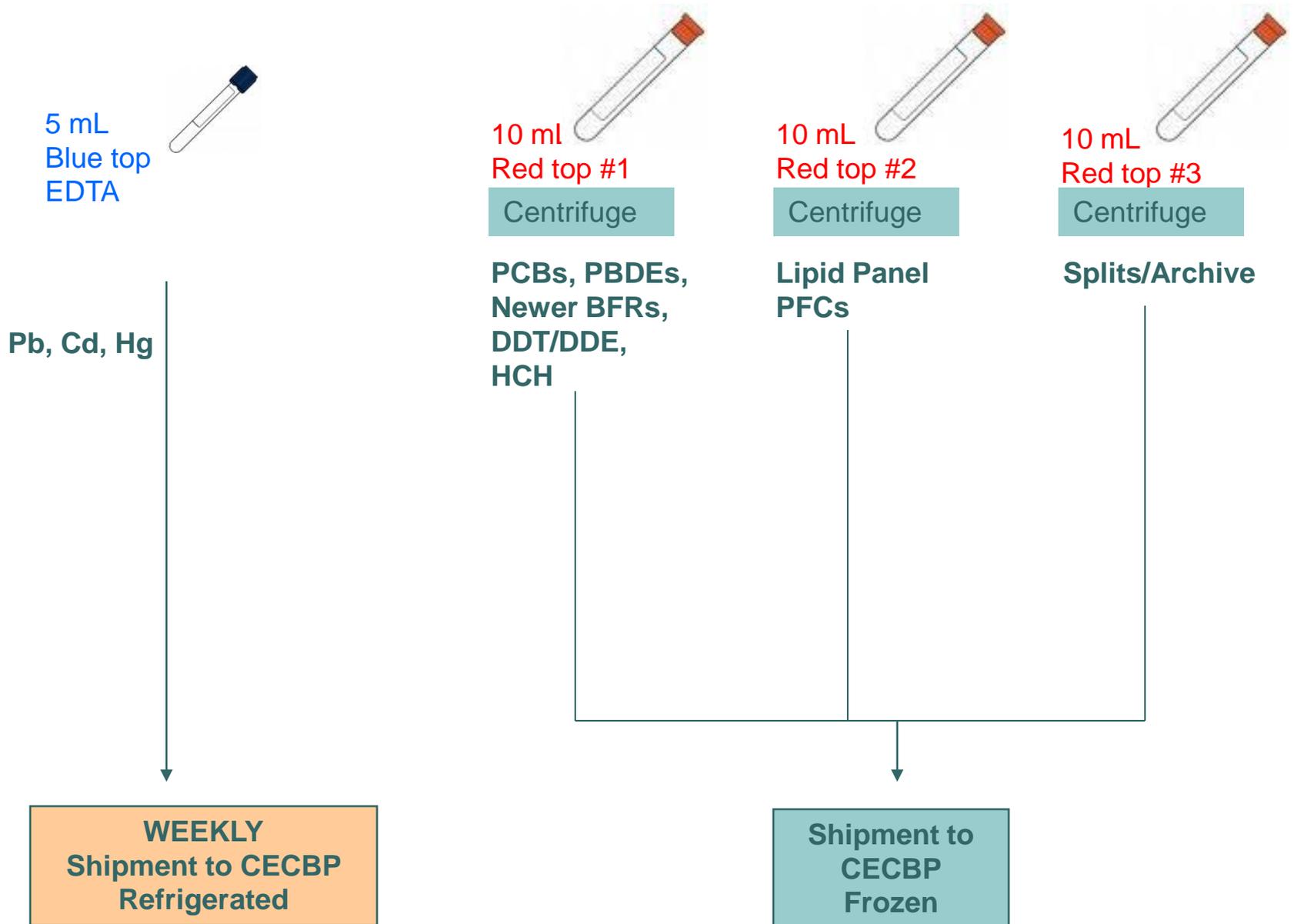


Chemicals in Our Bodies Project Design

Mother's Specimen Collection and Analysis



Cord Blood Specimen Collection and Analysis





Critical Values/Follow-Up

- Comparison with clinical reference values
 - Lead - >4.5 ug/dL for pregnant women
>10 ug/dL for infants
 - Mercury
 - other
- Protocol for follow-up
 - Review by UCSF or CECBP staff
 - Contact participant by phone and mail immediately if needed
 - Contact Dr. Naomi Stotland at Women's Health Center for referral to UCSF Occupational and Environmental Medicine Clinic



28-34 weeks gestation

34-38 weeks gestation

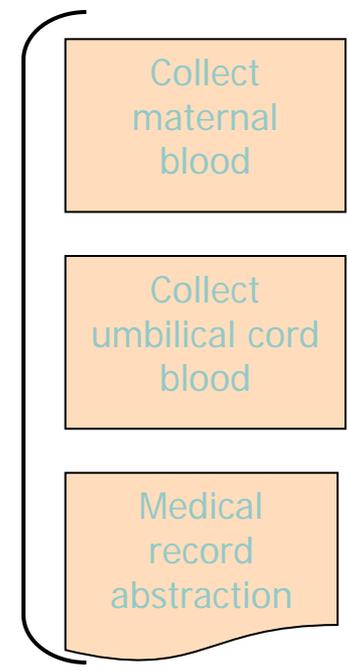
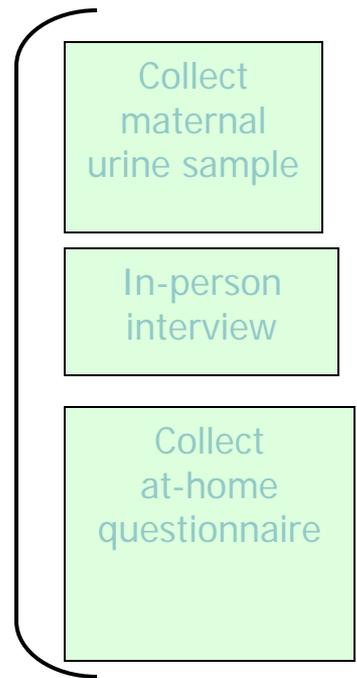
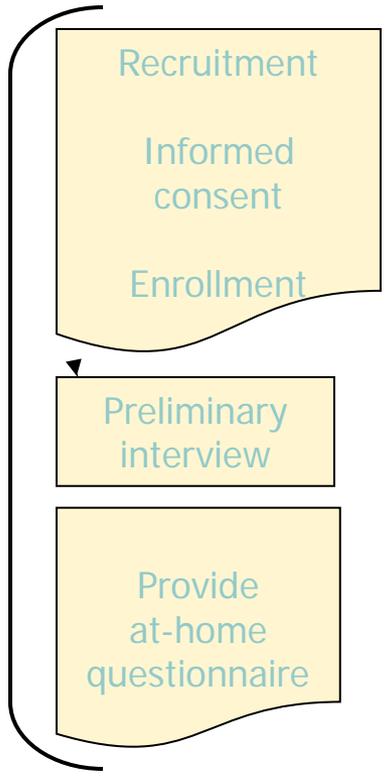
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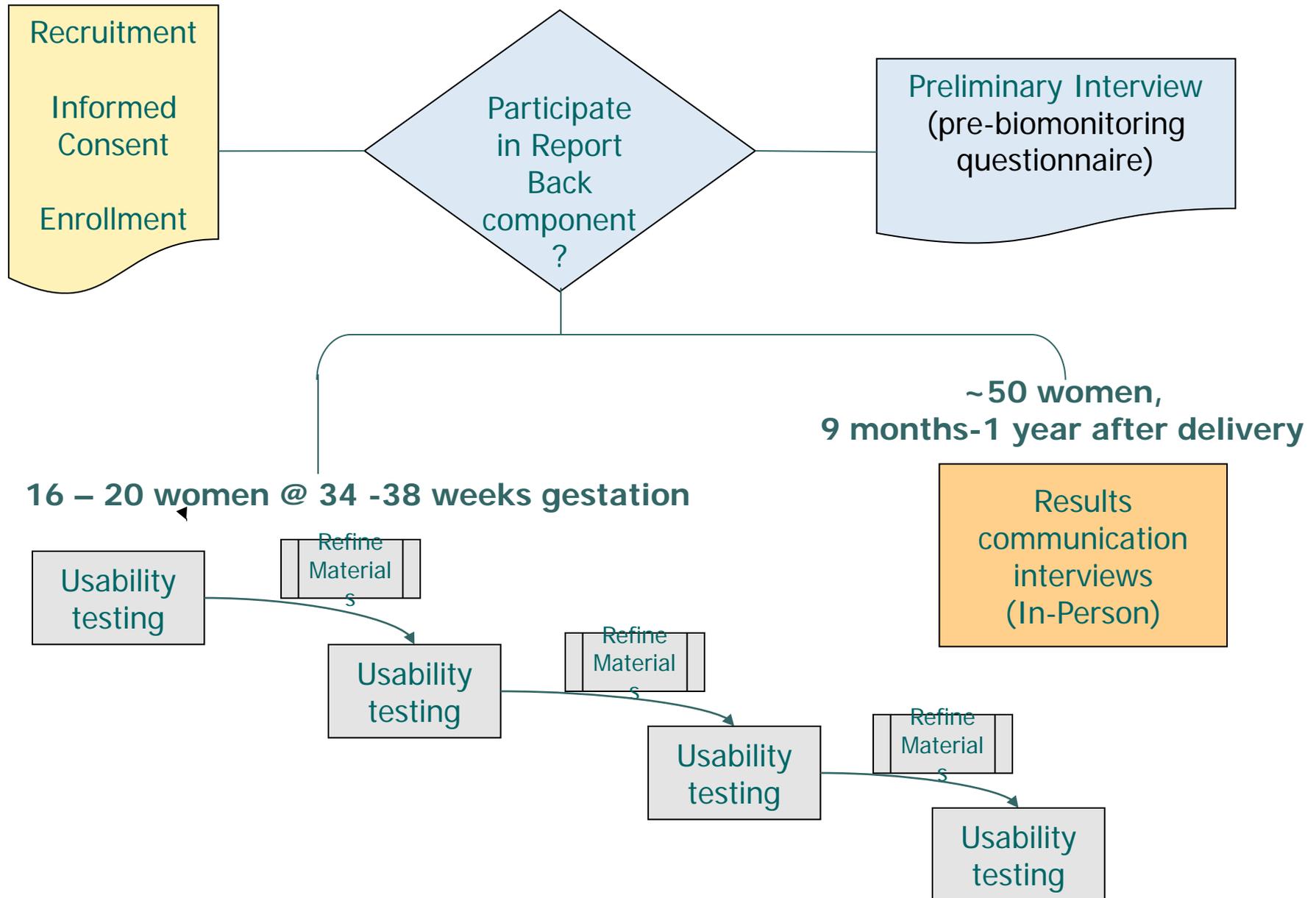
Chemicals in Our Bodies Project Design



Project Design: Report Back

- Participants indicated desire to receive results
- Receive by mail at two time points
 - 9 months-1 yr after delivery
 - **Results Communication Interview** with ~50 women
 - 18 months – 2 yrs after delivery
 - Participants will be provided name and contact information of designated UCSF or CECBP staff

Chemical in Our bodies – Report Back Component





● ● ● | Data Analysis

- Presence and distribution of levels of chemicals measured in pregnant women; compare with NHANES data for pregnant women
- Presence and distribution of levels of chemicals measured in infants (cord blood)
- Compare maternal levels to infant (cord blood) levels



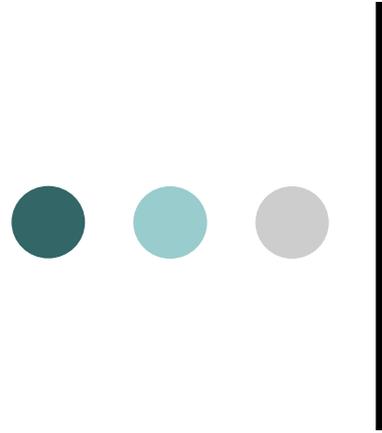
Data Analysis

- Demographic differences on chemical levels
- Associations between chemicals and exposure sources
- Relationships between perinatal outcomes and chemical levels
- Metrics of cumulative maternal and infant exposures to chemicals to be developed



Project Timeline

Jan 20, 2010	UCSF/UCB Institutional Review Board (IRB) Submission
Feb 18	CDPH IRB Submission
Mar	IRB Responses
Mar-Apr	Field test instruments and procedures
Apr	Submit revisions to respective IRBs
May-Jun	Begin recruitment
Dec	Complete all data and biospecimen collection
Jan 2011	Lab and data analysis begins
Oct 2011	Report generation

Three colored circles (dark teal, light teal, grey) and a vertical line.

Questions?