Informed Consent and Assent in PHACS:

Questions, Concerns, and Requirements

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* An accepted **moral rule**? Just **good manners?**

  or

* A **legal requirement**? A **contract** to be upheld?

  or

* A **summary** of the study? Handy **reference** tool?

* Something **beyond** all of this?

* What is informed consent really?

"Can they do *that*??"

* At two PHACS sites, why can't 18 year olds consent for themselves?
* How come one site assents children beginning at age 12, while another at age 7?
* Why do some sites only use an oral assent, while others use a written one?
* What do the U.S. federal regulations say?

* Why does consent and assent differ among sites?

What do the words mean?

- **Informed** – having information, educated, knowledgeable, achieving understanding
- **Consent/Assent –** agree, allow, give permission for something to happen or be done
- **Document/Form –** official paper that gives information or used as proof of something

* An accepted **moral rule**, just doing right?

  "Yes"

* Nuremberg Code, 1948. International document.
* Response to experiments on prisoners of war.
* Stressed ***voluntary*** participation and **consent** *before* medical research could occur.

* What is informed consent really?

A **legal requirement?**

"Yes" for the research team, and IRB.

* 1981- **Federal Law** – About how it's obtained
  * Code of Federal Regulations - **45 CFR 46.116,**

    (U.S. Department of Health & Human Services)
  * "*obtain legally effective informed consent*"
    * **Before** research starts
    * Given time to think over
    * Without sense of threat or too much reward
    * In language ***understandable*** to participant
    * **Written** document (signed; FDA signed, dated)

* What is informed consent really?

45 CFR 46.116 – Federal Law

Content requirements

(U.S. Department of Health & Human Services)

* Requires the informed consent to discuss
  * **8 distinct consent topics** for participants benefit: purpose and procedures, risks, benefits, alternatives, confidentiality, voluntary, medical treatment for injury, who to contact

* May include if applicable to study
  * **6 additional topics**: potential unknown risks, termination, withdrawing participation, # of participants, costs, new findings

* **What is informed consent really?**

A **legal contract?**

* You signed it - are you required to do everything to the end of the study?

* **"No"** for you, the participant.

* Your participation remains **voluntary** *throughout* the study.

* However . . .

* What is informed consent really?

Advantages of a written document:

* **Permanent record-** always can refer to, details explained, organized; risks, contact info
* **IRBs reviewed** – control of content
* **Legal document** – evidence that some requirements met for IRB, researchers

* What is informed consent really?

Problems with relying on just a written document:

* How "**understandable**" is it, really?
* What info to include or leave out?
  * *"If your Mom was in the study . . ."*
  * Too much vs. too little. No surprises.
* How to **move** info off the page **into** our **minds**?
  * Discussion, questions
  * Pictures, videos; quizzes on key points
  * Interactive electronic consent on laptop or IPad
  - Review, repetition very key
  - Checking understanding – informally or set method

* Beyond a written document

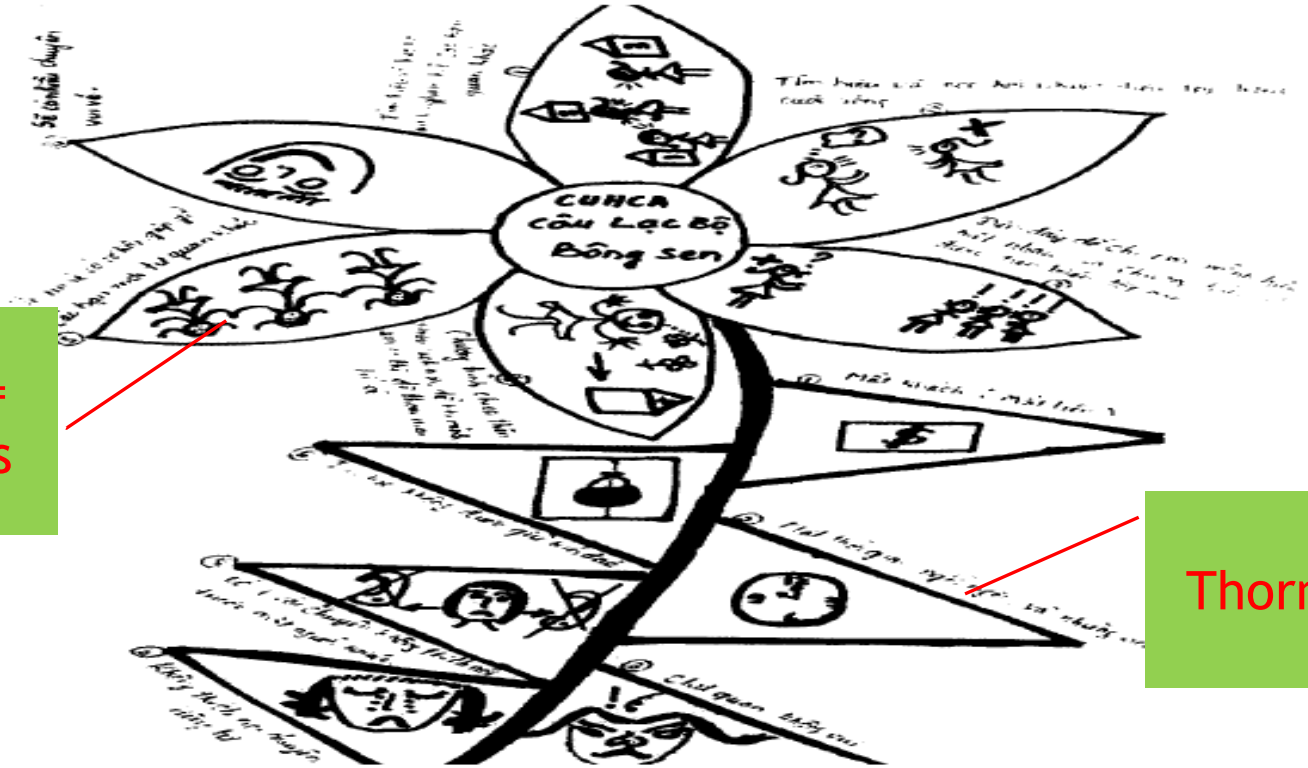
This chart shows how much blood we take at each visit for the study, what special tests are done, and how long you and your child will need for testing or to fill out forms:

Child's Age	Blood Collected for Tests Now	Blood Collected for Future Tests	Special Tests	Child Testing/ Forms*	Caregiver Testing/ Forms
Newborn	2 teaspoons	1 teaspoon	Collect dirty diaper		10 minutes
1 year old	½ - 1 teaspoon	1 ½ teaspoons		½ hour – 1 hour	1 hour
2 years old					½ hour
3 years old	1 – 1 ½ teaspoons	2 teaspoons	Mouth swab		½ hour
4 years old			(if not done at 3 years old)		
	teaspoons	2 – 2 ½ teaspoons	Mouth swab Possible echocardiogram (if not done at 3 or 4 years old)	2 – 2 ½ hours	½ - 1 hour
6 years old and every two years after that (i.e., at 8 years, at 10 years, etc.)	Phone interview with caregiver (1/2 hour) or face to face interview				
7 years old	1 – 2 teaspoons	2 – 2 ½ teaspoons	Mouth swab	1 hour	½ - 1 hour
9 years old	1 – 2 teaspoons	2 – 2 ½ teaspoons		1 – 1 ½ hour	½ - 1 hour
11 years old and every two years after that (i.e., at 13 years, at 15 years, etc.)	1 – 2 teaspoons	2 – 2 ½ teaspoons		2 – 2 ½ hour	½ - 1 hour

Use of Table – tests, time, blood summarized per visit

* Beyond a written document

Figure 1: The Flower Diagram[32]



Petals = benefits

Thorns = risks

Petals

- Learn more about women in other brothels.
- Get new information.
- You will learn more about us and life in Svay Pak.
- We will learn more about you.
- We can come here to "ease our mind" and talk to someone.
- Make new friends, have fun.

Thorns

- During the time spent participating, the opportunity to be with clients would be lost.
- Loss of leisure time usually spent napping, relaxing, socializing.
- Some (other) brothel managers might not be happy with sex workers who miss time with clients.
- Talking about some topics in front of other women can be dangerous. If managers or other sex workers heard some of the information that was supposed to be confidential, it could be damaging.

* Beyond a written document

Wood Sy, Friedland Ba, McGory CE. *Informed consent: from good intentions to sound practices*. New York: Population Council; 2001. P. 8-10.

Electronic consents: sound, video, quiz checks, privacy

* Beyond a written document

Federal Regulations?

* Lets **state law** dictate age requirements.
  * Age of consent and assent for **"medical treatment"**

  (the same state may have different "adult" ages for marriage, alcohol, criminal and financial liability)
* Law usually applied to "medical **research**"
* For Consent – most states, 18 years of age
  * Alabama, Nebraska – 19 years of age
  * Puerto Rico – 21 years of age

* Why does consent and assent vary from site to site?

Age of Assent

* State law **varies** widely
  * Federal regulations: vague; when and how per local law
  * Children mature at different rates, ages
  * Experts disagree – children's rights; a little understanding worthwhile?
    * Age 6 or 7 vs. age 12 or 14?
  * IRBs – as **policy**, can require stricter rules;
    - **per protocol**, stricter or remove requirement
  * Investigator – may need to adapt per child's abilities.

* Why does consent and assent vary from site to site?

Assent Content and Method

Federal regulations - brief, vague

* "**Assent**" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR 46.402(b))

* No federal requirement for documentation

* IRB – *decides* all: what info, how it's done
  * Oral, written, not at all

* **Why does consent and assent vary from site to site?**

Placed at end of site informed consent document

ASSENT DISCUSSION (Required for participants 7–13 years old)

☐ The assent discussion was initiated on _____(date) at _____ (time).
- ☐ The information was presented in age-appropriate terms.
- ☐ The minor agreed to take part in the study on _____(date) at _____ (time).

☐ An assent discussion was not initiated with the minor for the following reason(s):
- ☐ Minor is under 7 years of age.
- ☐ Minor is incapacitated.
- ☐ Minor refused to take part in the discussion.
- ☐ Minor declined to take part in the study. The minor declined for the following reason(s):

_____

☐ Other_____

RESEARCHER/DESIGNEE STATEMENT: I have discussed the research project with the research participant and his/her parent(s) or legal guardian(s). I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the research participant was encouraged to ask questions and that all questions were answered.

_____ _____ _____
Researcher/Designee signature Date Time

_____
Print Name

* Example of an oral assent process

Informed Consent and Assent

* Moral codes, ethics; good manners
* Federal law - content, method for informed consent
  - very vague for assent
* Legal document
* Summary, reference tool
* Beyond a document – towards understanding
* ***On going process, before and during study***
* Differences from site to site – State law, IRB policies

* In Summary – Questions?