Ethics, IRBs, and Network Research

Why we need to think about ethics in our projects

New York Times SEP 08, 2001

Scholar Sets Off Gastronomic False Alarm

By JOHN KIFNER

When Jean-Claude Baker, the owner of Chez Josephine, got the letter, he was, he said, "devastated."

It was a restaurateur's nightmare: a patron celebrating his wedding anniversary -- a Columbia professor no less -- said he had been sickened. "Extended nausea, vomiting, diarrhea and abdominal cramps all pointed to one thing: food poisoning," the letter said.

"Our special romantic evening became reduced to my wife watching me curl up in a fetal position on the tiled floor of our bathroom between rounds of throwing up," the letter, on Columbia Business School stationery from Frank Flynn, professor of organizational behavior, went on.

Chez Josephine's chef, Marvin James, was, if anything, even more heartbroken.

"My ego was hurt. I thought we had let Jean-Claude down," Mr. James said. "I ripped my cooks apart."

Unknown to the Chez Josephine crew, similar scenes were being played out at restaurants all over town -- 240 of them, Columbia now says -- that received the identically worded, totally fictitious letter from Professor Flynn as part of a study to determine how they responded to complaints.

The consequences…

- A LOT of yelling and reprimanding
- Closing of kitchens in some of the highest ends restaurants in NYC
- Time spent trying to identify when the problem happened
- Visits from the NYC Public Health Department, some of which required stool samples from kitchen employees
- A lawsuit was filed against Columbia University

A possible consequence that didn’t happen

- ALL federally-funded research at Columbia University is shut down for an entire year
- Happened at Johns Hopkins University

Lesson

- We need to think through the potential implications of our research on the people and organizations we choose to study
- We need to minimize any potential damage to our study subjects

Institutional Review Boards

- IRBs are one mechanism that has been established to help with protecting subjects
- Set up primarily to deal with medical research
- Our research is something of a nuisance for IRBs
  - While it doesn't fit neatly into their normal methods for conducting research…
  - …if we make an IRB-related mistake, it threatens the medical school researchers

Growing power of IRBs

- IRBs have grown in size and stature ever since the Johns Hopkins case

How to get your network study approved by an IRB

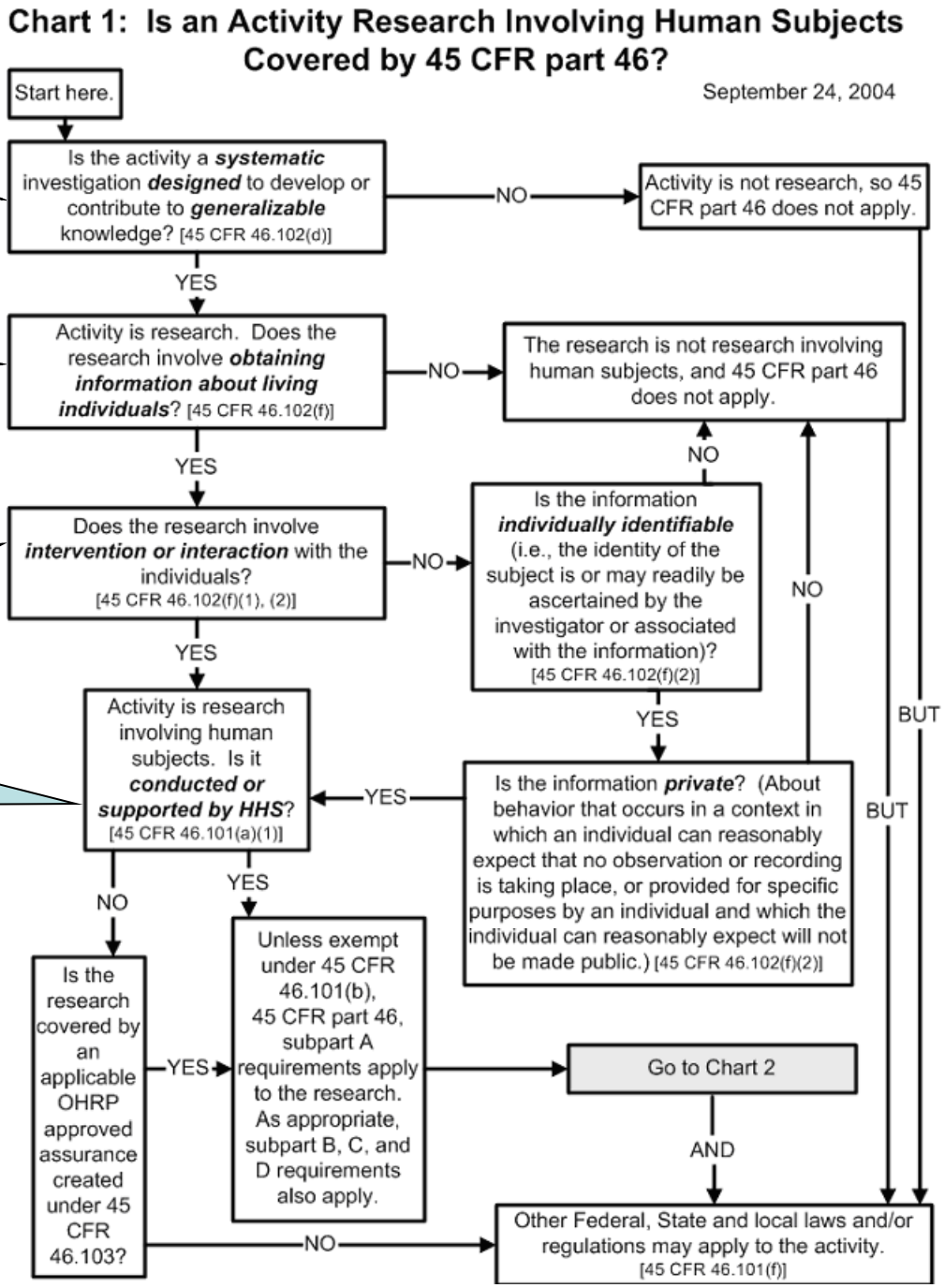
- Begin by figuring our whether you need IRB approval at all
  - Exempt review
  - Expedited review
  - Full board review
- Use the decision charts provided by Office for Human Research Protections (OHRP) in the Health and Human Services (HHS) Department.
- http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

Interviewing a few people about how they network might not count

The DeMedici's don't count. September 11 suicide terrorists don't either.

Suggests that doing research on Facebook is EXEMPT, as long as the information is not individually identifiable

However, many IRBs overstep their bounds because they argue that some people could interpret behavior as private behavior



IRBs are very sensitive to the idea that a subject might be coerced into participating; this is particularly so for prisoners and minors

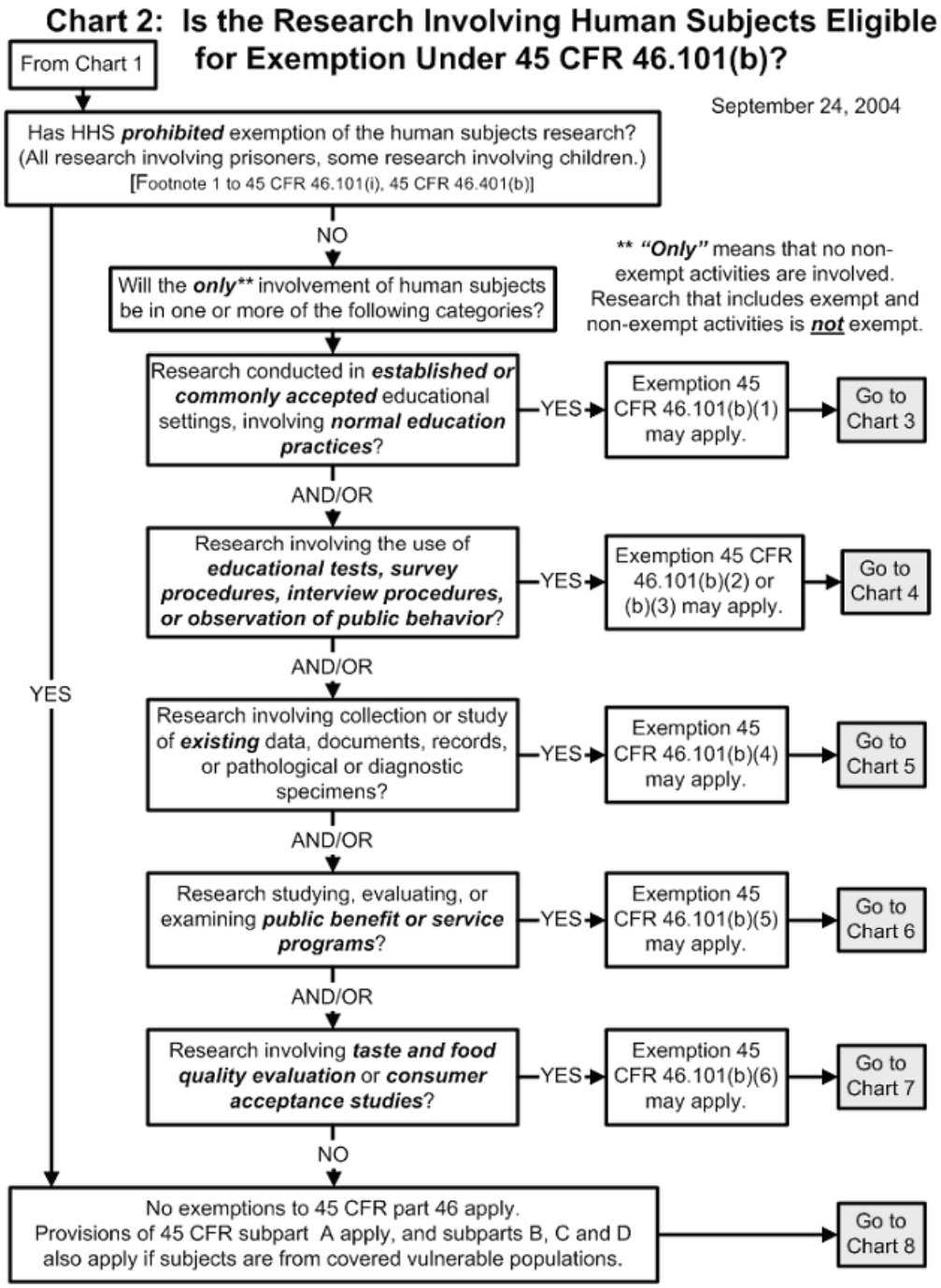


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Notice that collecting network data in classrooms is NOT exempt; you'll likely need to do an expedited review

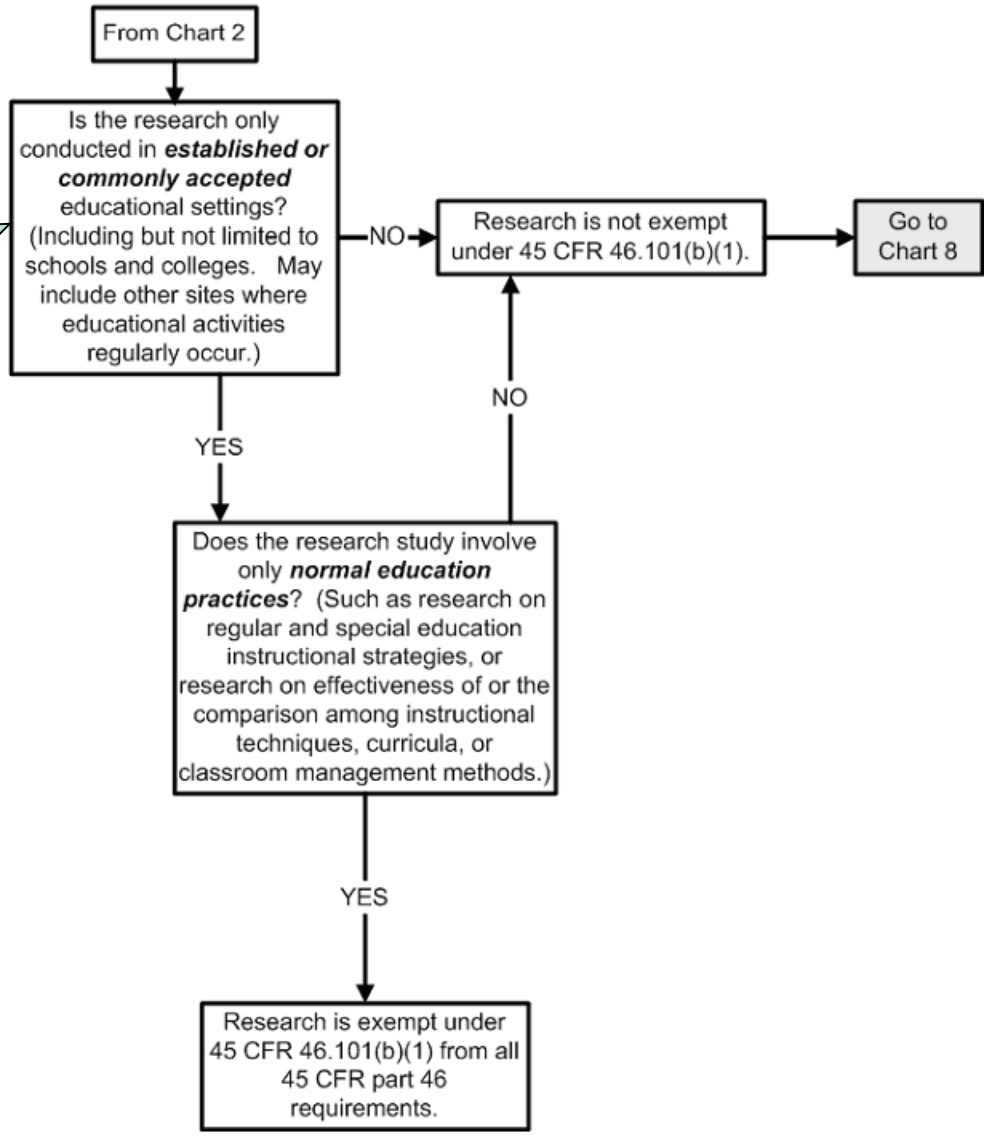
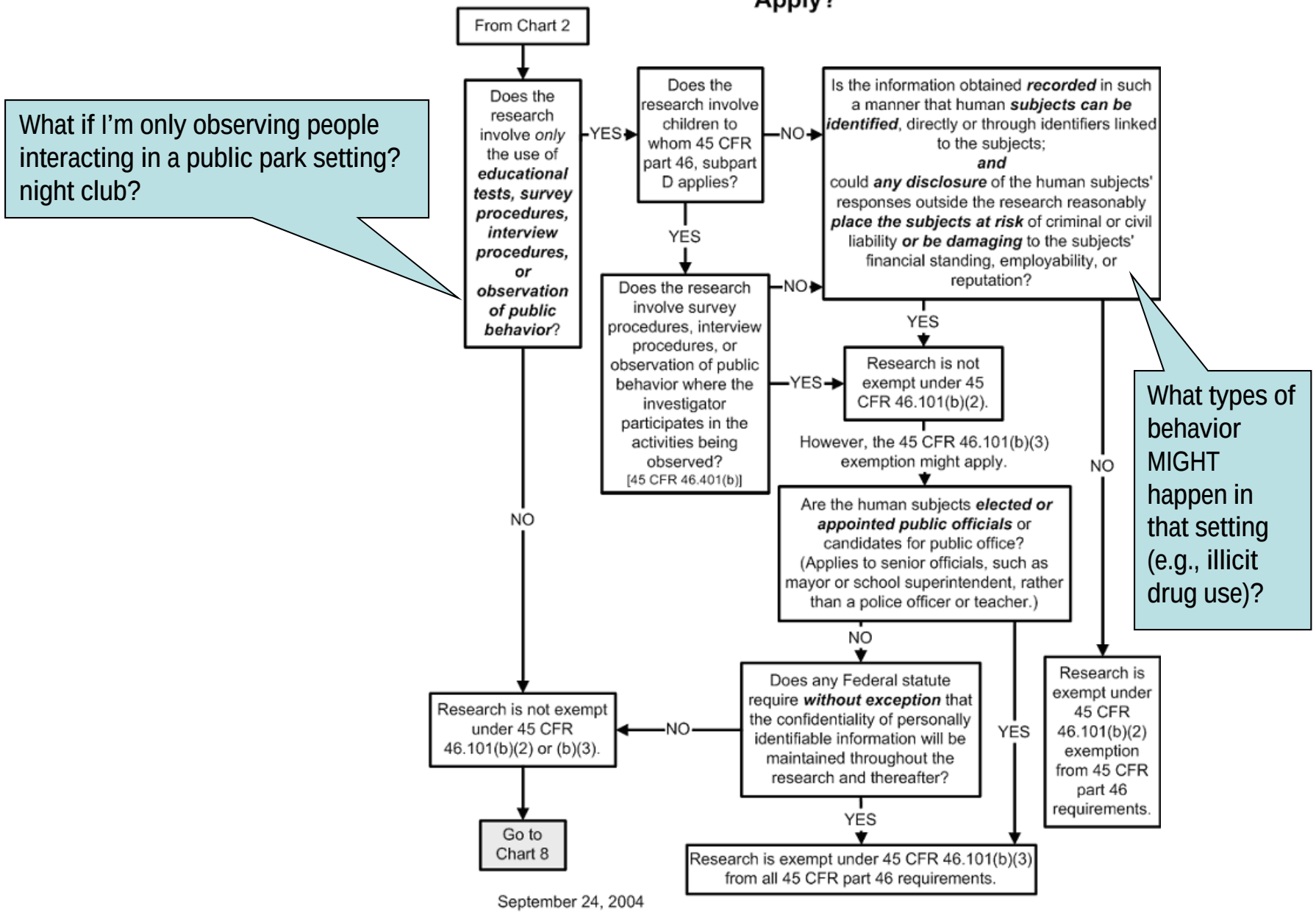
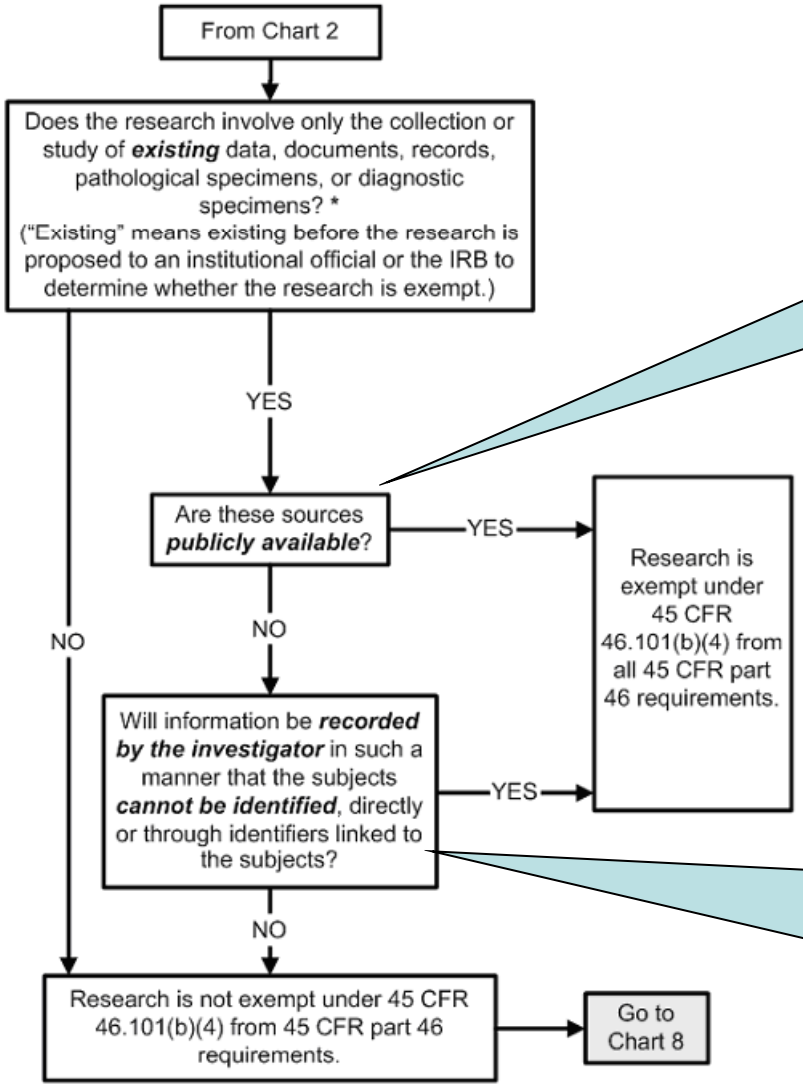


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



September 24, 2004

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



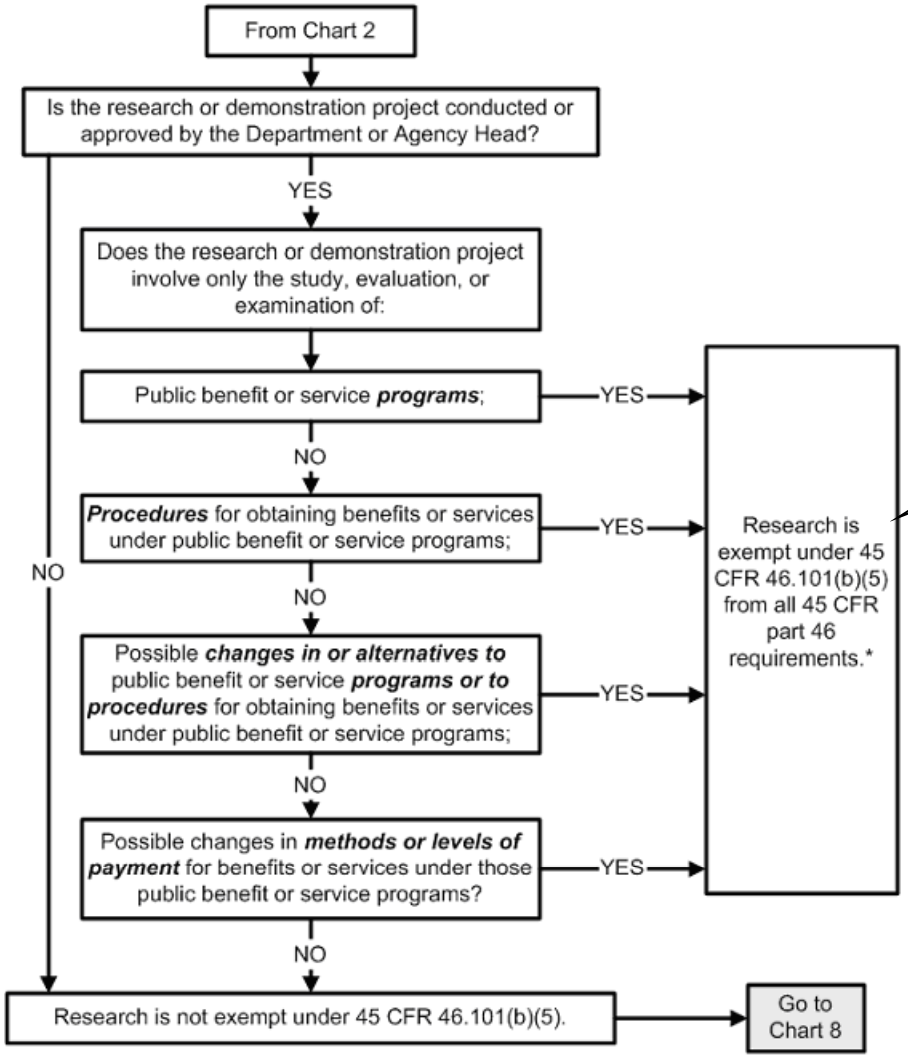
* Note: See **OHRP** guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.html#tissues and #stem, and on coded data or specimens at #coded for further information on those topics.

September 24, 2004

What about research on citation networks? It's publicly available, existing data on living human beings. Therefore, it's exempt from IRB regulation.

What about network research on who played together on YMCA softball teams and subsequent PTA involvement? Since YMCA rolls are not publicly available, you need to collect the data in an unidentifiable manner. Technically, exempt, but useful to go through IRB approval.

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

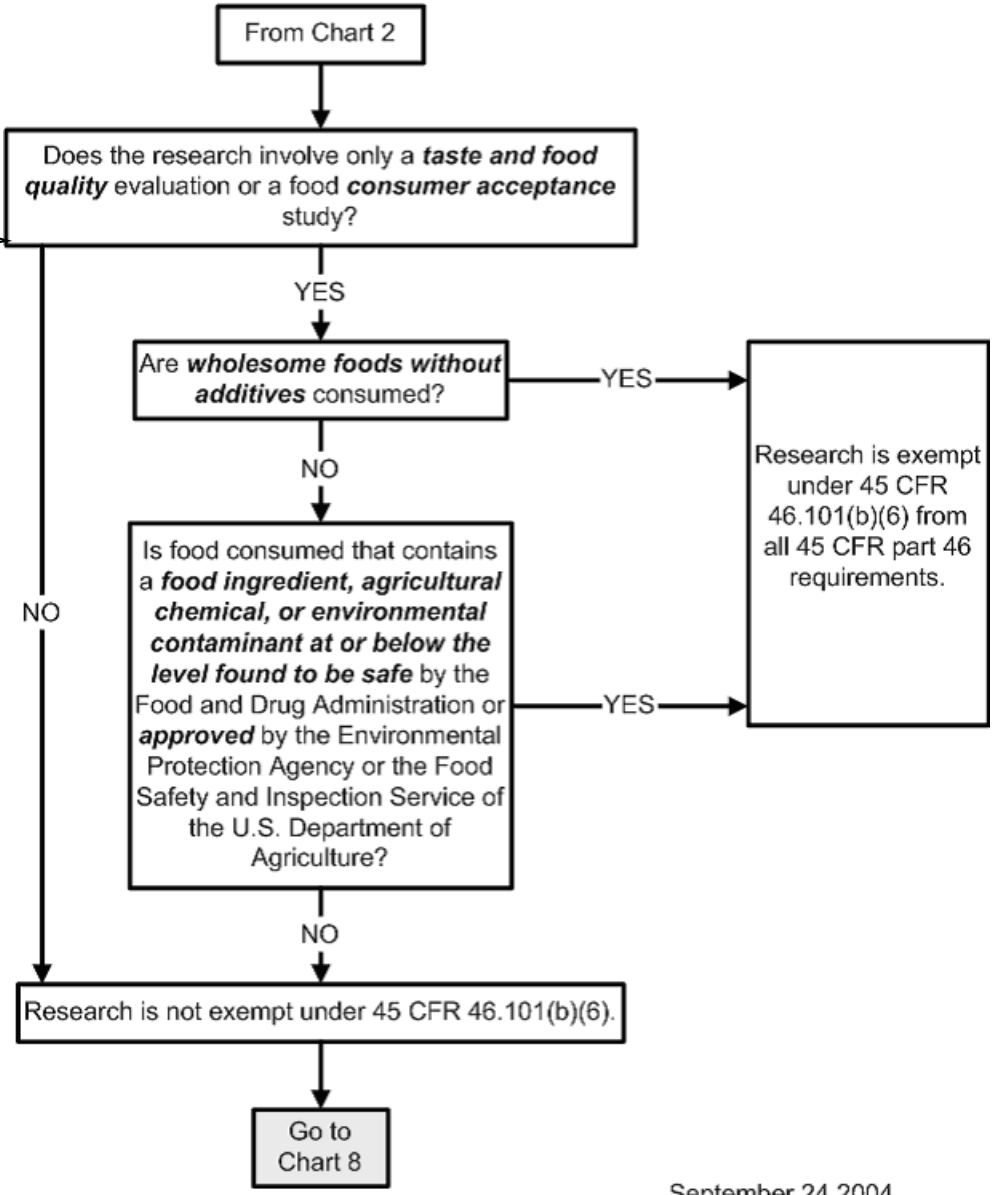


Examples here might include studies of how well the new Cash for Clunkers program works. Hard for me to imagine how this would apply to network research.

* Note: See **OHRP** guidance on exemptions at http://www.hhs.gov/ohrp/policy/index.html#exempt for further description of requirements for this exemption.

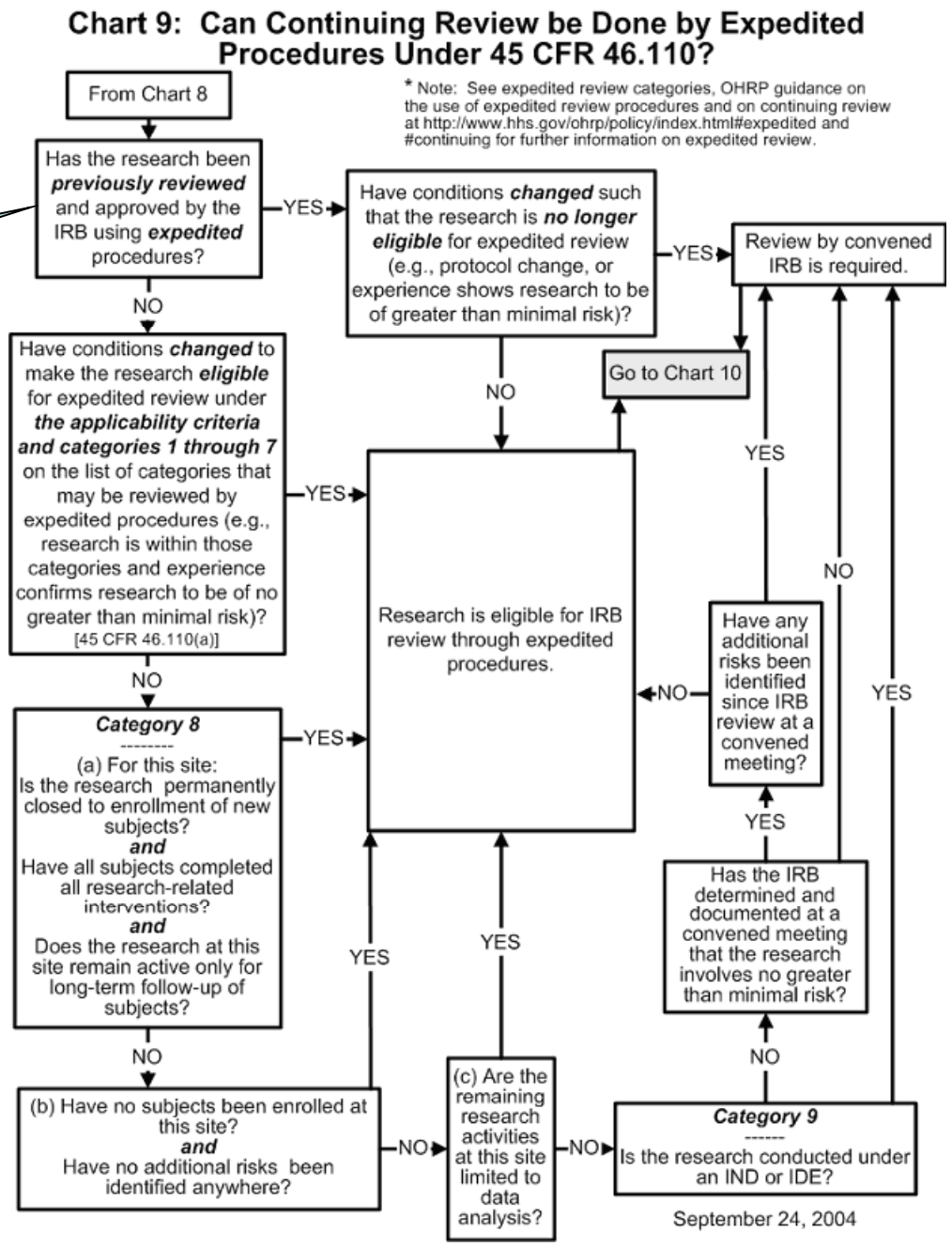
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

For the marketing researchers among us...



September 24 2004

If your project was previously reviewed by the IRB through expedited procedures, maintain your IRB approval (often needs to be done on an annual basis)



MAJOR issue for IRBs; their preference is to ALWAYS have a signed informed consent form on file, with minor exceptions

Your definition of "greater than minimal risk" is probably a lot more liberal than an IRB's

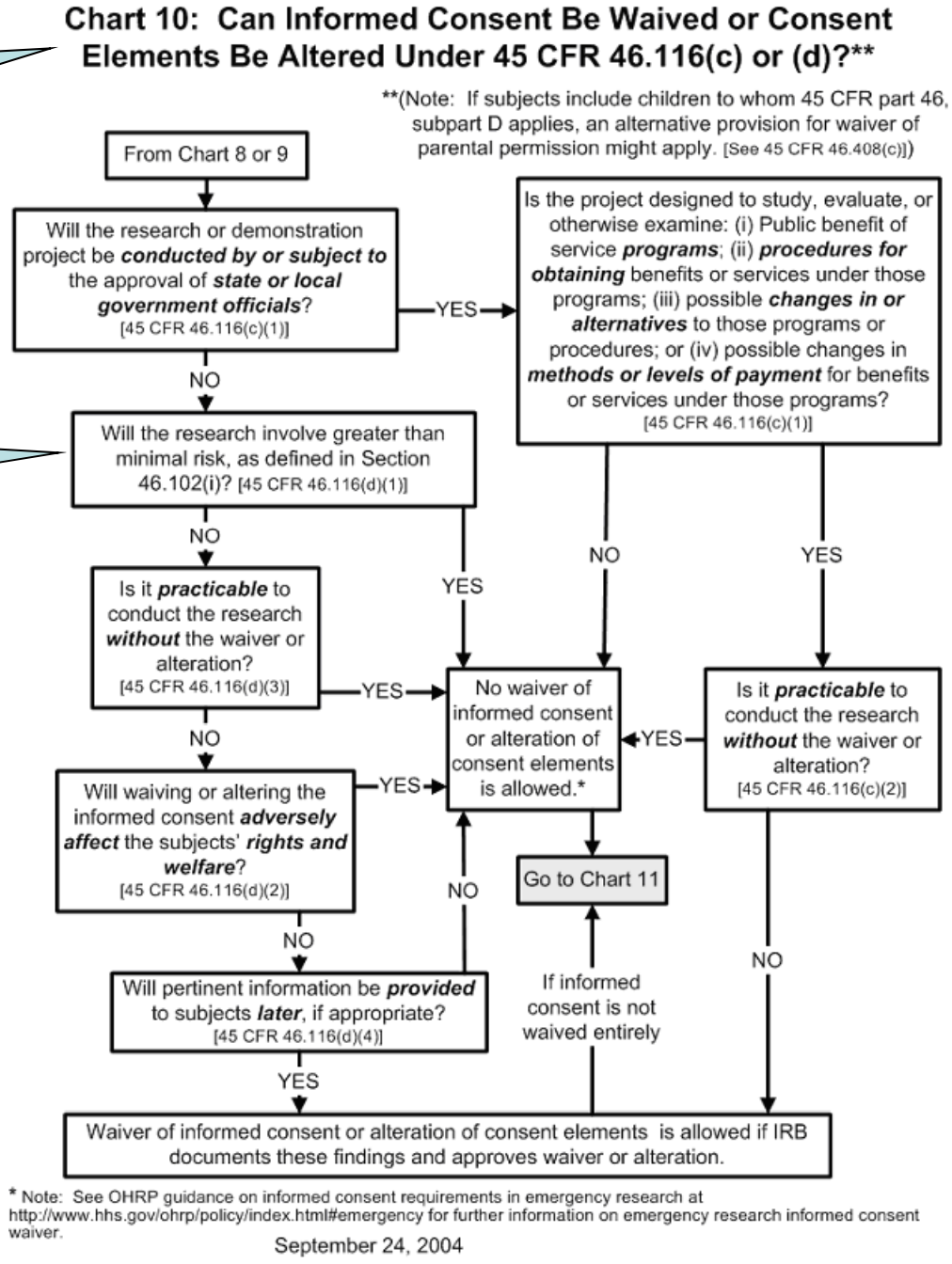
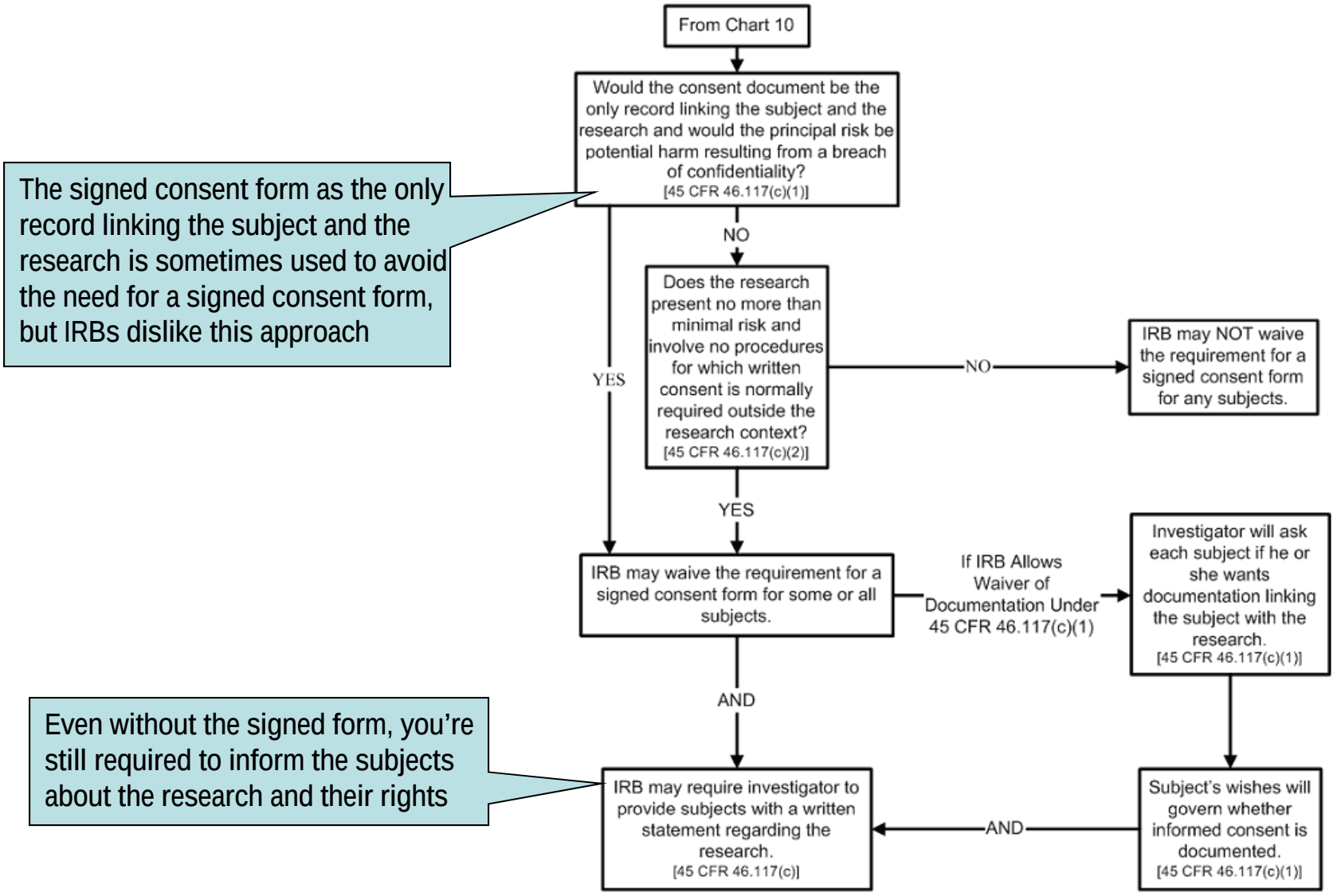


Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



The signed consent form as the only record linking the subject and the research is sometimes used to avoid the need for a signed consent form, but IRBs dislike this approach

Even without the signed form, you're still required to inform the subjects about the research and their rights

September 24, 2004

After IRB approval

- Apply for a Certificate of Confidentiality through the NIH
  - Prevents your research from being subpoenaed by any court of law
- See the following website for more information:
  - http://grants.nih.gov/grants/policy/coc/
- Your institution's IRB officer should be able to help you with application

Examples

- Example presentation to potential subjects
- Example consent form

FAQs

- What if the company wants us to report back with names?
  - Negotiate that you won't do this ahead of time
  - One way to do that is to complete a "contract" ahead of time (see Borgatti & Molina, 2005)

FAQs

- Some members of the organization are upset that their names are on the roster. What do I do?
  - There is nothing wrong with collecting a person's perceptions of others
  - You don't need the alter's informed consent
  - However, if you want, you can intentionally exclude the data on that person

FAQs

- The data are confidential, but not anonymous. How do we ensure that it doesn’t leak out?
  - Use ID numbers, rather than names
  - Use a different set of ID numbers in the analytical dataset, as compared to what is collected originally

Multiple ID numbers

"To further assure confidentiality, we will be working with two separate files:

- File 1 – A list of the employees' names along with a random three-digit code that has been assigned to those names will be provided to the organization's HR department by Kristin Scott. File 1 will be destroyed once File 2 is created.
- File 2 – Contains employee survey information matched with data requested from the HR department (i.e., performance appraisal, promotion and turnover data). In this file, the employee is only identified by the random three-digit codes provided in File 1."

Questions?