Study Background:
Thank you for agreeing to participate in this focus group. The purpose of this focus group is to understand your perspectives on the ethical aspects of research on standard medical practices, including randomization within standard care. We know that you have very busy schedules and we appreciate your willingness to participate in today’s discussion. This focus group is part of a larger study that we hope will provide much needed empirical work to inform policy. The specific goal of this focus group is to help us identify key issues that we will address in a broad survey of IRB members nationwide on the ethics of research on medical practice, as well as surveys of patients and the general public.

1. Introductions
Each person here has important expertise and we hope that you will all actively participate in the discussion. We would like to take a few moments for introductions. Could you please introduce yourself by giving us your first name and your professional background?

2. Warm Up Questions: Defining “Research on Medical Practice”
As a warm-up exercise, we would like to begin with a discussion of what research on medical practice means? We are less interested in the label and more interested in thinking through what activities count as research on medical practice as opposed to more familiar types of research. Consider these activities:

- Comparative Effectiveness Research
- Quality Improvement
- Learning Health Systems
- Standard of care
- Standard care
- Routine care
- Usual care

Example: A comparative effectiveness study across three regional hospital was conducted to determine the relative efficacy of three drug interventions that are currently being used to treat hypertension, but about which we still lack data on relative effectiveness. The aims were: To determine whether treatment with Drug A or Drug B, lowers the incidence of coronary heart disease or other cardiovascular disease events vs Drug C. Participants aged 55 years or older with hypertension and at least 1 other CHD risk factor were randomly assigned to receive Drug A, Drug B, or Drug C and followed for four years.

What type of distinction can be made between what is research and medical practice?

Probes:
- What types of activities would research on medical practice include?
- What are some examples of when standard care practices should be characterized as research?
c. What are the distinctions between clinical care data collected for quality control/improvement and comparative effectiveness?

d. Is there language that would better describe these types of activities?

With such activities in mind, could you share your perspective on the ethical issues related to the following approaches to studying medical practice?

- **Idiosyncratic Practice**
  - Each provider decides how to treat initial hypertension followed by a retrospective review of the impact of clinical practice variation. This is can also involve networks of providers at different sites.

- **Standard Clinical Work**
  - All providers agree to use a standard approach to treat hypertension with ongoing review of outcomes and implementation of revised standard approaches.

- **“Cluster” Randomization**
  - Networked sites agree to that each site will be assigned a particular approach to treat hypertension and data will be shared between.

- **Point of Care Randomization**
  - Providers agree to randomize eligible patients to different treatments for hypertension.

*Probes:*
  a. Are the ethical issues different? Why or why not?
  b. In your experience, what specific challenges are associated with these approaches?

3. **Identifying Risk**

Should the risks of standard practices be considered research risks in the context of research on medical practice?

*Probes:*
  a. Are there differences between risks in the context of clinical research vs. research on medical practice? Why do you feel think these risks are or are not different? What are examples?
  b. What are the factors that help you to identify risk in the context of research on medical practice?
If not mentioned, probe factors related to the population (vulnerable/non-vulnerable, low-resource setting).

How do you weigh obligations to respect patients with providing optimal care and assessing variation in clinical approaches?

Probes:
- a. What do you believe are patients’ perspectives on research on variation in clinical approaches?
- b. If and when should patient preferences play a role in how research is conducted?
- c. How should different types of risks be characterized to patients?

When there are randomization procedures, do the quality and level of risk change?

Probes:
- a. Does randomization itself present a risk?
- b. Are there instances when randomization would not change quality and/or level of risk?
- c. How do you think patients and families perceive risk in this context?

4. Consent and Waivers
Should consent forms disclose standard care risks and randomization activities in the context of research on medical practice?

Probes:
- a. What information should be disclosed? Should a scientific rationale for assessing variation be provided?
- b. Should the activities be characterized as “quality improvement”, “research” or some other set of terms?
- c. How should information be disclosed?
- d. When should patients be notified of these activities?
- e. Are there cases when disclosure would not be necessary?

As an ethical matter, would it be acceptable to “waive consent”?

Probes:
- a. In what context, would waiving consent be ethically appropriate? Would data collection alone be a context where consent could be waived?
- b. Are there conditions or contexts when waiving consent is never acceptable?
- c. How should such decisions be made?
- d. Would other modes of providing information be acceptable – such as notification?
  - i. Broad Notification - opt out or in
  - ii. Specific Notification – opt out or in
- e. What other educational opportunities or information sharing should be utilized outside of the formal consent/notification process?
How important is it to have input from patients/participants into research practices? For example, should a patient advisory be used and if so, what would they do, what types of issues might they address?

**Probes:**
- a. What kind of authority or power should be given to a patient advisory group?
- b. How important is it for patients/participants/community to learn about ongoing research activities within the clinical settings?
- c. How important is it for patients/participants/community to learn about interim or final results of research on medical practice?

**5. Oversight Measures**

What types of oversight of research on medical practice are currently in place?

**Probes:**
- a. Who is responsible for oversight?
- b. What information should be captured by oversight?
- c. Are there different levels and quality of risk where oversight should be required?
- d. Who is responsible for overseeing how research findings are acted upon in changes in practice? (interrupted flow)
- e. How do you know when oversight has been successful?

How might oversight of research of medical practice be improved?

**Probes:**
- a. Are there gaps or problems in current oversight approaches?
- b. What information should be provided to patients regarding oversight?
- c. What might be the role of community advisory boards for oversight?
- d. Are you aware of effective models of oversight? Could you describe what makes these successful?

**Wrap Up and Final Comments**

Thank you for participating in this focus group. To reiterate, your comments will be anonymized in the transcription process. If you have any follow up questions regarding what we have discussed, please do not hesitate to contact us.