

NIH Collaboratory

Health Care Systems Research Collaboratory

Collaboratory Coordinating Center Ethics of Standard of Care Research

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Rethinking Clinical Trials



Collaboratory Coordinating Center Ethics Supplement Team

- PI: Rob Califf
- Project leads: Jeremy Sugarman and Kevin Weinfurt
- Duke
 - Laura Beskow
 - Kate Brelsford
- Johns Hopkins
 - Juli Bollinger
 - Matt DeCamp
 - Rachel Dvoskin
 - Nancy Kass
 - Dave Kaufman
 - Debra Mathews

Policy Questions

1. What things are referred to as “usual care” or “standard of care” research?
2. What kind of oversight is needed for research on standard health care practices?
3. What kind of consent/notification is needed for research on standard health care practices?

I. What things are referred to as “usual care” or “standard of care” research?

What are the varieties of such interventions?

Do the different varieties differ in important ways?

Ethically

Scientifically

Requires careful conceptual analysis

Not a primary focus of our empirical work

2. What kind of oversight is needed for research on standard health care practices?

2a. Which types of learning activities require oversight (and why)?

2b. When should the oversight take place (and why)?

2c. Who should conduct the oversight (and why)?

2d. How should the oversight occur (and why)?

3. What kind of consent/notification is needed for research on standard health care practices?

3a. Which activities require some kind of consent/notification (and why)?

3b. What model of consent/notification is acceptable for different activities (and why)?

3c. Practical issues concerning when consent/notification should occur, who should be involved, and how the consent/notification should occur

Framing the Issues

Avoid language of “research,” “care,” “quality improvement,” etc.

Our working frame = *Healthcare Encounter(s)*
Describe various ingredients of each scenario within encounter(s)

Need to explore the effect of changing the frame

Literature on Decision Making in Clinical Care



Consent

**Shared Decision
Making**



<i>High</i>	<p>Shared Decision Making: ABSENT</p> <p>Consent: INFORMED</p>	<p>Shared Decision Making: PRESENT</p> <p>Consent: INFORMED</p>
Risk	<p>Shared Decision Making: ABSENT</p> <p>Consent: SIMPLE</p>	<p>Shared Decision Making: PRESENT</p> <p>Consent: SIMPLE</p>
<i>Low</i>	<p><i>High</i> Uncertainty <i>Low</i></p>	

Adapted from Whitney et al, 2004

Questions Motivated by Shared Decision-Making Literature

When is shared decision-making most needed?

- Medical uncertainty

- Preference/value-sensitive tradeoffs

What is patient's desired role in decision making for different scenarios?

What types of communication are viewed as acceptable by patients for different scenarios?

Wide Range of Potential Activities

Usual care by provider

Retrospective or prospective collection and analysis of data in EHRs

Medical center operations

Clinician education/support

RCT of approved interventions

... and more

Wide Range of Approaches to Decision Making and Consent

*General notification
upon entering health
system*

Oral discussion

Written information

Opt-out

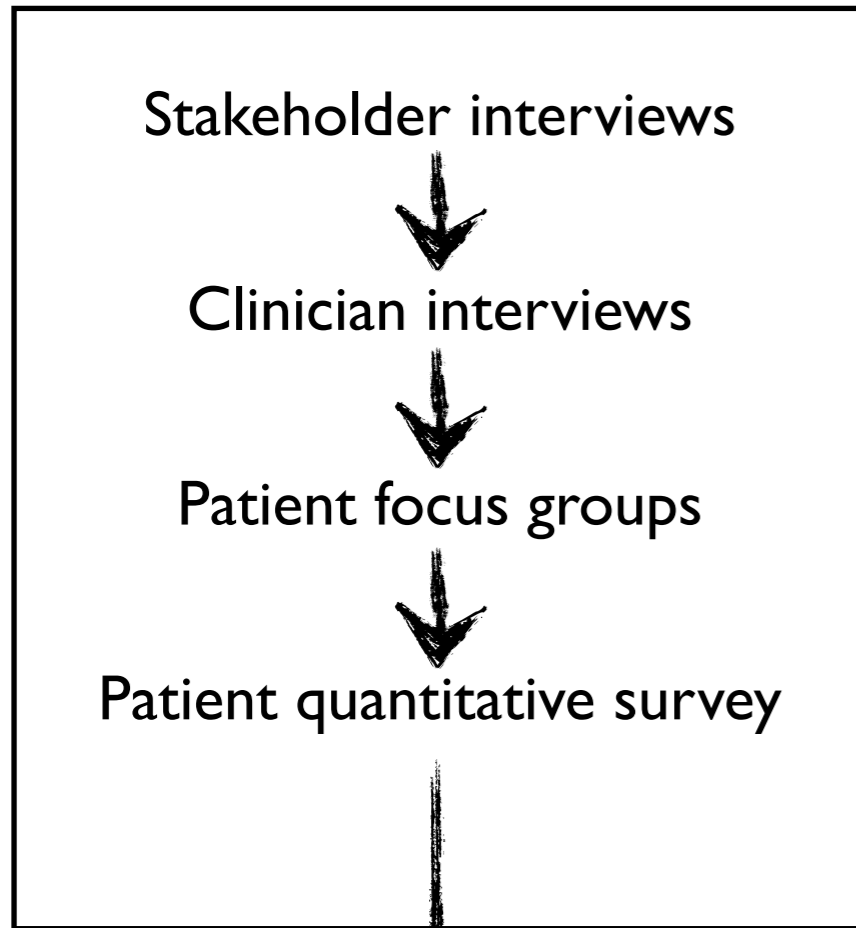
Written informed consent

Oral consent

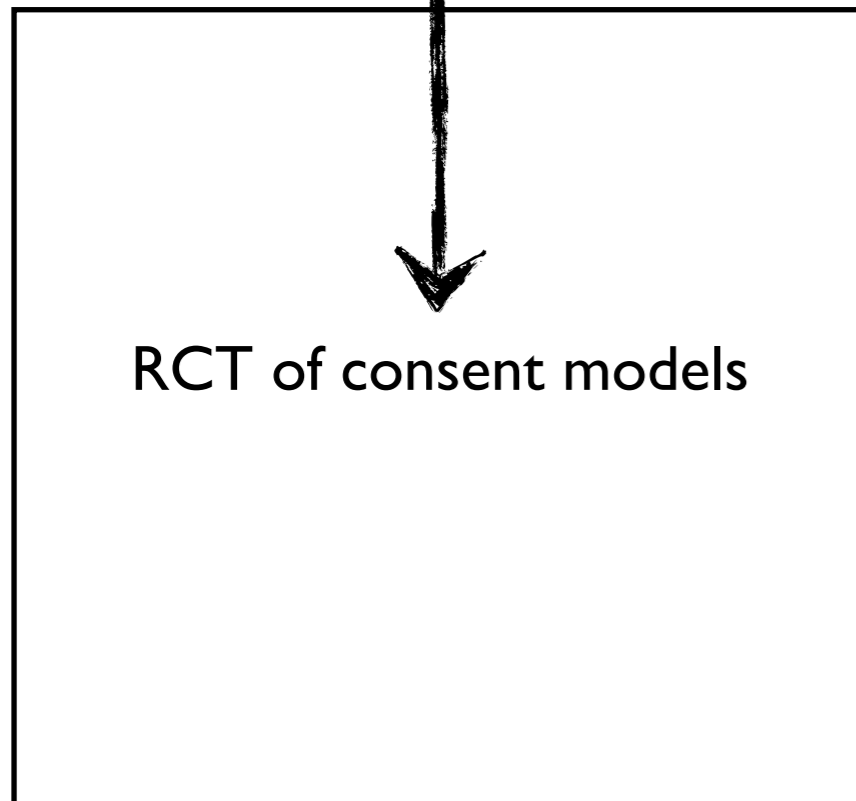
... and more

Original Plan

Year 1

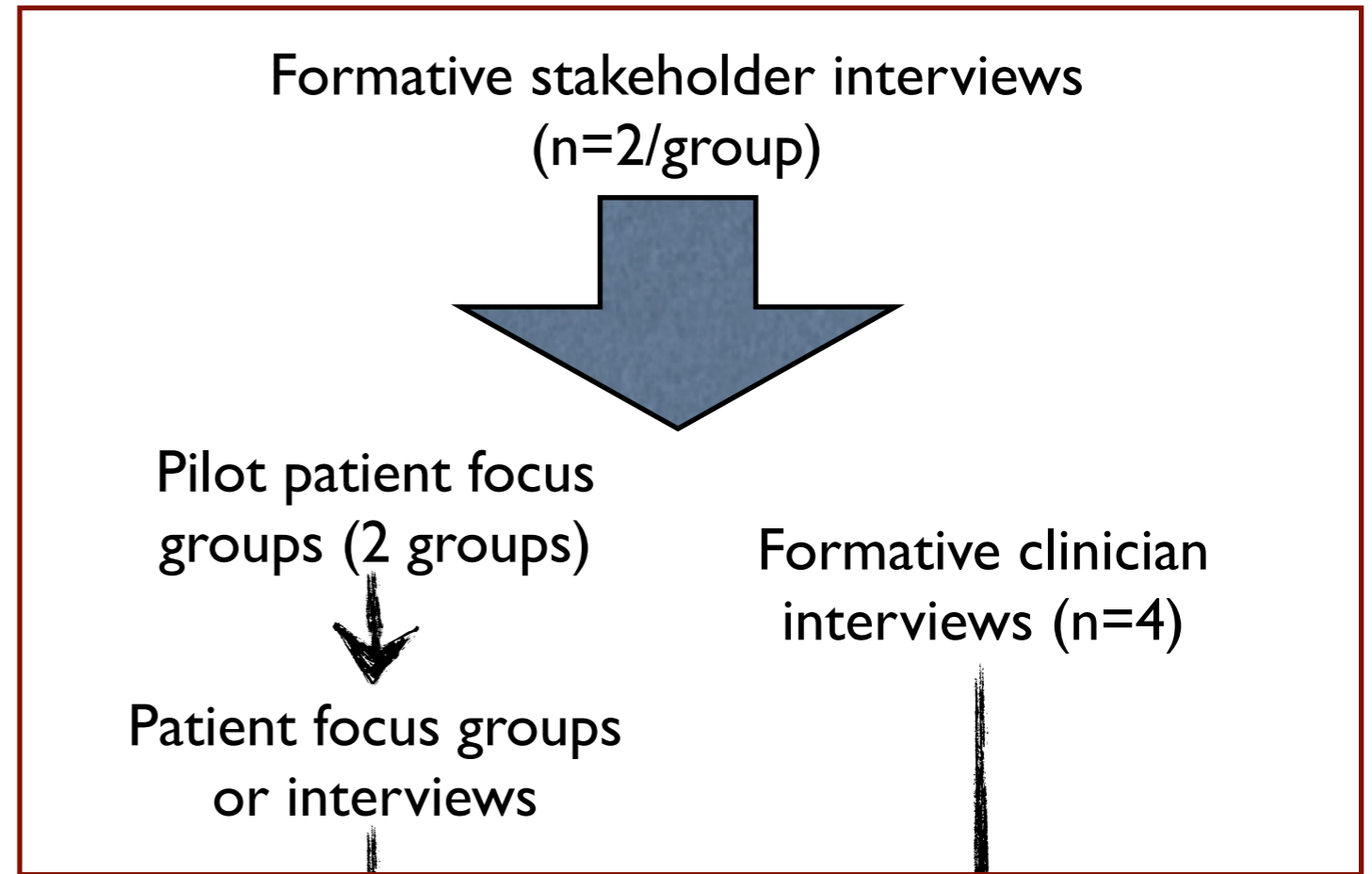


Year 2

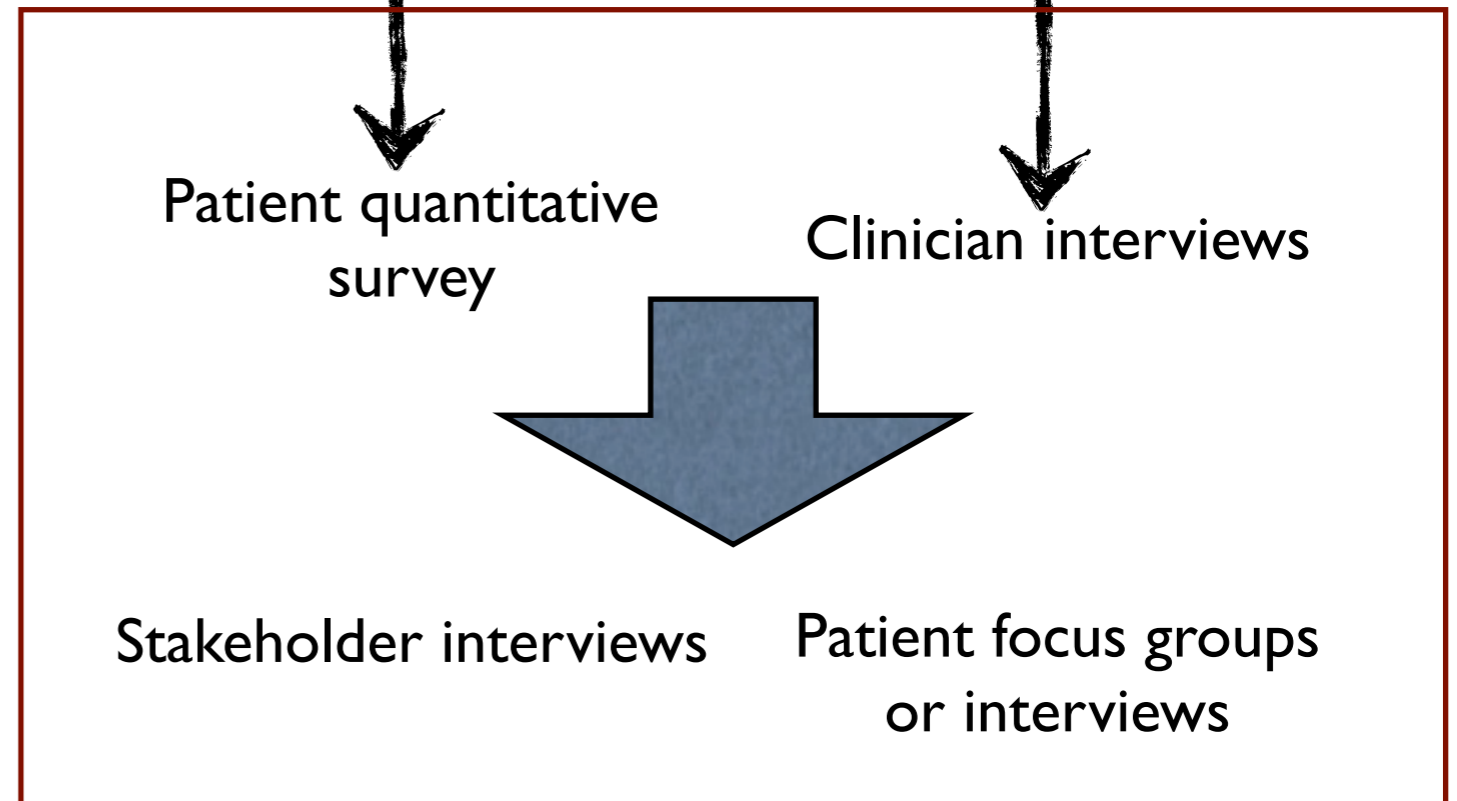


Proposed Revision

Year 1



Year 2

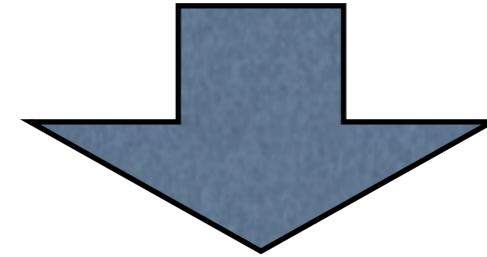


Proposed Revision

Ensure the general policy problems are identified.

Year 1

Formative stakeholder interviews
(n=2/group)



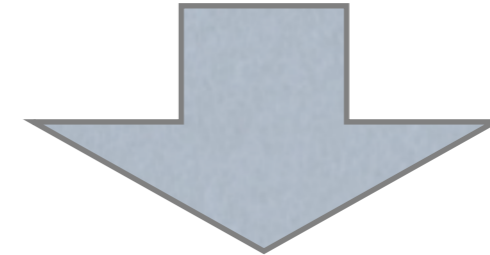
Year 2

Proposed Revision

Understand patient perceptions and interests concerning acceptable kinds of consent/notifications for different situations.

Year 1

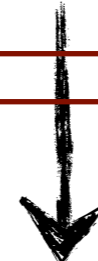
Formative stakeholder interviews
(n=2/group)



Pilot patient focus groups (2 groups)



Patient focus groups or interviews

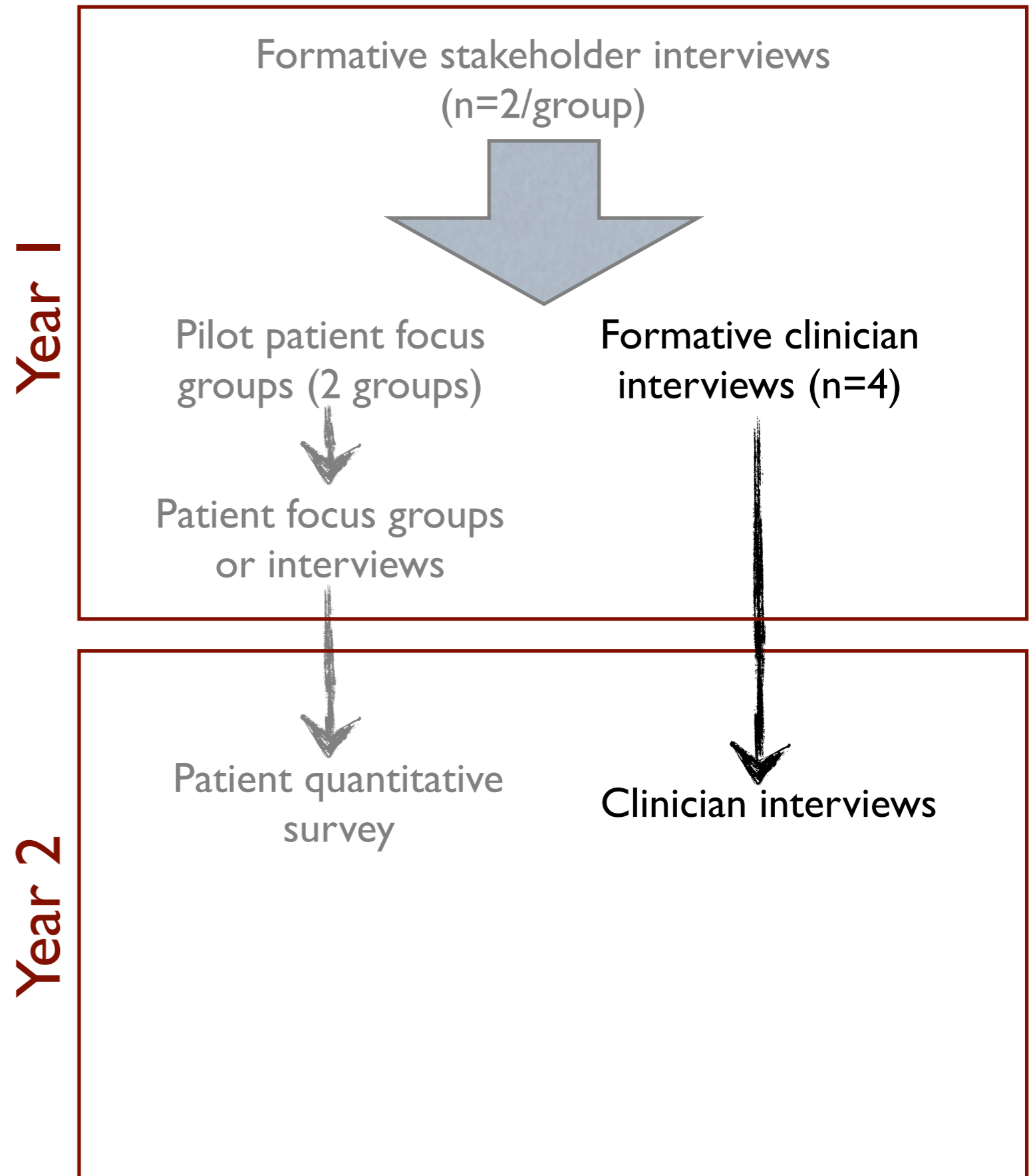


Year 2

Patient quantitative survey

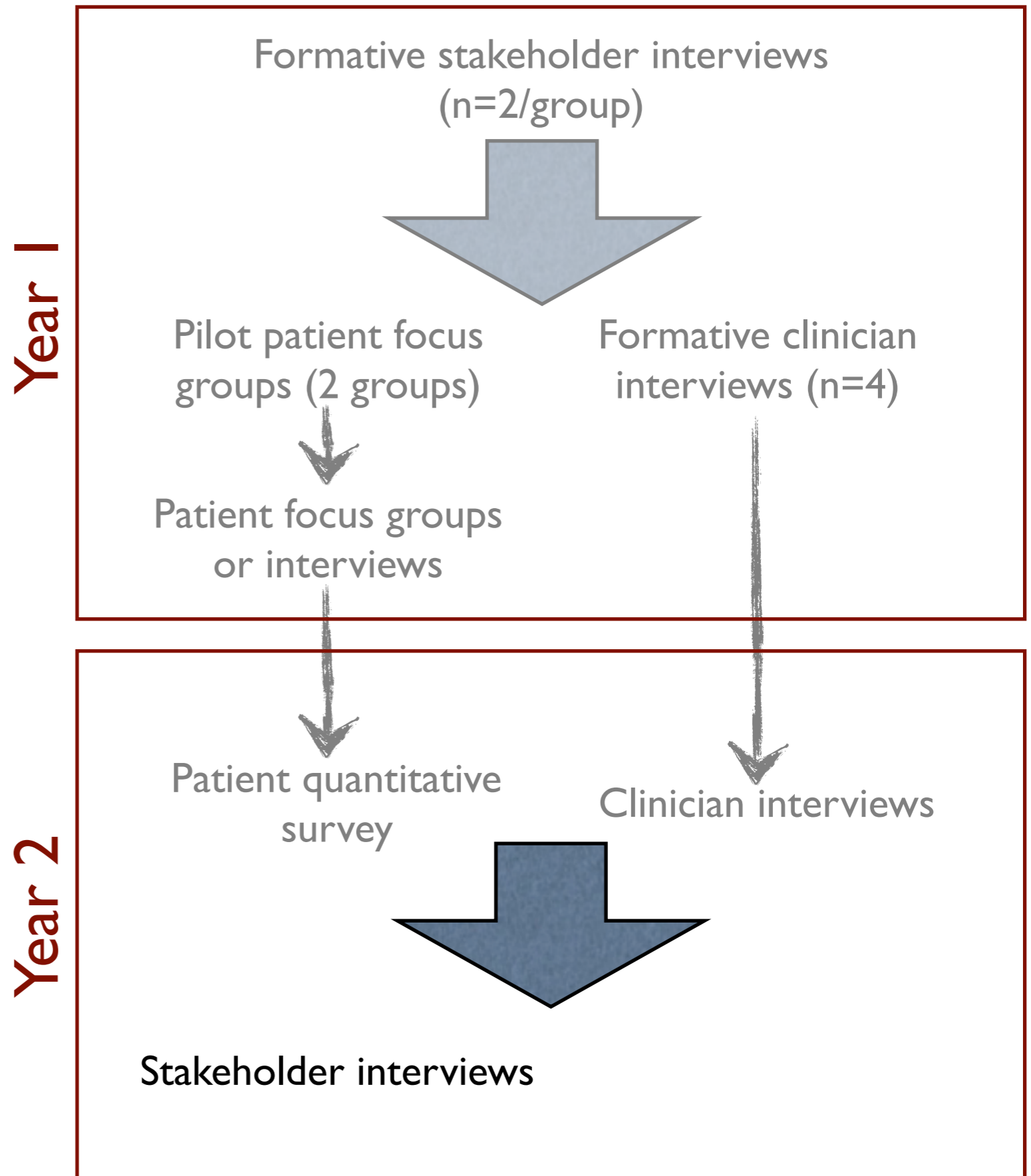
Proposed Revision

Understand clinicians' perceptions and interests regarding consent/notification.



Proposed Revision

Review data with stakeholders and solicit their feedback on the kind of oversight needed for research on standard health care practices.

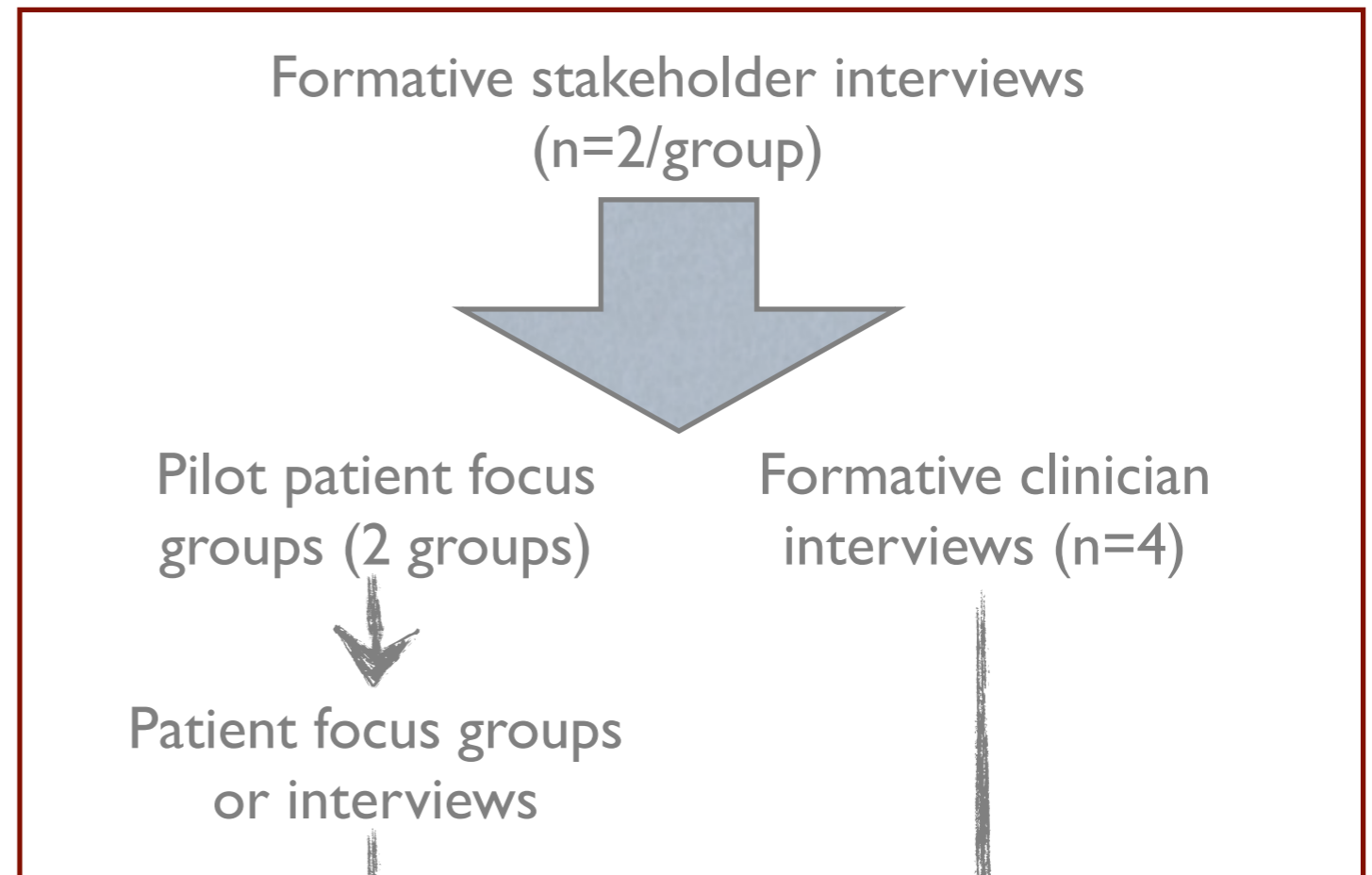


Proposed Revision

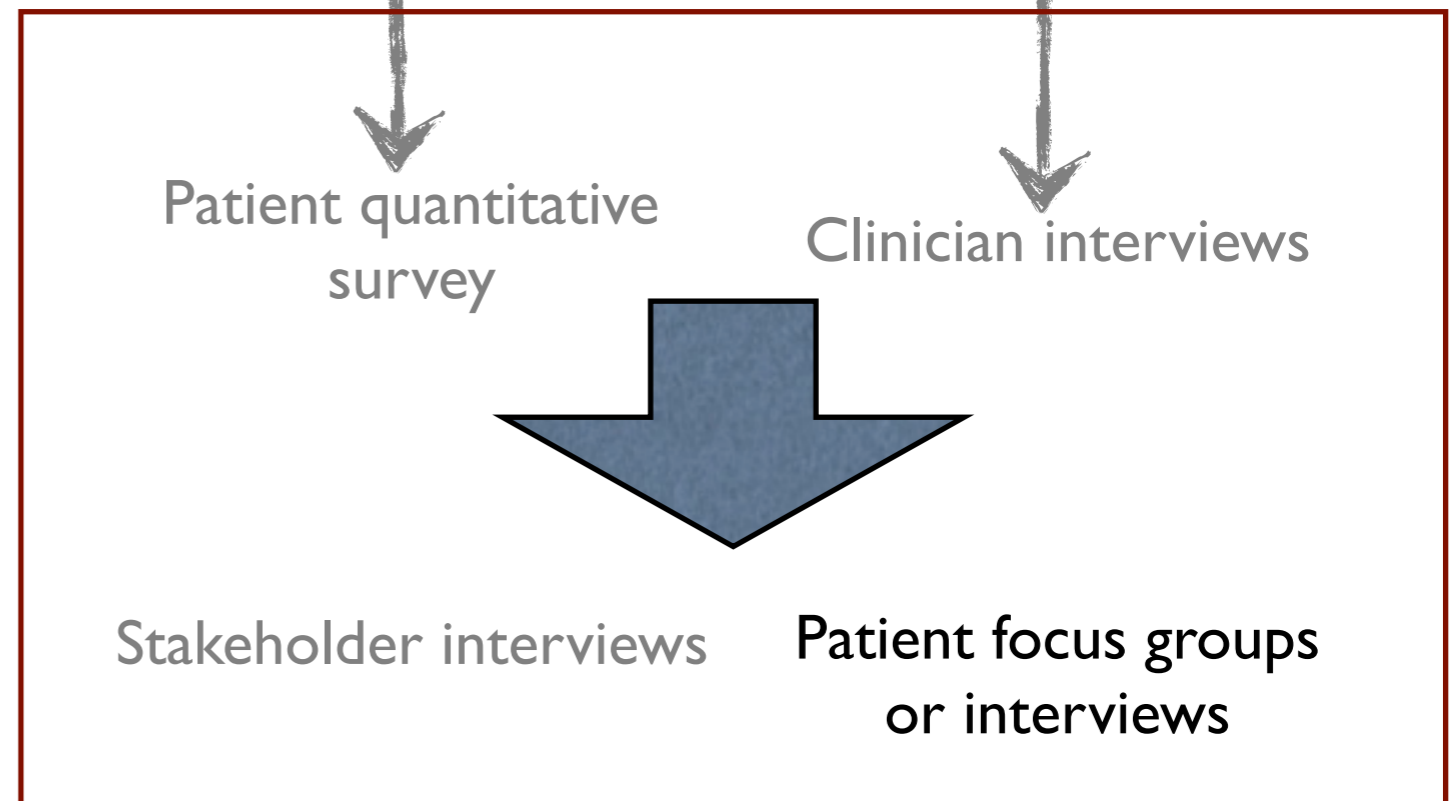
Understand patients' views regarding acceptable kinds of oversight.

As resources permit, collect more information on patient preferences regarding how to communicate (disclose) relevant information.

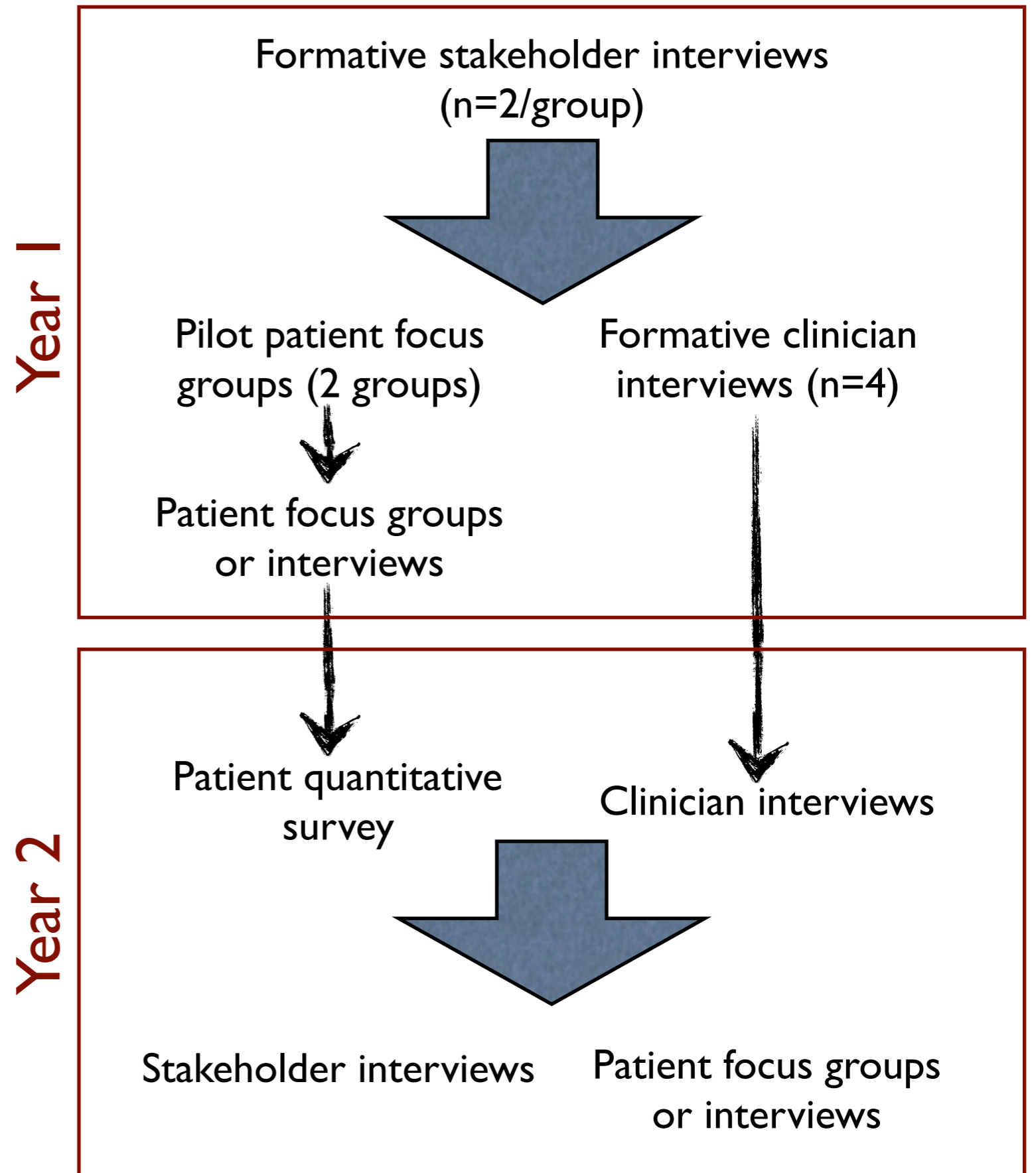
Year 1



Year 2



Revised Plan





Conclusion

Need for greater exploration of wide range of learning activities and potential models for consent.

Revised study plan addresses this need.

Plan allows us to learn as we go and make adjustments as needed.

Discussion