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JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

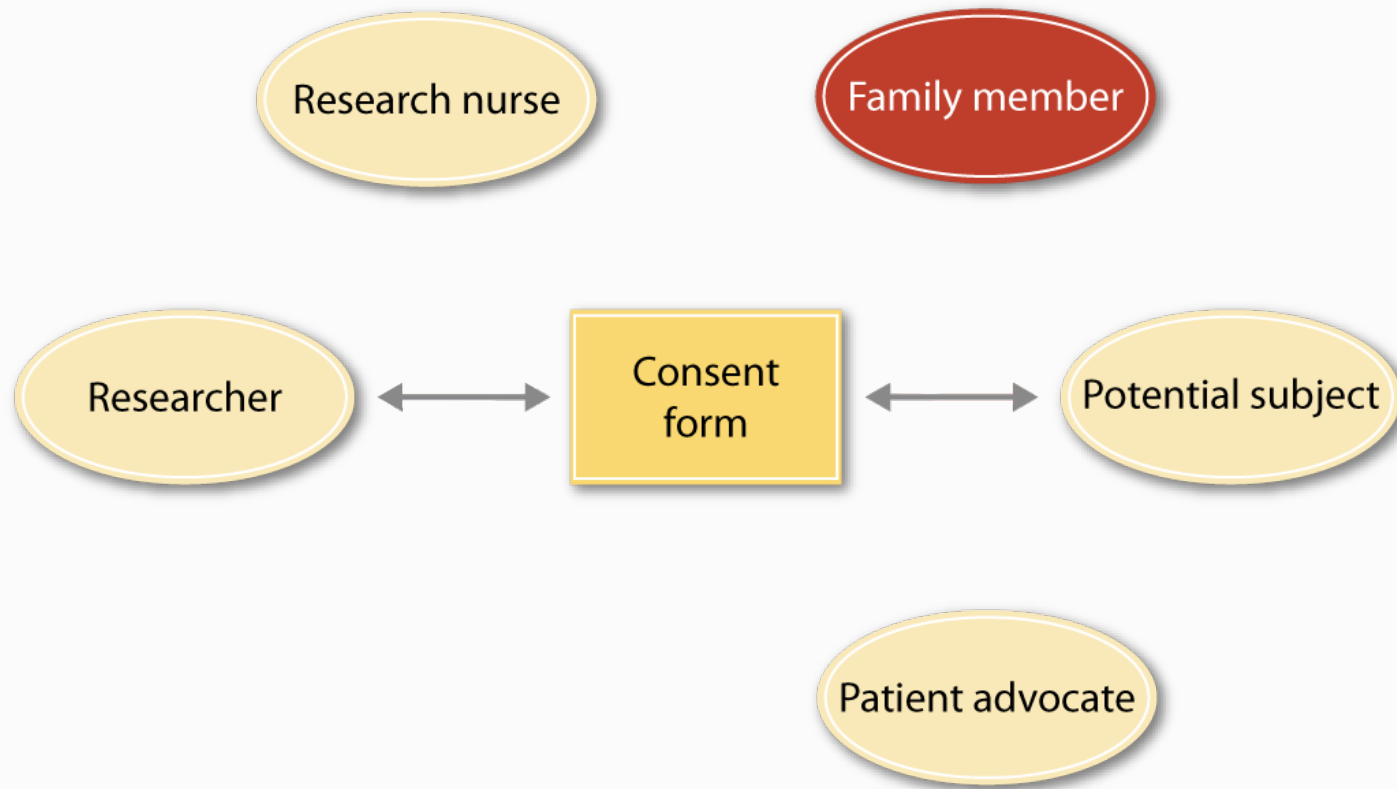
Section B

Process

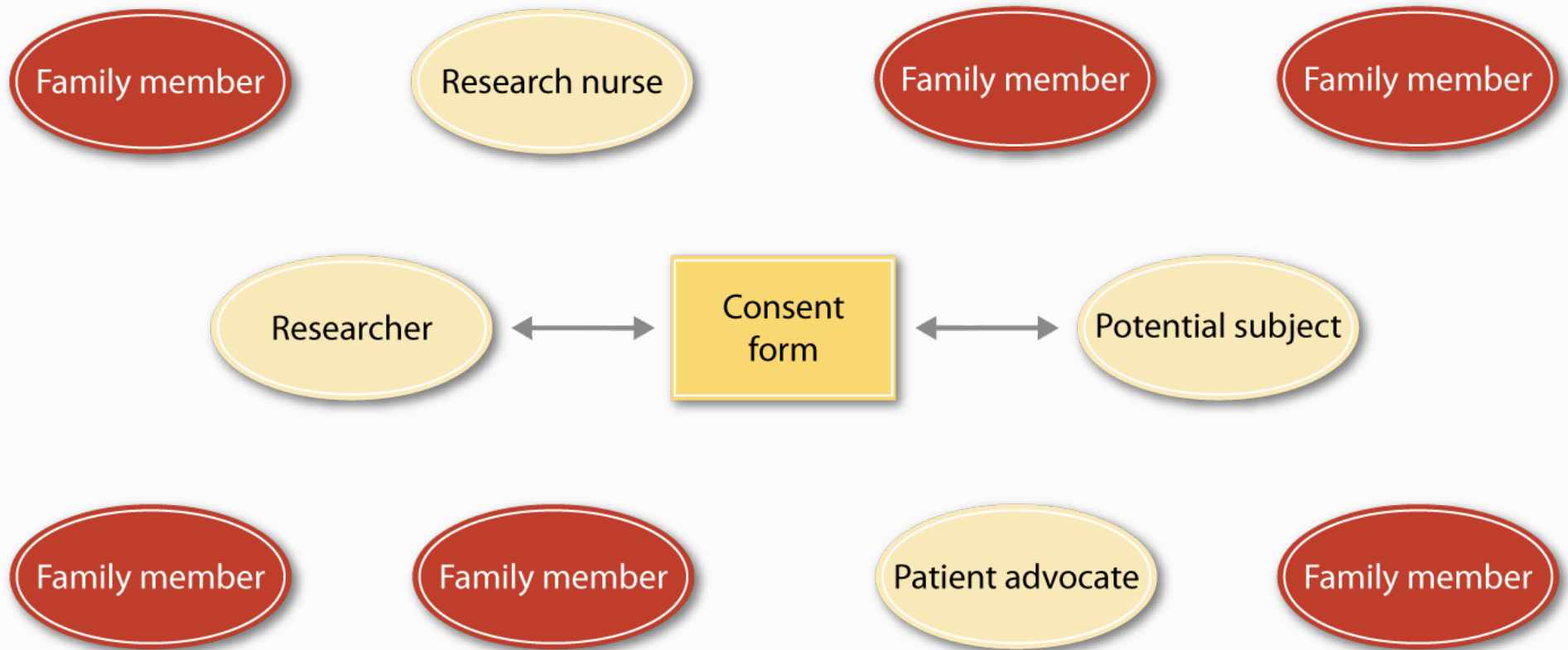
Process: Dynamic



Process: Dynamic



Process: Dynamic



Process: Timing

- Timing of consent discussion
 - Not right after diagnosis of disease
 - Not during labor

Process: Highlight

- Highlight key points
- Check-in after review of each section

Process: Supplement

- Supplement form
 - Flipchart
 - Video
 - ▶ Informational
 - ▶ Simulation
 - Drama
 - Group information session
 - Community meeting

Process: Time Allocation

- Time allocated to decision making and questions about protocol
 - Opportunity to digest information
 - Recommend they review with others
 - ▶ Primary care provider
 - ▶ Family/friends

Process: Understanding

- Assessment of understanding
 - Do you have any questions?
 - ▶ Yes

Process: Assessment

- Assessment of understanding
 - Do you have any questions? No
 - ▶ May not have understood enough to have any
 - ▶ Does not provide you with any confidence about their knowledge

Process: Assessment

- Assessment of understanding
 - Tell me about the study that I just told you about
 - Tell me what you believe to be the purpose of the study you just enrolled in
 - Tell me why you decided to join the study
 - Tell me what the benefits are—to you, to others
 - Tell me what the risks are—to you, to others

Process: Assessment

- Assessment of understanding
 - Tell me how many times you will need to come back to the research site
 - Tell me what you think would have happened if you had said no when you were asked to be in the study
 - **Do you have any further questions?**

Process: Assessment

- Assessment of understanding
 - Think about the answers in advance and consider how much the subject ought to know to feel comfortable with their responses

Process: Ongoing

- Ongoing
 - Consent happens over time; must be repeated, even informally
 - Particularly important for long and/or risky studies and/or easily misunderstood studies