

# CLINICAL TRIALS ADMINISTRATOR

*An essential resource for managers of clinical trials*



**AHC Media LLC**

## **Informed Patient Decisions Worksheet**

### **The Culture**

Ethnic differences in target population

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Attitudes toward health/sickness

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Perceptions of physicians

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General understanding of clinical research

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### **Patient Motivation**

Study opportunities

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Study challenges

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### **The Target Patient**

Age

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Physical barriers

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Health status

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Literacy

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Language

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Ethnicity

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### **Decision Influencers**

Community members/leaders

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Family members/spouse

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Others

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## Introducing the Study

Messaging (“script”)

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Attitudes

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Body language

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Tools

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## Informed Consent Form

First introducing the ICF:

Setting (home visit, in clinic)

Who explains it (PI, study coordinator)

How will the person presenting the ICF be perceived? (impact of race, gender, authority, education, nationality, etc.)

Best method for delivering ICF:

- Print
  - DVD/video
  - Interactive (web, CD-ROM, etc.)
  - Other
- Why?

Process for encouraging input from influencers

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## Checking Comprehension

How will you assess patient understanding of:

Risks

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Benefits

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Ability to withdraw

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Procedures

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Time commitment

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Access to IRBs/ethics and patient advocates

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## Ongoing Informed Decision

List the follow-up activities you plan to implement and when:

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**Source:** Linda Wolf, BS, Emerging Markets and Solutions, BBK Worldwide, Newton, MA. Radical ideas for transforming the informed consent process. Presented at the 44th Annual Meeting of the Drug Information Association; Boston, MA; June 26, 2008.