

# **Benefit in Research Project Instruments**

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**INFORMED CONSENT IN GENE TRANSFER RESEARCH  
SUBJECT QUESTIONNAIRE**

**First a few background questions about being in the [XX STUDY].**

1. Was this the first gene transfer research study that you've been in?

YES

NO → How many others have you participated in? \_\_\_\_\_

DK

2. Before you were in the [XX STUDY], had you ever been in a medical research study that did not involve gene transfer research?

YES → How many other studies have you been in?  
(IF UNSURE, ASK FOR AN APPROXIMATE ANSWER.) \_\_\_\_\_

NO IF NO or DK, USE SKIP PATTERN FOR Q. 14 AND Q. 18

DK

3. Turning to the [XX STUDY], what did you have to do to participate?  
(IF UNCLEAR HOW TO ANSWER, SAY: "Where did you go, how much time did it take, what procedures or medications were involved for you?")

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

DK

4. [PI NAME] is the principal investigator in the [XX STUDY]. Have you ever met or talked with him/her?

NO (GO TO Q. 5; AND SKIP Q. 8, 15a, and 25 ENTIRELY)

YES IF YES, ASK:

Did you first meet or talk with him/her before the [XX STUDY] or during the study?

\_\_\_ BEFORE THE STUDY

IF ANSWERED "BEFORE," ASK: Was that:

\_\_\_ In another study [OMIT IF R. HAS NO PREVIOUS RESEARCH EXPERIENCE]

\_\_\_ In a clinic or hospital?

\_\_\_ In another way? (SPECIFY) \_\_\_\_\_

\_\_\_ DURING THE STUDY

DK

How long ago was that?

\_\_\_ Days \_\_\_ Weeks \_\_\_ Months \_\_\_ Yrs.

Is he/she a medical doctor?

\_\_\_ YES

IF "YES," ASK: Has he/she ever been your doctor?

YES

IF "YES:" Was this before the study started or after?

BEFORE STUDY STARTED

AFTER STUDY STARTED

DK

NO

DK

\_\_\_ NO

DK

5. [SC NAME] is the study coordinator for the [XX STUDY]. Have you ever met or talked with him/her?

NO (GO TO Q. 6; AND SKIP Q. 9, 15b, and 29 ENTIRELY)

YES IF YES, ask:

Did you first meet or talk with him/her before the [XX STUDY] or during the study?

\_\_\_ BEFORE THE STUDY

IF ANSWERED "BEFORE," ASK: Was that:

\_\_\_ In another study [OMIT IF R. HAS NO  
PREVIOUS RESEARCH EXPERIENCE]

\_\_\_ In a clinic or hospital?

\_\_\_ In another way? (SPECIFY) \_\_\_\_\_

\_\_\_ DURING THE STUDY

DK

How long ago was that?

\_\_\_ Days \_\_\_ Weeks \_\_\_ Months \_\_\_ Yrs.

Is he/she a nurse or other health care provider?

\_\_\_ YES

IF ANSWERED "YES," ASK: What kind of health care provider is he/she?  
(CHECK ALL THAT APPLY)

- \_\_\_ NURSE (CAN INCLUDE LPN, RN, NURSE PRACTITIONER)
- \_\_\_ PHYSICIAN'S ASSISTANT (PA)
- \_\_\_ SOCIAL WORKER
- \_\_\_ GENETIC COUNSELOR
- \_\_\_ PHYSICAL THERAPIST
- \_\_\_ PHARMACIST
- \_\_\_ OTHER (SPECIFY) \_\_\_\_\_

IF ANSWERED "YES," ASK: Has he/she ever been your [INSERT ANSWER FROM ABOVE, e.g. Nurse, PA, etc.]?

YES

IF "YES:" Was this before the study started or after?

BEFORE STUDY STARTED

AFTER STUDY STARTED

DK

NO

DK

\_\_\_ NO (IF VOLUNTEERS—SPECIFY) \_\_\_\_\_  
DK

**Now we'll talk about how you got involved in the [XX STUDY].**

6. T How did you first hear about the [XX STUDY]?

\_\_\_\_\_

\_\_\_\_\_

7. How long was it from the time you first heard about the [XX STUDY] to the time you decided to join? Was it:

- The same day
- Within a few days
- Within a week
- Within a month

Or more than a month  
DK

8. During that [FILL IN TIME PERIOD INDICATED IN ANSWER TO Q. 7; IF ANSWERED DK OR MORE THAN ONE MONTH TO Q.7, JUST SAY, "time period"], how many times did you meet or talk with [PI NAME] about the study? \_\_\_\_\_  
PART OF SKIP PATTERN FROM Q. 4

9. During that [TIME PERIOD—FILL IN ANSWER TO Q. 6], how many times did you meet or talk with [SC NAME] about the study? \_\_\_\_\_  
PART OF SKIP PATTERN FROM Q. 5

10. And during that time period, how many times did you meet or talk with other people from the research team about the study, if you did? \_\_\_\_\_

11. T What did you think the researchers were trying to find out with the [XX STUDY]?

\_\_\_\_\_  
\_\_\_\_\_  
(PROBE FOR COMPLETE ANSWER)

12. How serious was your condition or illness when you decided to join the [XX STUDY]? Would you say:

Mild  
Mild to moderate  
Moderate  
Moderate to severe  
Or severe  
(VARIED FROM DAY TO DAY) (SPECIFY) \_\_\_\_\_)  
(UNABLE TO CHOOSE) (SPECIFY) \_\_\_\_\_)  
DK

13. T What concerns or anxieties, if any, did you have about joining the [XX STUDY]?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

DK

14. T In what ways, if any, did you feel differently about being in the [XX STUDY], than you felt about being in other, non-gene transfer studies? (IF SUBJECT HAS NO

REPLY, PROBE: Perhaps you felt less or more hopeful, or anxious, or had different kinds of questions?)

PART OF SKIP PATTERN FROM Q. 2

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DK

15. When you decided to join the study, you signed papers called consent forms, saying that you agreed to be in the study.

15a. Did [PI NAME] go over these papers with you? YES NO DK  
SKIP PATTERN FROM Q. 4

15b. Did [SC NAME] go over these papers with you? YES NO DK  
SKIP PATTERN FROM Q. 5

15c. How about other members of the research team? YES NO DK

15d. Did family or friends go over the papers with you? YES NO DK

15e. Any health care providers not connected with the study? YES NO DK

[IF R. ANS. NO TO 15a-e, INTERVIEWER SHOULD CONFIRM IT'S CORRECT]

16. T Next, let's talk about your decision to join the [XX STUDY]. Why did you decide to join?

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(PROBE FOR COMPLETE ANSWER)

17. Did you get input from family and friends in making the decision to join?

YES IF ANSWERED YES, ASK: How important was their input in your decision? Would you say it was:

\_\_\_ Very important  
\_\_\_ Somewhat important

\_\_\_\_ Not important at all  
DK  
NO  
DK

17a. Did anyone else influence your decision to join?

YES IF ANSWERED YES, ASK: Who? (SPECIFY) \_\_\_\_\_  
NO  
DK

18. (ASK FOR SUBJECTS WITH PREVIOUS RESEARCH EXPERIENCE)

T Did your previous experience being in a research study influence your decision to join the [XX STUDY]?

YES IF YES, ASK: Can you tell me about that? \_\_\_\_\_  
NO  
DK

19. T Did you expect that getting the gene transfer would improve your condition or help make you better? Would you say yes or no?

YES → Why did you expect that (it would improve your condition or help make you better)?

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NO → Why did you expect that (it would not improve your condition or help make you better)?

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DK

(PROBE FOR COMPLETE ANSWER)

20. T What other ways, if any, did you expect the study would benefit you? (IF DOESN'T UNDERSTAND "OTHER WAYS," SAY "Other than improvement in your health from getting the gene transfer")

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DK

21. T Did you expect that the [XX STUDY] would involve any risks for you? Would you say yes or no?

YES—What risks did you expect?

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NO

DK

22. As an alternative to joining the [XX STUDY], did you consider other options instead? (IF THEY DID SOME OF THESE THINGS WHILE IN THE STUDY, IT DOESN'T COUNT.) I'm going to read a list of options and tell me all that you considered. Did you think about:

Enrolling in a different study

Continuing or receiving standard medical treatment for your condition

Receiving comfort care (SUPPORTIVE, PALLIATIVE CARE TO RELIEVE PAIN)

Getting complementary or alternative treatment (HERBAL, MASSAGE)

Making lifestyle changes (SUCH AS CHANGING DIET OR GETTING MORE EXERCISE)

Did you consider doing nothing about your condition, as an alternative?

Did you consider doing anything else instead of joining the study?  
(SPECIFY) \_\_\_\_\_

DK

NONE

**Now, I want to ask you a little more about what [PI NAME] and [SC NAME] did in the study, and your relationship with them.**

23. T Could you tell me what (PI's name) did in the [XX STUDY]? (IF HARD TO ANSWER, SAY: "Your impression or best guess is fine.")

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DK

24. T In the [XX STUDY], did you see (PI NAME) as mostly taking care of you as a patient or mostly doing research?

\_\_\_ MOSTLY TAKING CARE OF ME AS A PATIENT

\_\_\_ MOSTLY DOING RESEARCH

\_\_\_ [VOLUNTEER] BOTH EQUALLY

[ASK FOR EVERYONE:] Can you tell me why? \_\_\_\_\_

DK

25. T Thinking about your relationship with (PI NAME) while you were in the [XX STUDY], do you think it was the same as your relationship with your personal doctor, or was it different?

SKIP PATTERN FROM Q. 4

THE SAME → What was the same? \_\_\_\_\_

DIFFERENT → What was different? \_\_\_\_\_

[VOLUNTEERS] BOTH THE SAME AND DIFFERENT

→ What was the same?

What was different?

\_\_\_\_\_  
[VOLUNTEERS] CHANGED OVER TIME

→ Could you tell me what changed?

DK

26. Was there another doctor involved in the [XX STUDY] (who) you've gotten to know?

YES → IF YES ASK, Can you tell me about that relationship? [IF MORE THAN ONE RELATIONSHIP, PICK THE ONE WHO KNOWS THEM BEST]

\_\_\_\_\_  
NO

DK

27. T Could you tell me what (SC NAME) did in the [XX STUDY]?

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DK

28. T In the [XX STUDY], did you see (SC NAME) as mostly taking care of you as a patient or mostly doing research?

MOSTLY TAKING CARE OF ME AS A PATIENT

MOSTLY DOING RESEARCH

[VOLUNTEERS] BOTH EQUALLY

[ASK FOR EVERYONE:] Can you tell me why? \_\_\_\_\_

DK

29. T Thinking about your relationship with (SC NAME) while you were in the study, was it the same as your relationship with nurses who have taken care of you, or was it different?

SKIP PATTERN FROM Q. 5

THE SAME → What was the same? \_\_\_\_\_)

DIFFERENT → What was different? \_\_\_\_\_)

[VOLUNTEERS] BOTH THE SAME AND DIFFERENT

→ What was the same?

What was different?

\_\_\_\_\_  
[VOLUNTEERS] CHANGED OVER TIME

→ Could you tell me what changed?

DK

30. Was there another study coordinator or nurse involved with the [XX STUDY] (who you've gotten to know)?

YES → IF YES ASK, Can you tell me about that relationship? [IF MORE THAN ONE RELATIONSHIP, PICK THE ONE WHO KNOWS THEM BEST]

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NO  
DK

31. Thinking about the [XX STUDY], would you say it was mostly intended to help you as a patient or mostly intended to gather knowledge?

- MOSTLY INTENDED TO HELP ME AS A PATIENT
- MOSTLY INTENDED TO GATHER KNOWLEDGE
- [VOLUNTEERS] BOTH EQUALLY

[ASK OF EVERYONE:] Can you tell me why? \_\_\_\_\_  
DK

32. How clear was that distinction to you, between helping you as a patient and gathering knowledge? Would you say:

- very clear
- somewhat clear
- somewhat unclear
- very unclear
- DK

**Now I'd like to ask about things that might have been a burden for you, or others who helped you, while you were in the [XX STUDY].**

33. Was travel or parking a burden for you or others who helped you?  
Y N DK

34. How many miles did you have to travel—one way—to participate in the study?  
\_\_\_\_\_ MILES [NOTE: IF ALREADY TRAVELING TO THE STUDY SITE FOR ANOTHER REASON, DON'T COUNT THAT DISTANCE]

- (CODE IF INFORMATION GIVEN:)
- RECRUITED WHILE PATIENT IN HOSPITAL
  - MOVED TO BE NEAR STUDY

35. How about the amount of time that you or others had to spend—was that a burden or not?

Y N DK

36. How about extra expenses or lost wages for you or others?

Y N DK

37. Were side effects or physical discomforts you might have experienced in the study a burden for you?

Y N DK

38. What about special precautions or restrictions that were required by the study, such as isolation, were those a burden?

Y N DK

39. Was there anything else that was a burden?

Y (SPECIFY) \_\_\_\_\_

N

DK

(SKIP Q. 40 IF Q. 33 AND 35-39 ANSWERED ALL "NO" OR ONLY ONE "YES"; IF "DK", CONSIDER A "YES" FOR THIS SKIP PATTERN)

40. Of [INSERT LIST WITH SUBJECT'S ANSWERS CHECKED AND READ THESE], which was the most burdensome? (CHECK ONE, OFFER TO READ LIST IF R. CAN'T REMEMBER)

TRAVEL AND PARKING

TIME

EXTRA EXPENSES OR LOST WAGES

SIDE EFFECTS OR PHYSICAL DISCOMFORTS

SPECIAL PRECAUTIONS OR RESTRICTIONS, SUCH AS ISOLATION

OTHER \_\_\_\_\_

41. What organizations, if any, promoted or talked about the [XX STUDY]? Groups like the American Cancer Society or the March of Dimes? (ANYTIME DURING THE STUDY)

\_\_\_\_\_

NONE  
DK

IFGAVE AT LEAST ONE ORGANIZATION, ASK: What did they do?

(CHECK ALL THAT APPLY)

- PROVIDE INFORMATION (LECTURES, PUBLICATIONS, WEBSITE)
- RECRUIT SUBJECTS (WITH TEL #, BROCHURE OR OTHER MEANS)
- FUND PRIOR RESEARCH
- FUND THIS STUDY
- OTHER (SPECIFY) \_\_\_\_\_

42. Was there anything about the [XX STUDY] on TV, radio, newspapers, or the internet?

YES → Where?

TV

RADIO

NEWSPAPER

INTERNET

Other (SPECIFY) \_\_\_\_\_

NO  
DK

**Now, two questions about financial aspects of the [XX STUDY], and one about gene transfer studies in general.**

43. Who covered the cost of the study, if you know?

(CHECK ALL THAT APPLY, DON'T PROMPT HERE)

INDUSTRY (BIOTECH FIRM, PHARMACEUTICAL COMPANY)

FEDERAL FUNDING (INCLUDES NATIONAL INSTITUTES OF HEALTH [NIH], NATIONAL CANCER INSTITUTE [NCI], AIDS CLINICAL TRIAL GROUP [ACTG], ETC.)

ACADEMIC MEDICAL CENTER (INCLUDES UNIVERSITY, MAYO CLINIC)

PRIVATE NON-PROFIT FOUNDATION (CYSTIC FIBROSIS FOUNDATION, AMERICAN CANCER SOCIETY, MARCH OF DIMES, ETC.)

FDA (FOOD AND DRUG ADMINISTRATION—NOTE, THIS IS NOT A  
CORRECT CHOICE BUT SUBJECTS MAY SAY IT)

INSURANCE

HMO (SUCH AS KAISER PERMANENTE)

OTHER (SPECIFY) \_\_\_\_\_

(IF ANSWER UNCLEAR, WRITE R'S RESPONSE HERE)

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DK

REF

44. Did anyone on the [XX STUDY] research team have a financial agreement with, or a financial interest in, a company involved in the research, that you're aware of?

YES → (SPECIFY IF VOLUNTEERS DETAILS) \_\_\_\_\_

NO

DK

REF

45. T In this interview we've asked a lot of questions about the gene transfer study you participated in. Before we finish the interview, we'd like to ask what you think about gene transfer research in general.

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DK

**Finally, a few background questions**

46. What is the highest degree or level of school you have completed?

LESS THAN HIGH SCHOOL

HIGH SCHOOL GRADUATE/GED

SOME COLLEGE/ASSOCIATE'S DEGREE/TRADE SCHOOL CERTIF

BACHELOR'S DEGREE

SOME GRADUATE SCHOOL

GRADUATE DEGREE(S) (SPECIFY) \_\_\_\_\_

DK

REF

47. What is your age? \_\_\_\_\_

48. What best describes your employment situation at this time? For example, are you employed full or part-time, taking care of home or family, in school, retired, unable to work because of an illness or condition, or something else?

(CHECK ALL THAT APPLY)

- EMPLOYED PART TIME
- EMPLOYED FULL TIME
- TAKING CARE OF HOME OR FAMILY
- IN SCHOOL
- RETIRED
- UNABLE TO WORK BECAUSE OF AN ILLNESS OR CONDITION
- SOMETHING ELSE (SPECIFY) \_\_\_\_\_

49. What would you say your primary occupation is or has been?

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DK  
REF

50. Are you of Spanish or Hispanic origin or descent?

YES  
NO  
DK  
REF

51. What do you consider to be your race? Please tell me all that apply to you.

(CHECK ALL THAT APPLY. READ IF NEEDED; DO NOT FORCE CHOICE.  
HISPANICS MIGHT WANT TO ANSWER HISPANIC FOR THIS QUESTION—IF SO,  
CODE AS OTHER AND WRITE "HISPANIC")

WHITE  
 BLACK  
 ASIAN OR PACIFIC ISLANDER  
 AMERICAN INDIAN  
 OTHER? → (SPECIFY) \_\_\_\_\_  
DK  
REFUSED

52. (CODE, BUT IF UNCERTAIN, ASK) For statistical purposes, I need to ask: what is your gender?

MALE  
 FEMALE  
DK  
REFUSED