

# **Benefit in Research Project Instruments**

Gail E. Henderson  
Nancy M. P. King  
Larry R. Churchill  
Arlene M. Davis  
Daniel K. Nelson

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Received consent to conduct interview \_\_\_\_\_  
Received consent to tape interview \_\_\_\_\_

IRB # \_\_\_\_\_  
Date of Interview \_\_\_\_\_

# IRB QUESTIONNAIRE

## INFORMED CONSENT IN GENE TRANSFER RESEARCH

[DON'T READ IF IN CAPS]

In this interview, we are going to ask about your IRB's experience reviewing clinical research, particularly gene transfer research. We would like to begin by asking about the organizational structure of your IRB and your position in it.

### 1. First, does your IRB have multiple boards or committees?

\_\_\_ YES

IF YES, ASK:

1a. How many? \_\_\_\_\_

1b. How many members are on each board/committee?

#1 \_\_\_ #2 \_\_\_ #3 \_\_\_ #4 \_\_\_ #5 \_\_\_ #6 \_\_\_ #7 \_\_\_ #8 \_\_\_

1c. Do you think that your comments about IRB review will represent all boards/committees or just the one(s) that you serve on?

\_\_\_ ALL BOARDS/COMMITTEES

\_\_\_ JUST THE ONES SERVED ON

\_\_\_ NO

IF NO, ASK:

1d. How many members are on the board/committee? \_\_\_\_\_

DK

REF

### 2. Is there a subcommittee or designated individual(s) within your IRB that reviews gene transfer studies?

\_\_\_ YES

IF YES, ASK:

2a. Are you (on) it? Y N

2b. Can you tell me about the persons(s) on that committee?

\_\_\_ NO

\_\_\_ IT VARIES

\_\_\_ TOO FEW TO SAY

DK

REF

3. Does your IRB use a primary reviewer process, or do all members review all protocol materials without one or more primary discussants?

- PRIMARY REVIEWER PROCESS
- NO PRIMARY DISCUSSANTS
- IT VARIES
- DK
- REF

4. How many times per month does your IRB meet?

- TIMES/ MONTH
- TIMES/YEAR (ONLY USE THIS IF LESS THAN ONCE PER MONTH)
- DK
- REF

5. For how many hours at each meeting, on average?

- HOURS
- DK
- REF

Now, let's turn to your IRB experience.

6. How did you first get involved in IRB work? [CHECK ALL THAT APPLY]

- INVITED / RECRUITED
- VOLUNTEERED
- COERCED
- OTHER \_\_\_\_\_
- DK
- REF

7. How long have you been a member of your current IRB?

- YEARS
- MONTHS (ONLY USE THIS IF LESS THAN ONE YEAR)
- DK
- REF

8. What is your current position on your IRB?

9. How long have you held this position?

\_\_\_ YEARS  
\_\_\_ MONTHS (ONLY USE THIS IF LESS THAN ONE YEAR)

DK  
REF

10. How many total years of IRB experience do you have, including all IRBs you have served on?

\_\_\_ YEARS  
\_\_\_ MONTHS (ONLY USE THIS IF LESS THAN ONE YEAR)

DK  
REF

11. What is your area of scientific or medical training?

DK  
REF

12. Have you ever done clinical research with humans?

\_\_\_ YES  
IF YES, ASK: 12a. Have you conducted or been involved with early phase clinical trials? [EARLY PHASE = PHASE I AND II]

\_\_\_ YES  
\_\_\_ NO  
DK  
REF

\_\_\_ NO

DK  
REF

**13. Have you ever conducted or been involved with gene transfer research in humans?**

- YES
- NO
- DK
- REF

**Now let's turn to recent activity within your IRB.**

**14. About how many new protocols were reviewed by your IRB in the last 12 months? \_\_\_\_\_**

- DK
- REF

**15. How many gene transfer research protocols has your IRB reviewed since January 1990? Would you say:**

- 1-5
- 6-10
- 11 or more
- DK
- REF

**16. Of the GTR protocols, how many are currently active? Would you say:**

- 0
- 1-5
- 6-10
- 11 or more
- DK
- REF

**17. In addition to IRB review, what other reviews do gene transfer protocols receive at your institution, if any? (CHECK ALL THAT APPLY) (READ IF NEEDED)**

- SCIENTIFIC REVIEW COMMITTEES
- INSTITUTIONAL BIO-SAFETY COMMITTEES
- DATA SAFTEY MONITORING BOARDS (DSMB)
- OTHER (SPECIFY) \_\_\_\_\_
- NO OTHER REVIEWS
- DK
- REF

**18. Does your IRB have written guidelines or policies that are specific to the review of gene transfer studies?**

- YES  
IF YES, "Could you please send me a copy via email?"  
[PROVIDE YOUR EMAIL ADDRESS]
- NO
- DK
- REF

**19. Review of gene transfer research at the federal level can be confusing to IRBs. What is your understanding of this review?**

(IF NEEDED, PROBE: Which agencies or committees conduct reviews?  
(IF NEEDED SUPPLY NAMES: FDA, NIH, RAC))

(PROBE: Are any of these reviews required?)

(PROBE: What feedback is provided and to whom?)

- DK
- REF

The next questions are about benefit in all research studies.

**20. When assessing benefits in research, does your IRB rely primarily on the investigator's assessment, or rely primarily on its own, independent assessment?**

- RELY ON INVESTIGATOR
- RELY ON OWN INDEPENDENT ASSESSMENT
- RELY ON BOTH
- IT VARIES → Can you tell me more about that?

DK  
REF

**21. There are several kinds of benefits that might be associated with research. What kinds of benefits does your IRB look for when reviewing a study?**

[BLIND CODES, CHECK EVERYTHING THAT IS MENTIONED:]

- BENEFIT TO INSTITUTION / INVESTIGATOR
  
- BENEFITS TO SUBJECTS
  - DIRECT MEDICAL BENEFIT
    - NATURE
    - MAGNITUDE
    - LIKELIHOOD
  - INDIRECT OR COLLATERAL MEDICAL BENEFIT
    - CLOSER MONITORING
    - ACCESS TO BETTER HOSPITAL OR DOCTORS
  - PAYMENT
  - PSYCHOLOGICAL BENEFIT OF BEING IN STUDY

BENEFIT TO SOCIETY

→ Is there anything else you'd like to add?

NONE  
DK  
REF

**In the next three questions, I'd like to ask about how people perceive the distinction between benefit to subjects and benefit to society.**

**22. In your view, how clear is that distinction to your IRB? Would you say it is:**

- Very clear
- Somewhat clear
- Somewhat unclear
- Very unclear

IT VARIES (IF THEY VOLUNTEER THAT IT VARIES, CIRCLE AND ASK: )  
“Can you tell me more about that?”

DK  
REF

**23. In your view, how clear is the distinction to investigators? Would you say it is:**

- Very clear
- Somewhat clear
- Somewhat unclear
- Very unclear

IT VARIES (IF THEY VOLUNTEER THAT IT VARIES, CIRCLE AND ASK: )  
“Can you tell me more about that?”

DK  
REF

**24. In your view, how clear is that distinction to subjects? Would you say it is:**

- Very clear
- Somewhat clear
- Somewhat unclear
- Very unclear

IT VARIES (IF THEY VOLUNTEER THAT IT VARIES, CIRCLE AND ASK: )  
“Can you tell me more about that?”

DK  
REF

**Now, I'd like you to restrict your thinking to benefit in all early phase research. We'll turn to gene transfer research in a moment.**

**25. Can you give examples of discussions or controversies about the evaluation of benefits specific to early phase studies? [CHECK ALL THAT APPLY]**

- ESTIMATE OF BENEFIT IN EARLY PHASE TRIALS
- WHAT GETS COUNTED AS BENEFIT (INDIRECT VS. DIRECT BENEFIT—  
E.G., DOES MONEY COUNT? DOES ACCESS TO DRUGS COUNT?)
- RISK-BENEFIT RATIO (VALUE)
- SCIENTIFIC VALIDITY
- WHETHER ALTERNATIVES EXIST
- OTHER (SPECIFY:) \_\_\_\_\_
- NO CONTROVERSIES

DK  
REF

**26. Has the complexity of language describing benefit been an issue in early phase studies?**

YES → Can you tell me about that?

NO  
DK  
REF

**27. Has vagueness of language (such as “cannot guarantee benefit” or “may benefit”) been an issue in early phase studies?**

YES → Can you tell me about that?

NO  
DK  
REF

**28. Has research being described as treatment been an issue in early phase studies?**

YES → Can you tell me about that?

NO  
DK  
REF

**29. Still thinking about early phase research, have there been times when your IRB noted that the prospect of benefit described in consent forms was inconsistent with the protocol?**

YES → Can you tell me about that?

NO  
DK  
REF

**Now let's turn to (the) gene transfer study(ies) your board has reviewed, and repeat these same questions about benefit.**

**30. Can you give examples of discussions or controversies about the evaluation of benefits specific to gene transfer studies? [CHECK ALL THAT APPLY. IF MANY, "Tell us the 2 or 3 that stand out in your mind."]**

- ESTIMATE OF BENEFIT IN EARLY PHASE TRIALS
- WHAT GETS COUNTED AS BENEFIT (INDIRECT VS. DIRECT BENEFIT—  
E.G., DOES MONEY COUNT? DOES ACCESS TO DRUGS COUNT?)
- RISK-BENEFIT RATIO (VALUE)
- SCIENTIFIC VALIDITY
- WHETHER ALTERNATIVES EXIST
- OTHER (SPECIFY:) \_\_\_\_\_
- NO CONTROVERSIES

DK  
REF

**31. Has the complexity of language describing benefit been an issue in gene transfer studies?**

\_\_\_YES → Can you tell me about that?

\_\_\_NO  
DK  
REF

**32. Has vagueness of language, such as “cannot guarantee benefit” or “may benefit” been an issue in gene transfer studies?**

\_\_\_YES → Can you tell me about that?

\_\_\_NO  
DK  
REF

**33. Has research being described as treatment been an issue in gene transfer studies?**

\_\_\_YES → Can you tell me about that?

\_\_\_NO  
DK  
REF

**34. Still thinking about gene transfer research, have there been times when your IRB noted that the prospect of benefit described in consent forms was inconsistent with the protocol?**

\_\_\_YES → Can you tell me about that?

\_\_\_NO  
DK  
REF

Now, we would like you to make a direct comparison between gene transfer research and other early phase research.

35. When your IRB evaluates benefits in a gene transfer study, are there any differences—compared to the way benefits are evaluated in other early-phase studies?

YES → Please describe:

NO  
 DK  
 REF

We just have a few more questions. As you know, physician-investigators often enroll their patients as subjects in research.

36. Has this dual role been an issue in your IRB's evaluation of research?

YES  
 NO  
 DK  
 REF

37. Has this dual role been an issue in your IRB's evaluation of gene transfer studies?

YES  
 NO  
 DK  
 REF

Two final questions.....

**38. Has your IRB's approach to gene transfer research changed with the increased media attention and regulatory scrutiny of gene transfer research?**

YES  
 NO

Can you tell me about that?

DK  
REF

**38a. What about your own thinking?**

**39. Are there other issues related to benefit in gene transfer studies—or in any studies—that you think we should consider?**

**A HEARTY THANK YOU!**

**Reminder: email written guidelines if available!**

**INTERVIEWER:**

PLEASE CIRCLE GENDER OF RESPONDENT HERE:            M        F