

# **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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**CONSENT FORM CODING FORM  
2002**

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**Assessment of Benefit and Care-Giving Language in GTR Consent Forms**

**General Questions**

**Code**

**PS=Protocol Summary; CF=Consent Form**

**PS    CF**

- |                                                                                                                                                                      |            |                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------------------------------|
| 1.-2. Term “Gene Therapy” is in title.                                                                                                                               | 0 No 1 Yes | 1 ___ 2 ___                      |
| 3.-4. Term “Patient” is in title.                                                                                                                                    | 0 No 1 Yes | 3 ___ 4 ___                      |
| 5.-6. Term “Treatment” <u>inappropriately</u> used in title.                                                                                                         | 0 No 1 Yes | 5 ___ 6 ___                      |
| 7.-8. Term “Phase” is in title.                                                                                                                                      | 0 No 1 Yes | 7 ___ 8 ___                      |
| 9. CF title is less technical than PS title.<br>0 No (for example, they are very similar or identical)<br>1 Yes                                                      |            | 9 ___                            |
| 10. Disease category is<br>1 Inherited<br>2 Cancer<br>3 HIV<br>4 Cardiovascular<br>5 Other _____                                                                     |            | 10 ___                           |
| 11.-12. Phase in <b>protocol summary</b> and in <b>consent form</b> :<br>1 I<br>2 I/II<br>3 II<br>4.III<br>6 Can’t determine                                         |            | <b>PS    CF</b><br>11 ___ 12 ___ |
| 13. Is this a dose escalation study? ( <i>NOTE</i> : should be doses for different people not different doses for same person)<br>0 No<br>1 Yes<br>6 Can’t determine |            | 13 ___                           |
| 14. Is this a placebo-controlled study?<br>0 No<br>1 Yes<br>6 Can’t determine                                                                                        |            | 14 ___                           |
| 15. Does this study include other kinds of comparison groups (e.g., standard treatment, more than one fixed dosage group)?<br>0 No<br>1 Yes<br>6 Can’t determine     |            | 15 ___                           |

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16. Is this intervention a 16\_\_\_\_\_
- 1 Gene transfer (GT) only study
  - 2 GT combined with standard therapy study (including palliative)
  - 3 GT combined with investigational therapy study
  - 4 GT combined with both standard and investigational therapy
  - 5 GT and IT linked or dependent (e.g, GT is chemoresistance gene & IT is high-dose chemo; GT is virus gene & IT kills virus) Specify: \_\_\_\_\_
  - 6 Can't determine
  - 8 Other (specify) \_\_\_\_\_
17. What delivery vehicle does this intervention use? 17\_\_\_\_\_
- 1 None (naked plasmid DNA)
  - 2 Viral vector
  - 3 Non-viral vector (e.g. lipid or liposome)
  - 4 Other (specify) \_\_\_\_\_
  - 6 Can't determine
18. Is the gene transfer 18\_\_\_\_\_
- 1 *ex vivo* (that is, the GT is done with material removed from subject's body, and then injected or infused back)
  - 2 *in vivo*
  - 6 Can't determine
19. Is the GT intended to have systemic or local effect? 19\_\_\_\_\_
- 1 Clearly systemic
  - 2 Clearly local
  - 3 Both (e.g., vaccine)
  - 6 Can't determine
20. Route of administration: 20\_\_\_\_\_
- 1 intravenous
  - 2 intramuscular (unless muscle itself is target area, then code 4)
  - 3 intra-arterial administration
  - 4 administration specific to local area to be affected (e.g., tumor, skin lesion, joint, prostate, lung, peritoneal cavity, respiratory tract, etc.)  
Specify: \_\_\_\_\_
  - 5 Other (specify) \_\_\_\_\_
  - 6 Can't determine

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QUESTIONS 21-30 APPLY ONLY TO **CONSENT FORM**

21. Does **consent form** use headings? 21\_\_\_\_  
 0 No  
 1 Yes

22. How many pages in **consent form**? (not including consent for HIV testing or assent forms) *NOTE*: If double-spaced, divide by 2 22\_\_\_\_

23. Can the funding type be determined from the **consent form**? 23\_\_\_\_  
 0 No (*NOTE*: If vector is supplied to subjects at no cost, but not clear who is paying, then code 0)  
 1 Yes

FUNDING TYPE, per **consent form**: *NOTE*, use NA if 23 is coded 0

|                                                  |                 |        |
|--------------------------------------------------|-----------------|--------|
| 24. NIH and other Federal                        | 0 No 1 Yes 7 NA | 24____ |
| 25. Private (e.g. foundations)                   | 0 No 1 Yes 7 NA | 25____ |
| 26. Industry                                     | 0 No 1 Yes 7 NA | 26____ |
| 27. Investigator generated (no external funding) | 0 No 1 Yes 7 NA | 27____ |
| 28. Other Specify _____                          | 0 No 1 Yes 7 NA | 28____ |

29. Is the term “sponsor” used in the **consent form**? 29\_\_\_\_  
 (code even if boilerplate, but note in Q94)  
 0 No  
 1 Yes

30. How is financial involvement linked to authority over study in **consent form** 30\_\_\_\_  
 (*NOTE*: If rights for same sponsor described in more than one way, code the greatest level of rights specified)  
 1 No rights specified (e.g., only info is “X corp. is supplying the vector for free” or “X corp. is paying for tests”)  
 2 No rights specified but are implied (e.g., “study sponsored by X corp.” or “this is an NIH study”)  
 3 Rights are specified (e.g., X corp. can review records, stop study)  
 6 Can’t determine (e.g., vector supplied at no cost, but can’t tell who is paying;  
*NOTE* if answer to Q. 23 is No, then should code “can’t determine”)

31. Are Children (under 18) Enrolled? 31\_\_\_\_  
 0 No  
 1 Yes

32. Is there an Assent Form? 32\_\_\_\_  
 0 No  
 1 Yes  
 2 NA because children under 7  
 7 NA (no children)

*Coding hint: note pages and phrases in margins thruout II.*

## II. Assessment of Benefit

**Code Section in Consent Form:**  
bkgrd/purp. proced. risk benefit alt.

- 33-37. Is any information or evidence about the results of previous pre-clinical or clinical trials of the experimental intervention mentioned in the whole **consent form**? Include discussion of uncertainty or lack of information. This applies to risks as well as benefits.
- 33\_\_\_\_ 34\_\_\_\_ 35\_\_\_\_ 36\_\_\_\_ 37\_\_\_\_
- 0 No mention at all  
1 Some information but no specifics (“This has only been given to humans once before.”)  
2 Specific description (“Safety in over 175 patients, with no cancer developed”)  
7 NA (there is no such section)
- (NOTE: include related trials BUT NOT treatment uses of similar interventions AND NOT unrelated trials (e.g., “In a completely different study, one subject died.”))
38. Is this information linked to description of direct benefit, in **any** section of the **consent form**? 38\_\_\_\_
- 0 No  
1 Yes  
7 NA (q.33-37 answered with all 0s/7s)
39. Is this information linked to description of risks, in **any** section of the **consent form**? 39\_\_\_\_
- 0 No  
1 Yes  
7 NA (q.33-37 answered with all 0s/7s)
40. Does discussion in **consent form** acknowledge that benefit might be related to being in different study groups? (NOTE: Refer back to questions Part I, 13-15) 40\_\_\_\_
- 0 No  
1 Yes  
7 NA
- (NOTE: code NA if no benefit promised or if no study groups; code 0 if no study groups mentioned in CF)

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**Code Section in Consent Form:**  
bkgrd/purp. proced. risk benefit alt.

41-45. Rate the amount of information 41 \_\_\_ 42 \_\_\_ 43 \_\_\_ 44 \_\_\_ 45 \_\_\_

about **nature** of direct benefit in the **consent form**

0 No information (e.g., “you may not benefit”)

1 Some information, but no specifics (could be surrogate endpoint, or clinical endpoint stated vaguely and generally, e.g., “reduction in symptoms,” “tumor shrinkage”)

2 Specific description, must include clinical endpoint

(e.g. “reduction in cardiac symptoms that may improve breathing,”  
“tumor shrinkage that could lengthen survival time”)

7 NA (there is no such section)

8 CF section says “you will not benefit”

(NOTE Q41-64: If there is no ben. section, but ben. language is in another section, code ben. 7 and code other sections appropriately. This distinguishes 8 from 7, but either can have 1 and 2 elsewhere (or not). Note unusual misplacements etc. in Q94.)

46 In the **consent form**, is **nature** of direct benefit defined or measured 46 \_\_\_

in terms of a surrogate endpoint (for example, cell death, tumor shrinkage, lab marker like CD4 count or PSA value), a clinical endpoint (something experienced by subject, relating to morbidity or mortality), or both or neither?

1 Surrogate *Specify* \_\_\_\_\_

2 Clinical *Specify* \_\_\_\_\_

3 Both (specify under 1 and 2)

6 Can't determine (q. 41-45 answered with all 0s)

7 NA (q. 41-45 answered with all 7s/8s)

**Code Section in Consent Form:**  
bkgrd/purp. proced. risk benefit alt.

47-51. Rate the amount of information in 47 \_\_\_ 48 \_\_\_ 49 \_\_\_ 50 \_\_\_ 51 \_\_\_

the **consent form** about the **magnitude**

of the direct benefit (e.g., improve, cure):

0 No mention

1 Some information but no specifics (“improve”)

2 Specific description (relates improvement or surrogate endpoint to clinical endpoint)

7 NA (there is no such section)

8 CF section says “you will not benefit”

52. What does the **consent form** say about 52 \_\_\_

**magnitude** of the direct benefit? *Specify* if possible \_\_\_\_\_

1 Small/mild

2 Medium/moderate

3 Large/major

6 Can't determine

7 NA (q. 47-51 answered with all zeros/7s/8s)

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**Code Section in Consent Form:**  
 bkgrd/purp. proced. risk benefit alt.

53-57. Rate the amount of information in the **consent form** about the **duration** of the direct benefit (e.g., temporary, long term): 53 \_\_\_ 54 \_\_\_ 55 \_\_\_ 56 \_\_\_ 57 \_\_\_

- 0 No mention
- 1 Some information but no specifics (“temporary”)
- 2 Specific description (gives time period, days, weeks, of effect lasting)
- 7 NA (there is no such section)
- 8 CF section says “you will not benefit”

58. What does the **consent form** say about **duration** of direct benefit? *Specify* if possible \_\_\_\_\_ 58 \_\_\_

- 1 Very temporary—days
- 2 temporary—months
- 3 Long term—years
- 6 Can’t determine
- 7 NA (q. 53-57 answered with all zeros/7s/8s)

**Code Section in Consent Form:**  
 bkgrd/purp. proced. risk benefit alt.

59-63. Rate the amount of information in the **consent form** on **likelihood** of direct benefit. 59 \_\_\_ 60 \_\_\_ 61 \_\_\_ 62 \_\_\_ 63 \_\_\_

- 0 No mention
- 1 Some information, but no specifics (“You may/might benefit,” “not possible to predict benefit”) *NOTE:* this gets a 0 under nature of benefit, but a 1 here, if this is the only statement.
- 2 Specific description (a more specific estimate of likelihood, e.g., additional language modifying likelihood statement, or % or ratio; could be as little as, “You are not likely to benefit”)
- 7 NA (there is no such section)
- 8 CF section says “you will not benefit”

64. What does the **consent form** say about the **likelihood** of direct benefit? *Specify* if possible \_\_\_\_\_ 64 \_\_\_

- 1 Very likely
- 2 Likely
- 3 Unlikely
- 4 Very unlikely
- 6 Can’t determine
- 7 NA (q. 59-63 answered with all zeros/7s/8s)

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65. Is collateral benefit mentioned in the **consent form**? 65\_\_\_\_\_  
 (NOTE: payment to subjects is not collateral benefit)  
 0 No  
 1 Yes
66. Is collateral benefit distinguished from direct benefit in the **consent form**? 66\_\_\_\_\_  
 0 No (i.e., collateral benefit is mentioned but not distinguished)  
 1 Yes  
 7 NA (coded 0 in q. 65)  
 8 NA because direct benefit is not mentioned in CF
67. Is benefit to society mentioned in the **consent form**? 67\_\_\_\_\_  
 (NOTE: code yes even if “society” not specifically mentioned)  
 0 No  
 1 Yes
68. Is benefit to society distinguished from direct benefit? 68\_\_\_\_\_  
 0 No (i.e., benefit to society is mentioned but not distinguished)  
 1 Yes  
 7 NA (coded 0 in q. 67)  
 8 NA because direct benefit is not mentioned in CF

ID \_\_\_\_\_

QUESTIONS 69-72 ARE FOR PROTOCOL (APPENDIX M RESPONSES,  
ABSTRACT, AND PROTOCOL SUMMARY)

69. In the **protocol**, is **nature** of direct benefit defined or measured in terms of a surrogate endpoint, a clinical endpoint, or both, or neither? 69\_\_\_\_\_
- 1 Surrogate *Specify* \_\_\_\_\_
- 2 Clinical *Specify* \_\_\_\_\_
- 3 Both (specify under 1 and 2)
- 6 Can't determine
- 7 NA (protocol focuses on safety not efficacy)
70. What does the **protocol** say about **magnitude** of the direct benefit? *Specify* if possible \_\_\_\_\_ 70\_\_\_\_\_
- 1 Small/mild
- 2 Medium/moderate
- 3 Large/major
- 6 Can't determine
- 7 NA (protocol focuses on safety not efficacy)
71. What does the **protocol** say about **duration** of direct benefit? *Specify* if possible \_\_\_\_\_ 71\_\_\_\_\_
- 1 Very temporary—days
- 2 temporary—months
- 3 Long term or permanent—years
- 6 Can't determine
- 7 NA (protocol focuses on safety not efficacy)
72. What does the **protocol** say about **likelihood** of direct benefit? *Specify* if possible \_\_\_\_\_ 72\_\_\_\_\_
- 1 Very likely
- 2 Likely
- 3 Unlikely
- 4 Very unlikely
- 6 Can't determine
- 7 NA (protocol focuses on safety not efficacy)

### III. Assessment of Care-Giving Language Applied to Research

*Note:* don't count verbs

**Counting Instructions:** Count only if terms in CF are circled. Only study ID numbers in multiples of 5 will be circled, and should be counted. NOTE: X out mistakenly circled terms; circle and star any terms that should have been circled; discuss to reconcile.

(NOTE: If not circled, answer IIIC, IIIE, and IV, but code NA=7 for all other Qs)

#### A. **Physician or Investigator(s):** How many times is each term mentioned?

*Coding Instructions:* If the terms physician or doctor are used appropriately, i.e., in a care-giving situation, then do not code them. If the use of the terms physician or doctor is ambiguous, then code.

73. Physician: \_\_\_\_\_ 74. Mixed term (specify): \_\_\_\_\_ 75. Investigator: \_\_\_\_\_

|           |                 |              |
|-----------|-----------------|--------------|
| Physician | Study doctor    | Investigator |
| Doctor    | Study physician | PI           |
|           |                 | Researcher   |

#### B. **Patient or Subject(s):** How many times is each term mentioned?

*Coding Instructions:* Again, if the term patient is used appropriately, i.e., in a care-giving situation, then do not code it. If the use of the term is ambiguous, then code.

76. Patient: \_\_\_\_\_ 77. Mixed term: \_\_\_\_\_ 78. Neutral term: \_\_\_\_\_ 79. Subject: \_\_\_\_\_

|         |                 |            |                      |
|---------|-----------------|------------|----------------------|
|         | (Specify)       | Person     | Subject              |
| Patient | Patient subject | Individual | Volunteer            |
|         |                 | Woman      | Study Subject        |
|         |                 |            | Experimental Subject |
|         |                 |            | Participant          |
|         |                 |            | Research Subject     |

#### C. **Signature Lines:**

80. Does Subject signature line use term 80 \_\_\_\_\_

- 1 subject (or term from subject list above)
- 2 patient (or term from patient list above)
- 3 mixed term
- 4 neutral term (e.g., from list above) specify \_\_\_\_\_
- 7 NA (absent or unlabeled signature line)

81. Does Investigator signature line use term 81 \_\_\_\_\_

- 1 investigator (or term from investigator line above)
- 2 physician (or term from physician line above)
- 3 mixed term
- 4 neutral term (e.g., person obtaining consent) specify \_\_\_\_\_
- 7 NA (absent or unlabeled signature line)

ID \_\_\_\_\_

**D. Treatment or Research:**

For the Specific Research Intervention: Is it called treatment or research intervention? *Coding Instructions:* If treatment is used appropriately, do not count. NOTE: Do not count terms describing the whole study, only those describing intervention.

82. Treatment: \_\_\_\_\_ 83. Mixed term: \_\_\_\_\_ 84. Neutral Term: \_\_\_\_\_ 85. Study Intervention: \_\_\_\_\_

|                    |                 |           |                      |
|--------------------|-----------------|-----------|----------------------|
| Treatment          | Study treatment | Procedure | Study procedure      |
| Active treatment   | Experimental Tx | Infusion  | Experimental product |
| Gene treated cells | Gene therapy    | Injection | Gene transfer        |
| Therapy            | Unproven Tx     |           | Experimental vaccine |
| New treatment      |                 | Insertion | Experimental agent   |
| SCOB treatment     | New Vaccine     | SCOB      | Experimental SCOB    |
| Treatment group    | Drug            | Product   | Investigational drug |
| Treatment phase    | Vaccine         |           | Experimental drug    |
|                    |                 |           | Study drug           |

E. Usually consent forms use the terms “study,” “research,” “protocol,” “investigation”... (NOTE: Q86-92 should capture only things not captured in counting.)

86. Is the whole study ever referred to with treatment terms in the **consent form**? 86\_\_\_\_\_

0 No

1 Yes

*If Yes, specify* \_\_\_\_\_

87. Is the whole study ever referred to with mixed (treatment-research) terms in this **consent form**? 87\_\_\_\_\_

0 No

1 Yes

*If Yes, specify:* \_\_\_\_\_

88. Do terms change in different sections in the **consent form**? (clear, major shift in “boilerplate” sections on voluntariness, confidentiality, right to refuse or withdraw, or signature section) 88\_\_\_\_\_

0 No

1 Yes

*If Yes, specify:* \_\_\_\_\_

89. Are there unusual juxtapositions in the **CF**, such as “patients in this study”? 89\_\_\_\_\_

0 No

1 Yes

*If Yes, specify:* \_\_\_\_\_

90. Are there alternating references to “treatment of patients” and “subjects in the study” in the text of the **consent form**, both referring to research? 90\_\_\_\_\_

0 No

1 Yes

*If Yes, specify:* \_\_\_\_\_

ID \_\_\_\_\_

91. Do section headings use different terminology from section text in the **consent form** (e.g., research and subject in heading, patient and treatment in text under heading)? 91 \_\_\_\_\_

0 No

1 Yes

*If Yes, specify:* \_\_\_\_\_

92. Are there noteworthy uses of verbs in the **consent form**, such as “you will be treated with”? 92 \_\_\_\_\_

0 No

1 Yes

*If Yes, specify:* \_\_\_\_\_

#### IV. General Impressions:

93. Rate the overall readability and understandability of the **consent form** 93 \_\_\_\_\_

1 Clear

2 Partly cloudy, partly clear

3 Cloudy

(NOTE: 2 is default. Consider consent form alone, not in comparison with protocol.)

94. **LIST** anything noteworthy, not captured by the previous sections. *Write neatly.*

[NOTE HERE your reasons for your answer in 93, and related **consent form** issues (e.g., use of 1st person (often confusing), model language that is especially good, terms like “treatment phase,” language characteristics in noncounted protocols that would be captured by counting, e.g., “lots of inappropriate treatment language,” and things not captured by counting, e.g., “purpose section strongly implies efficacy & benefit section does not”).

ALSO NOTE HERE things not captured by 93 in the **consent form** and/or **protocol**, if any, such as major discrepancies between protocol and CF (e.g, protocol says benefit is not likely but CF says “benefit cannot be guaranteed”); missing information, e.g., protocol uses dose escalation design but CF does not mention this; missing sections, e.g, no mention of alternatives or of confidentiality; rare inclusions, e.g., required consent to storage and use of blood and tissue, or child abuse disclosure boilerplate; etc.]