

# Concise ICD Study

## Formative Evaluation Survey for Concise Informed Consent Document

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You received a document titled "Informed consent form" that explains a clinical trial to patients who have colorectal cancer. (A clinical trial is called a "study" in this questionnaire.) This consent form covered a lot of information. The rest of this survey will focus on the consent form and the information in it.

The first set of questions asks you about the consent form you read that describes the colorectal research study (trial).

### 1. How many treatment groups are being compared in this study?

- Two
- Three
- Four
- Five
- More than Five

### 2. How many cancer-fighting drugs will patients in Group 1 receive?

- One
- Two
- Three
- Four

### 3. If you were in Group 2, how long might you stay on the drugs if your cancer improves?

- 6 weeks
- 6 months
- 1 year
- Unclear

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### 4. If you were to agree to be part of this study, how is it decided what group you will be in?

- You (the participant) decides
- Your doctor decides
- Chance (random)
- Don't know

### 5. Which of the following drugs are being tested in this study?

	Yes	No	Unsure
Taxol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Adriamycin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cisplatin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carboplatin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methotrexate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Continue Survey

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### 6. For this next set of questions, please answer each by saying whether you “agree” or “disagree.”

	Agree	Disagree	Unsure
The side effects from the drugs will affect all patients in the same way.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If I signed the consent form, I would be agreeing to participate in a research study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
One reason you would be taken off this study is if the doctor feels it is harmful to your health.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The only reason you will be taken off this study is if the drugs make you so sick that it is unbearable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
According to the consent form, the purpose of this study is to see what amount (or dose) of cancer fighting drugs is better for treating colorectal cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is unlikely that the drugs that are part of this study will cure your cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It's up to you to decide if you will be part of this treatment study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The consent form makes it clear what persons I should contact if I have any concerns about the clinical trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
You may be responsible for some of the treatment costs not covered by your insurance for this study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
What is learned from this study will help future cancer patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
You could choose not to have any treatment for your cancer at all.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If you agree to be part of this study you must stay on the treatment until the study is over.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Published information about this study may include your name.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The study drugs might not be any better than other cancer drugs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The drugs that are part of this study may cause your hair to fall out.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
You will be paid for taking part in this study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
According to the consent form, there are other treatment options for colorectal cancer other than the drugs in this study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
According to the consent form, the reason this study is being conducted is to find the treatment that will cure your cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The consent form stated that this study is being done to find the treatment that will most benefit you	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
According to the consent form, the purpose of this study is to see which of the treatments is better at slowing the growth of colorectal cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The drugs in this study will have no effect on your level of energy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Your doctor can take you off the study without asking you.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
By signing the consent statement for this study, you agree that tissues taken from you can be used for other studies of cancer genes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Only staff from the hospital or clinic can look in your medical records for information about your treatment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Continue Survey**

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**7. For the next questions, please show how much you agree or disagree with the following statements about the consent form for this study.**

**Please read each statement and rate how much you agree with each statement, using a scale of Strongly Disagree to Strongly Agree.**

	Strongly Disagree					Strongly Agree	N/A
I read the consent form very carefully.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The consent form was easy to understand	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The information in the consent form was clearly presented	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The consent form gave me enough information about this study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
After reading the consent form, I feel I can make an informed choice about participating in this study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**8. These questions are about taking part in cancer clinical trials.**

	NOT AT ALL likely					VERY likely	Don't Know
As a result of reading this consent form, how likely is it that you would consider participating in a clinical trial if you were diagnosed with cancer again and it was offered to you?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
As a result of reading this consent form, how likely is it that you recommend clinical trials to others who have been diagnosed with cancer?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**9. The following statements describe attitudes about participating in cancer clinical trials. Please read each statement and circle how much you agree with each statement, using a scale of Strongly Disagree to Strongly Agree.**

	Strongly Disagree					Strongly Agree	Don't Know
Other people will benefit from the clinical trial results if I participate in a clinical trial.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being in a clinical trial is a way for me to help others.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would receive better care if I participated in a clinical trial.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My health would be followed more closely if I were in a clinical trial.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being in a clinical trial would give me the best and newest treatments.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being in a clinical trial could give me a better chance of being cured.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Patient Education Materials

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**10. For the last part of this questionnaire, please show how much you agree or disagree with the following statements about the patient education materials you received.**

	Strongly Disagree					Strongly Agree	Don't Know
I read the materials very carefully.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The materials were easy to understand.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The materials provided information that was useful to me in deciding to join the study or not.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The materials helped me decide whether or not to participate in this study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The information in the materials was clearly presented.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I liked the way the materials looked.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The materials served as a useful reference when I needed to remember specific information about this study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Demographics

The following questions are asked for statistical purposes and are only used in aggregate. Results for these questions remain secure, as do all other answers in this survey.

**\*11. Are you...?**

- Female
- Male

**12. What is your approximate annual household income?**

- Under \$25,000
- \$25,000-\$49,999
- \$50,000-\$74,999
- \$75,000-\$99,999
- \$100,000-\$149,999
- \$150,000 or over

**13. What was the last grade you completed in school?**

- Some high school
- High school graduate
- Some college
- College graduate
- Postgraduate/professional

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**\*14. Which of the following best describes your ethnicity?**

- Hispanic/Latino
- Not Hispanic or Latino

**\*15. Which one or more best describes your race?**

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White

**\*16. What is your zip code of the area your home is located in?**

## Thank You for Your Help

This completes the survey. Thank you very much for your time and opinions.

SPECIFIC INSTRUCTIONS FROM THE PANEL PROVIDER WILL BE ADDED WITH REGARDS TO INCENTIVES, ETC.