OVERARCHING QUESTIONS

(Can be applied to all the later categories)

1. What phase is this trial (I, II or III)?
2. Am I willing and able – physically and financially – to travel to appointments if necessary? Should I consider traveling to another country?
3. Can any of the test monitoring requirements of the trial protocol be done by my local oncologist/local lab?
4. If mutation testing is done as part of the trial protocol, will I be told my mutation status?
5. Will using this drug preclude any future protocols (including other clinical trials)?
6. What are the likely side-effects and are those acceptable to me?
7. Is this a limited-duration drug or a "forever" drug?
8. How will they decide whether to stop the trial and how long will that take if it is not working? Are dose reductions a potential response to AEs (adverse events)?
9. If they stop the trial, what is my next protocol likely to be?
10. If the drug is working and they complete the trial, will I be able to continue on the drug (and at what cost)?
11. Overarching for all categories: Please help me fully understand the risks, expected level of response and PFS (progression-free survival), and potential reactions and side effects of this treatment. What are the expected outcomes and goal of this trial? How well do the trial investigators communicate with me and my oncologist?

Altruism: Advance Research for Others

1. Based on the Phase:
    a. If it is a Phase I or II, am I comfortable with largely unknown possible side effects?
    b. If it is a double-blind phase III, am I willing to be in the comparison group?
2. Is there something that makes this particular drug interesting for me to be a subject (e.g. it hopes to achieve lasting CR (complete response); it is a mechanism that I find scientifically interesting)?
3. What are the approved therapies that are available as alternatives? Will they still be available if this trial does not work for me?

Optimism:
Blind Optimism – Doc Says This Will Cure Me
Considered Optimism – My Research Says Go for It

1. Why do I think this is a better alternative than established protocols?
    a. Less severe probable side effects?
    b. Less likely probable side effects?
    c. More profound results?
    d. Time limited rather than "forever"?
2. How will we decide if it is not working, and if it does not work, what is next?

Out of Approved Options – Into the Wild

1. Have I truly exhausted approved options, including commonly used off-label protocols?
2. Are there protocols that I am more or less likely to have developed resistance to through my prior protocols?
3. At this point am I looking more for a profound response even if the likelihood of a response is lower or the possible AEs (adverse events) higher; or a "maintenance" response with a higher likelihood of achieving a response and AEs of lower likelihood and severity?
4. What is compassionate care authorization and how does it work?