

Withdrawal of Consent to Continue in Research Form

In order for a participant to orderly remove themselves from a study, study team members may advise the participant to write a letter to document their request to withdraw from the study. The study team may also need to explain to the participant the different ways they may want to withdraw – from the research entirely, from the study treatment only, etc. If a letter is written, this information should be specified in the participant's letter. In order to make the documentation of withdrawal process less onerous on participants and study teams, the DFCI IRB has approved the use of the *Withdrawal of Consent to Continue in Research Form* which can be used in lieu of a letter from the participant.

If you choose to use this form with participants, please note the following:

1. This form is not required to be used to document a participant's withdrawal from a DF/HCC study. Alternate methods for documenting withdrawal of consent may be utilized.
2. This form can be used by any participant enrolled under the DFCI IRB. This form should not be used by outside sites participating on a DF/HCC trial that are not using the DFCI IRB as their IRB of record.
3. Study team members are responsible for providing this form to study participants and participants must be advised as to where the completed form should be returned. This form should not be submitted to OHRS or ODQ for processing.
4. This form may be used to document withdrawal from one or more studies. However, participants must be advised that the selection(s) they make in Part B must apply to all studies listed in Part A. If a participant would like indicate a different response in Part B depending on each study listed in Part A, they should be advised to complete a separate form for each study.
5. If a participant would like to remove or destroy previously-collected data or samples on a non-FDA regulated trial, the participant should be advised not to use this form. An alternate method, such as a letter to the Principal Investigator, should be used to document this type of withdrawal request.