The purpose of the FC Form is to report the vital status of the participant (deceased/alive) and to document how the vital status and follow-up information (F1) was obtained. The purpose of the Q1-dates is to document your follow-up efforts, as they correspond to the follow-up time-points. The “F1 interval period” is an entirely different issue and is derived from the time-point and completion date of the previous F1 Form. The FC Form is submitted every 6 months whether the F1 Form was completed or not. The FC Form is completed by the RA and is NOT given to the participant as part of the F1. The shaded/boxed areas of the coversheet are not submitted to ACRIN.

Basically, the first date field is the date follow-up was initiated and the second date is the date the follow-up was completed (whether you successfully administered the F1 or not). Please refer to revised FC instructions.

1. **Date of vital status update/follow-up:** Both date fields are required data elements, no blanks. The date fields must be completed as mm/dd/yyyy.

   If submitting the FC to report a participant death (vital status change):
   - Record the date of discovery (the date the site became aware of the death) in the first and second date fields.
   - Refer to Section XXX for full description of vital status/death reporting.

   If the F1 Form is administered by mail:
   - Record the date the F1 Form was mailed in the first date field.
   - Record the receipt date of the completed F1 Form in the second date field.
   - If the F1 Form has not been returned after approximately 3 weeks, the RA should call the participant to ensure that the form was received and completed. The F1 Form may need to be administered by phone.
   - If, by the end of the follow-up window, you are unable to obtain a completed F1 Form after multiple attempts (mail/phone), record the date of last attempt in the second date field and submit the FC.

   If the F1 Form is administered by phone interview:
   - Record the date of the first phone interview and/or attempt in the first date field.
   - Record the date of the last phone interview and/or attempt in the second date field.
   - If the F1 Form is completed during the first interview attempt record the date of the interview in the first and second date fields.
   - If the F1 Form is not completed, multiple attempts (mail, phone, certified mail) and/or participant refusal, record the date of the last attempt in the second date field.

   If the F1 Form is administered by in-person interview:
   - Record the date of the interview in the first and second date fields.
   - If the F1 Form is not completed, multiple attempts (mail, phone, certified mail) and/or participant refusal, record the date of the last attempt in the second date field.

   If the F1 Form is administered by more than one method:
   - Record the date the follow-up was initiated, whether by mail, phone, or in-person interview.
   - Record the date the follow-up was completed, whether by mail, phone, or in-person interview.

**NOTE:** Regardless of the method of administration, it is expected that you make multiple attempts to contact the participant for completion of the F1 Form, if need be (refer to MOP, Appendix 8-3). At a minimum, obtaining the participant's vital status (dead or alive) at each time point is important, as this relates to the primary endpoint. If at the end of the follow-up window the F1 Form is not completed, submit the FC. For each time point, a FC Form should be completed, whether the F1 is completed or not.

2. **Participant vital status:** Report the vital status of the participant (Alive, Deceased, Unknown) by placing a check mark in the appropriate response box.
If the participant is alive or vital status is unknown, skip to 3.

If the participant is deceased, complete Q2a-e then skip Q3 and complete Q3-5.

a. If the participant is deceased, record the date of death in the space provided. The date must be recorded as month/day/year. If unable to obtain any portion of the date, record ‘99’. For example, if the contact is unable to provide the day and provides only 10/2003, the RA should record the day as ‘99’. The date would then read 10/99/2003. WEB: mm/dd/yyyy required; if unknown, use ‘99’ as directed.

b. If the participant is deceased, record the cause of death on the line provided. WEB: data field is limited to 100 characters.

c. Indicate the source of the information by checking the appropriate response(s).

d. If able to obtain, record the place of death. WEB: not submitted to ACRIN.

e. Indicate whether or not the death certificate has been requested. If requested, document the date of the request.

3. Follow-up reporting period: Select the follow-up time point from the list provided. The FC and F1 are completed every 6 months from the date of randomization, with the annual time points corresponding with the annual imaging windows.

4. Source of follow-up contact: Select each appropriate response from the list provided indicating all sources of follow-up information. When direct contact with the participant was unsuccessful, some sites have chosen to record the type of contact attempts made (in-person, telephone, or mailing) for their own tracking purposes and ‘no contact’. This method is fine as long as the FC documents when no direct contact is made with the participant.

• In-person interview: Select this response if all or part of the follow-up data (vital status, F1) was collected during an in-person interview. This response, absent of the ‘no contact’ response, signifies direct contact with the participant and expectation of F1 Form submission.

• Telephone interview: Select this response if all or part of the follow-up data (vital status, F1) was collected during a phone interview. This response, absent of the ‘no contact’ response, signifies direct contact with the participant and expectation of F1 Form submission.

• Mailing: Select this response if all or part of the follow-up data (vital status, F1) was collected via the mail (i.e., return of completed F1). An unreturned F1 Form is not considered a direct contact. Unreturned F1 Forms should be followed up on, as described in the F1 Form instructions. If direct contact attempts with the participant were unsuccessful (mail or phone), the ‘no contact’ response should be utilized so that the date of last direct contact is known. This response, absent of the ‘no contact’ response, signifies direct contact with the participant and expectation of F1 Form submission.

• Contact made by participant refused F1 completion: Select this response if the participant/proxy refused F1 completion or an abbreviated F1 interview (as described in F1 instructions addendum). Every attempt should be made to meet the participant’s needs for F1 completion. This response will trigger suppression of the F1 Form.

• No contact: Select this response if no contact was made, despite multiple attempts (mail, phone, certified mail), record the date of last direct contact with the participant. Date must be recorded as mm/dd/yyyy. This response will trigger suppression of the F1 Form.

• Other: Select this response only if unable to use the above responses. Document the other source of follow-up contact on the line provided. WEB: data field is limited to 60 characters. Using this field to document non-response or an unreturned F1 will NOT trigger suppression of the F1 Form, you will need to submit a GCM.

5. Was there any change in the participant contact information since last contact or study follow-up?

Check “No,” if the participant reported no change in her/his contact information.
Check “Yes,” if the participant reported a change in her/his contact information. Both group 1 and group 2 sites should update their local database/records. Group 1 sites are required to fax/mail the annual contact sheet to the Biostatistical Center.

Check “Not applicable,” if the participant did not complete an annual contact worksheet associated with this reporting period (e.g. interim time point, no contact made).

**Signature of person responsible for data:** Legible signature of the RA responsible for the data recorded and completed of the form.

**Date of form completion:** Date the FC form was completed by the responsible RA.

**Person entering data onto web:** Legible signature of staff entering the data, signed upon completion of this task.