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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on documenting each participant’s study completion status. Update it as necessary for your specific study.** * All participants should have study completion status documented. Specifically, the end-point at which they were no longer considered to be in the study should be documented. This type of documentation can assist greatly during regular monitoring visits, audits, and even with staff onboarding when there is transition among team members.
* There are a number of completion statuses that can be used in a study. The following bullets are only examples of what can be included, there may be others that a study team would want to include. What is documented should be specific for the study design, intervention, and patient population. It should be noted that these definitions might not align with the specific study’s protocol, sponsor, or other oversight body. Research teams should be sure to update this form so that it aligns with their specific study requirements and definitions.
	+ *Completed study* – final per-protocol visit was completed, regardless of total number of visits completed.
	+ *Withdrawn* – Participant has withdrawn consent and no longer wants to be in the study. Note that this is different than a participant who is no longer, for example, taking a study drug but is remaining in the study for data collection purposes including physical assessments, biospecimen collection, and surveys.
	+ *Terminated* – The PI makes a decision to remove a participant from the study completely. This is usually because the PI feels it is no longer in the participant’s best interest to continue in the study. Again, this is different than a participant who is discontinuing an intervention but continuing in the study for data collection.
	+ *Lost to Follow-Up* – Participant is unable to be contacted and is not coming to scheduled visits. All contact attempts and missed visits should be documented elsewhere in the participant’s study record. If a protocol does not specific how many contact attempts should be made, the research team should use their best judgement.
	+ *Deceased* – Participant died during study, regardless of expectedness or relatedness. For studies with long-term follow-up, it might be helpful to split this into active intervention and follow-up.
* It should be noted that for both Withdrawn and Terminated, there may be per-protocol visits expected in these situations for safety or otherwise. This would be different than the standard per-protocol final visit as noted in a Completed status.
* When designing this form for a specific study, it could be useful to review any requirements including CONSORT-type diagrams from the journal that the study team expects to submit to.
* This form can be entirely built within REDCap, as an electronic case report form to allow for data analysis.
* Delete the CRRO template version date and add in the study-specific version date of this document.
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| Study Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*(Last visit attended, last point of data collection, last contact if withdrawal/termination/lost to follow-up, or death date)* |
| Study Completion Reason | [ ]  Completed last study visit, regardless of total number of visits completed[ ]  Deceased *(Additional information the death should be captured on an Adverse Event Form or other study form)**If one of the below reasons, additional information will need to be completed)*[ ]  Withdrawn, completed partial number of visits, participant decision[ ]  Terminated, completed partial number of visits, investigator decision[ ]  Lost to follow-up – Missed scheduled visits, unable to contact[ ]  Other reason for study completion |
| Additional Information, if required from Study Completion Reason*Only one of these sections should be completed, all others should remain blank.*  |
| Withdrawal – Participant DecisionReason for withdrawal: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Termination – Investigator DecisionReason for termination: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Lost to Follow-UpBriefly describe contact attempts: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| OtherReason for other study completion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| General comments or notes on study participation or participant not otherwise noted: [ ]  *No notes or notes documented elsewhere: specify where: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Research Staff Completing Form** | Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |