LABS-2 Off Protocol (OFF) – Version 06/01/2013 FORMV

Patient ID __ __ __ - __ __ __ __ - __ __   **ID**   **Form Completion Date** __ __ / __ __ / 20 __ __
                                                   OFFDAT   mm   dd   yy

Certification number: __ __ __ __ __   **CERT**   **Visit:** _____ **VISIT**

                                 SURGDAT Surgery Date (for issues related to surgery): __ __ / __ __ / 20 __ __

1. Was the entire visit missed? **VISMISS**
     ☐ 0. No   ☐ 1. Yes
     ∨   ∨
   Skip to   1.1 Reason for **Missed Visit** (*check only one*) **REAMISS**
   Question 2
           ☐ 1. Participant out of town
           ☐ 2. Participant could not be located/contacted
           ☐ 3. Participant could not be scheduled due to other commitments
           ☐ 4. Participant too ill
           ☐ 5. Hospitalization
           ☐ 6. Refused
           ☐ 7. Other (Specify____ **REAMISSS**_____)
           ☐ 8. Participant scheduled but did not attend research visit

                   If refused, specify (*check only the one **primary** reason*) **REFUSE**
                   ☐ 1 Relationship with research staff
                   ☐ 2 Relationship with bariatric team
                   ☐ 3 Visit wasn't coordinated with the clinical follow-up
                   ☐ 4 Family responsibilities
                   ☐ 5 Not enough compensation/reimbursement
                   ☐ 6 No or not enough feedback of study results
                   ☐ 7 Travel time to medical facility
                   ☐ 8 Work responsibilities
                   ☐ 9 Previous visit was too long
                   ☐ 10. Can't fit available visit times in my schedule
                   ☐ 11. Participant is not doing well and embarrassed to come back
                   ☐ 12. Refused to provide a reason for refusing/Just don't want to do this now.
                   ☐ 13. Didn't think the study was going to be going on this long/thought research was over and did not wish to come in.
                   ☐ 14. Other, (Specify: _____ **REFUSEOS** _____)

       1.2 Status Date: __ __ **STATDATE** __ __ (*most recent date participant known to be alive*)

       1.3 Was the LABS-2 Options Letter sent? ☐ 0. No ☐ 1. Yes **ONOVIS**

2. Was the LABS-2 Options Letter sent to the participant? **OYESVIS**
     ☐ 0. No   ☐ 1. Yes
     ⋁   ⋁

Skip to Question 3

2.1 What was the response *(check yes or no to each)*?
No   Yes
☐   ☐   Participant scheduled the LABS research visit. **OSCHED**
☐   ☐   Participant was not able or willing to come in for a LABS research visit, but willing to complete the questionnaires and return them by mail. **OSEND**
☐   ☐   Participant was not able or willing to come in for a LABS research visit, but was willing to complete portions of the visit over the phone. **OPHONE**
☐   ☐   No response from participant. **ORESP**
☐   ☐   Other **OOTH** (Specify: _____ **OOTHS** _____)

3. Indicate type of off-protocol event (*check "no" or "yes" for each*)

  No   **Yes**
  ☐   ☐   3.1 Samples not drawn/shipped to NIDDK Biosample Repository **LABSBIO**
  ☐   ☐   3.2 Samples not drawn/shipped to Central Laboratory **LABSCLAB**
  ☐   ☐   3.3 Samples not drawn/shipped to NIDDK Genetics Repository **LABSGEN**

Reason for missing labs *(check "no" or "yes" for each)*:
No   **Yes**
☐   ☐   Difficult or incomplete draw **LABSDRW**
☐   ☐   Kits/tubes were not available **LABSKIT**
☐   ☐   Participant out of town during protocol window **LABSOUT**
☐   ☐   Participant could not be located during protocol window **LABSLOC**
☐   ☐   Participant could not be scheduled during protocol window due to other commitments **LABSSCH**
☐   ☐   Participant too ill during protocol window **LABSILL**
☐   ☐   Participant hospitalized during protocol window **LABSHOSP**
☐   ☐   Participant refused **LABSREF**
☐   ☐   Other **LABSOTH** (Specify: ___ **LABSOTHS** _____)

Indicate type of off-protocol event, continued...

No   Yes

☐   ☐   3.4 Not selected for LABS-2 but consented and enrolled (pre-operative visit only) **NOTSEL2**

☐   ☐   3.5 Missing Assessments **MISSFORM**

3.5.1 Missing Assessment (*check "no" or "yes" for each*):

No	Yes		No	Yes	
☐	☐	Self-Assessment forms **SELFAF**	☐	☐	Clinician-Assessment forms **CLINAF**
		If yes, check "no" or "yes" for each			If yes, check "no" or "yes" for each

No	Yes		No	Yes	
☐	☐	WGT **WGTSA**	☐	☐	RCAB/RCAF **RCABRCAF**
☐	☐	DIB/DIF **DIBDIF**	☐	☐	MWF **MWF**
☐	☐	BB/BF **BBBF**	☐	☐	WEF **WEF**
☐	☐	ISEL **ISEL**	☐	☐	SMAB/SMAF **SMABSMAF**
☐	☐	SF36 **SF36**	☐	☐	FO6 **FO6**
☐	☐	WPAI **WPAI**	☐	☐	HC **HC**
☐	☐	PETSB/F **PETSBF**	☐	☐	MAQ **MAQ**
☐	☐	IW **IW**	☐	☐	SHORT **SHORT**
☐	☐	GSRS **GSRS**	☐	☐	EC **EC**
☐	☐	UIB/UIF **UIBUIF**			
☐	☐	BS **BS**	☐	☐	Forms administered at the 4 year, or 5 year visit **YEAR45AF**
☐	☐	SFB/SFF **SFBSFF**	☐	☐	CD **CD**
☐	☐	MED **MED2**	☐	☐	ESS **ESS**
☐	☐	RHB/RHF **RHBRHF**	☐	☐	SBQ **SBQ45**
☐	☐	RHP **RHP**			
☐	☐	MAB/MAF /MVF **MABMAF**			
☐	☐	WHQ **WHQ**			
☐	☐	BU **BU**			
☐	☐	EQ5D **EQ5D**			
☐	☐	CDF **CDCDF**			
☐	☐	RSF/NIV **RSF**			
☐	☐	BDI **BDI**			
☐	☐	SBQ **SBQSBQF**			
☐	☐	SLS **SLS**			

3.5.2 Reason(s) for missing assessment (*check "no" or "yes" for each*)

No	Yes	
☐	☐	Participant unable/unwilling to complete all assessments **MISSPUU**
☐	☐	Participant did not return participant rated (self)assessments **MISSPDR**
☐	☐	Clinician/surgeon-rated assessments incomplete due to scheduling conflicts **MISSCINC**
☐	☐	Participant did not attend scheduled evaluation **MISSPDA**
☐	☐	Assessment(s) incomplete due to hospitalization **MISSAI**
☐	☐	Assessment(s) completed outside the protocol window **MISSACO**
☐	☐	Unable to get medical records **MISSMR**
☐	☐	Didn't see medical doctor **MISSMD**
☐	☐	IRB did not approve form(s) yet **MISSIRB**
☐	☐	Participant wasn't given form(s) or offered assessment **MISSWGF**
☐	☐	Other **MISSOTH** (Specify: _____ **MISSOTHS**_____)

No **Yes**

☐ ☐ 3.6 Liver biopsy taken but slides never made/sent to the pathologist **LIVBIO**

☐ ☐ 3.7 Stepwatch protocol violation *(check no or yes for each)* **SAMPV**

> **Sam given but no file because…**
>
> **No** **Yes**
>
> ☐ ☐ a. Participant did not return the SAM. **SAMNORET**
>
> ☐ ☐ b. Data file lost before transfer to the DCC. **SAMTRANS**
>
> ☐ ☐ c. Data could not be read off the monitor due to a problem with the program or docking station. **SAMREAD**
>
> **SAM not given because…**
>
> **No** **Yes**
>
> ☐ ☐ d. Participant refused to accept/wear the SAM. **SAMREF**
>
> ☐ ☐ e. SAM not available to give to participant . **SAMNOAV**
>
> ☐ ☐ f. It would exacerbate a health condition (for example, edema). **SAMEXAC**
>
> ☐ ☐ g. Of a health condition, **unrelated to weight**, that limits walking (for example, paralysis, M.S.). **SAMUNR**
>
> ☐ ☐ h. A temporary injury or health condition, **unrelated to weight,** that effects walking (for example, sprained ankle). **SAMWAL**
>
> ☐ ☐ i. Participant is exclusively bound to wheelchair. **SAMWCH**
>
> ☐ ☐ j. The SAM program or docking station was not working. **SAMDOCK**
>
> ☐ ☐ k. The monitor could not be programmed (i.e., there was no computer with SAM software available). **SAMPROG**
>
> ☐ ☐ l. Coordinator deemed participant not trustworthy with SAM. **SAMTRUST**
>
> ☐ ☐ m. No in-person assessment and not able to reach by phone for SAS assessment. **SAMASSES**
>
> **Other SAM protocol violation**
>
> ☐ ☐ n. Participant failed to complete or return the SAM Log/Diary for one of the expected wear days. **SAMCOMP**
>
> (How many days? __ **SAMDAYS** ___)
>
> ☐ ☐ o. Other SAM violation. **SAMOTH**
>
> (Specify _____ **SAMOTHS** _____)

☐ ☐ 3.8 Corridor walk performed despite ineligibility of the participant. **WALKINEL**

☐ ☐ 3.9 Other **OTHOFF** (Specify: ____ **OTHOFFS** _____)