

Withdrawal / Close Out Form

Please Use Black Pen To Fill Out Form.

46269

Week #

Date of Assessment

Patient ID

Patient Letter Code

week [] [] [] []

assessdt [] [] / [] [] / [] [] [] []
mm dd yyyy

idn [] - [] [] [] - [] [] []

letcode [] [] [] []

corrfix
Correction

Use this form for all therapy groups to report why a randomized patient is withdrawing from the study and will have no subsequent visits.

1. Date of withdrawal / close out:

wddt [] [] / [] [] / [] [] [] []
mm dd yyyy

CRA Use Only

2. Reason for patient withdrawal / close out (Answer each item)

- | | Yes | No | |
|---|-----------------------|-----------------------|-----------------|
| A. Parent refused | <input type="radio"/> | <input type="radio"/> | <i>wdprtref</i> |
| B. Patient refused | <input type="radio"/> | <input type="radio"/> | <i>wdpatref</i> |
| C. Positive urine or serum pregnancy test at BL before the start of therapy | <input type="radio"/> | <input type="radio"/> | <i>wdpreg</i> |
| D. Patient died | <input type="radio"/> | <input type="radio"/> | <i>wddied</i> |
| E. Concurrent medical condition | <input type="radio"/> | <input type="radio"/> | <i>wdmedcon</i> |
| F. Non-serious adverse event | <input type="radio"/> | <input type="radio"/> | <i>wdnsae</i> |
| G. Serious adverse event | <input type="radio"/> | <input type="radio"/> | <i>wdsae</i> |
| H. Lost contact with patient | <input type="radio"/> | <input type="radio"/> | <i>wdlstcon</i> |
| I. Patient moved out of area | <input type="radio"/> | <input type="radio"/> | <i>wdmoved</i> |
| J. Active substance abuse | <input type="radio"/> | <input type="radio"/> | <i>wdsubabs</i> |
| K. End of Protocol visits (close out) | <input type="radio"/> | <input type="radio"/> | <i>wdendprt</i> |
| L. Other | <input type="radio"/> | <input type="radio"/> | <i>wdothr</i> |

Specify: _____

Signature: _____

Certif. #:

staffid1 [] [] - [] [] [] []