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| ESETT | | _____ | | |
| | | Subject ID | | |

Form 211: Informed Consent Log (version 2)

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|---|--|---|--|--|
| Q01 | Is this subject known to have been previously randomized into the ESETT Trial at any participating site? | | <input type="radio"/> No <input type="radio"/> Yes | |
| Q02 | If Q01 = 'Yes' | Previous Subject ID for this subject: | _____ | |
| Document all attempts made to obtain informed consent (in the order that they occurred) | | | | |
| | A. Date/time of consent attempt | B. Contact person | C. Description of consent attempt | D. Outcome |
| Q03-1 | _____ dd-mmm-yyyy ____:____ <input type="radio"/> AM <input type="radio"/> PM | <input type="radio"/> Subject <input type="radio"/> LAR <input type="radio"/> Other | | <input type="radio"/> Consent obtained <input type="radio"/> Consent declined <input type="radio"/> Notification only <input type="radio"/> Notification only - subject deceased <input type="radio"/> No determination of consent or notification |
| Q03-2 | _____ dd-mmm-yyyy ____:____ <input type="radio"/> AM <input type="radio"/> PM | <input type="radio"/> Subject <input type="radio"/> LAR <input type="radio"/> Other | | <input type="radio"/> Consent obtained <input type="radio"/> Consent declined <input type="radio"/> Notification only <input type="radio"/> Notification only - subject deceased <input type="radio"/> No determination of consent or notification |
| General Comments: | | | | |
| Name of person who collected data: If this worksheet is a source document, sign/date here: | | | | |

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| ESETT | Visit: | _____ | Subject ID | |
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| Document all attempts made to obtain informed consent (in the order that they occurred) | | | | |
|---|---|---|--------------------------------------|--|
| A. Date/time of consent attempt | | B. Contact person | C. Description of consent attempt | D. Outcome |
| Q03-3 | _____ dd-mmm-yyyy ____:____ <input type="radio"/> AM <input type="radio"/> PM | <input type="radio"/> Subject <input type="radio"/> LAR <input type="radio"/> Other | | <input type="radio"/> Consent obtained <input type="radio"/> Consent declined <input type="radio"/> Notification only <input type="radio"/> Notification only - subject deceased <input type="radio"/> No determination of consent or notification |
| Q03-4 | _____ dd-mmm-yyyy ____:____ <input type="radio"/> AM <input type="radio"/> PM | <input type="radio"/> Subject <input type="radio"/> LAR <input type="radio"/> Other | | <input type="radio"/> Consent obtained <input type="radio"/> Consent declined <input type="radio"/> Notification only <input type="radio"/> Notification only - subject deceased <input type="radio"/> No determination of consent or notification |
| Q03-5 | _____ dd-mmm-yyyy ____:____ <input type="radio"/> AM <input type="radio"/> PM | <input type="radio"/> Subject <input type="radio"/> LAR <input type="radio"/> Other | | <input type="radio"/> Consent obtained <input type="radio"/> Consent declined <input type="radio"/> Notification only <input type="radio"/> Notification only - subject deceased <input type="radio"/> No determination of consent or notification |
| General Comments: | | | | |
| Name of person who collected data: If this worksheet is a source document, sign/date here: | | | | |

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| Q04 | Identify any informed consent errors of which the study team becomes aware: Check all that apply. | <input type="checkbox"/> Lost original IC <input type="checkbox"/> Missing documentation of IC process <input type="checkbox"/> Incorrect IC version signed <input type="checkbox"/> IC missing subject/LAR signature <input type="checkbox"/> IC missing/incorrect subject/LAR signature date <input type="checkbox"/> IC missing investigator signature <input type="checkbox"/> IC missing/incorrect investigator signature date <input type="checkbox"/> Other |
| Q05 | If Q04 = 'Other' | Please specify 'other' errors: |
| Q06 | LAR/Subject post-enrollment survey: | <input type="radio"/> Completed <input type="radio"/> Not given <input type="radio"/> Refused <input type="radio"/> Other |
| General Comments: | | |
| Name of person who collected data: If this worksheet is a source document, sign/date here: | | |

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