DESCRIPTION: Having already gone through one IRB you must now go through a second one. This IRB must conduct an initial review of your on-going study. This form describes what is to be transferred is to be submitted by the person responsible for overall operations. This can be a sponsor for a multi-site study or the investigator for an investigator initiated study.

**Please submit to E&I:**

[ ]  A packet of study materials including the protocol, amendments (if not already incorporated), and any supplemental materials. For any modified materials include both clean and track change versions.

[ ]  A packet of Investigator materials including any supplemental materials and local or site related documents and modified materials showing both clean and track change versions.

**MAKE A COPY FOR YOUR STUDY CORRESPONDENCE FILE.**

**Send to: submit@eandireview.com**

|  |
| --- |
| 1. Identification
 |
| A.1 Primary Contact Person  |
| Name (with degrees) |       | Phone |       |
| Company |       | Cell |       |
| Mailing Address |       | Fax |       |
| City, State, Zip |       | E-mail |       |
| **A.2. Study**  |
| Every new study must have an E&I Form 21A or 21B and the materials requested there. |
| Study Name |       |
| Study Number, if any |       |
| A.3 Principal Investigator  |
| Each investigator must be reviewed. For each, submit E&I Form 30A or 30B or 82 and the materials requested there. |
| Name (with degrees) |       | Phone |       |
| Company |       | Email |       |
| Number of study sites total?       Number of sites to be transferred to E&I?       |

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| A.4 Prior IRB  |
| Name of IRB |       | Phone |       |
| Institution/Company |       | Email |       |
| Why is transfer being requested?       |
| Expiration date of study:      Transfer cannot be effective until the E&I IRB has reviewed and approved. |
| Will the prior IRB be sending review materials (IRB minutes, records) separately?       |

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| 1. History and Continuing Review
 |
| B.1 Enrollment  |
| Enrollment is now | [ ]  Open [ ]  Closed |
|  | Sample | Cumulative total of all subjects **start to now** | The numbers reported here are current as of date      |
| **A How many people signed a consent form / were enrolled?** | **53** |       | [ ]  Consent was waived or [ ]  Consent documentation was waived |
| 1 Screen failures | - 0 |       | Specifically explain each screening failure, or attach separate list:      |
| 2 Number being screened now | - 3 |       |
| **3 Enrolled** | **= 50** |       |
| 4 Active: In interventional phase |  30 |       | Include explanation for any entry in lines 6 through 8 or attach separate list:       |
| 5 Active: In follow-up only | + 10 |       |
| 6 Gone: Removed by investigator | + 4 |       |
| 7 Gone: Subject withdrew | + 2 |       |
| 8 Gone: Lost to follow-up | + 2 |       |
| 9 Completed | + 2 |       |
| **10** Add 4 to 9. Total must equal the number enrolled  | = 50 |       |
| B.2. Risks, Problems, Harms and Discomforts Evaluation  |
| Summarize any reports that were or should have been made to the prior IRB. |
| Have there been any: | For any box checked ***YES***, provide a report or explain what happened either here or as an attachment:      |
| - Unanticipated problems (including any breach in confidentiality)? | [ ]  No [ ]  Yes |
| - Serious adverse events?  | [ ]  No [ ]  Yes |
| - Problems that were more frequent than anticipated? | [ ]  No [ ]  Yes |
| - Subject claims for research related injury?  | [ ]  No [ ]  Yes |
| - Data monitoring report(s)?  | [ ]  No [ ]  Yes |
| - Subject complaints | [ ]  No [ ]  Yes |

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| 1. Changes
 |
| C.1 What documents will need to be changed or proposed? |
| Protocol and amendments | [ ]  No [ ]  Yes | Version(s) requested:       |
| Consent forms? | [ ]  No [ ]  Yes | Number included:      Languages other than English:       |
| Notice to already enrolled subjects? | [ ]  No [ ]  Yes |  |
| Recruitment materials? | [ ]  No [ ]  Yes |  |
| **C.2. Are there any special instructions, notices or people who must be notified??** |
| 1. |       |
| 2. |       |
| 3. |       |

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| D. Signatures |
| Signatures | Sponsor representative or Investigator | Person who prepared the form, if different |
| Signature |  |  |
| Printed name |       |       |
| Title |       |       |
| Date |       |       |