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](mailto: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 |  |  |