**FORM 8.1A INVESTIGATOR RESPONSIBILITIES – IDI REC REQUIREMENTS**

Submission Materials

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|  |  | DEADLINE |  |
| **INITIAL REVIEW** | **Full IDI REC**  (Review by convened meeting of IDI REC members) | At least 21 days prior to the review meeting. (Complete submissions received less than 21 days to the IDI REC meeting will be reviewed at the next IDI REC meeting) | **Submission items**   1. Completed and signed IDI REC Face Sheet \* 2. Study Summary Form complete with required attachments \* 3. Research protocol 4. Informed consent document and checklist \* 5. Proposed participant instructions 6. Other supporting material (sample of proposed advertising, patient diaries, etc.) 7. Investigator Brochure or insert/device description (Required for NDA regulated products) 8. Financial disclosure statement 9. Questionnaires & assessment instruments (two copies) 10. Documentation that the study has been reviewed and approved by other committees charged with oversight of research. |
|  |  | \*Required for all research participant to IDI REC review |
| **Exempt Review** | None | Completed and signed IDI REC Face Sheet \* |
|  |  | Form 3.2A Exemption Screening Questions |
|  |  | Form 3.2B Claim of Exemption |