**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.
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|  |  | \*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 |