**FORM 3.1C IDI REC SUBMISSION CHECKLIST**

Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study

1. Complete IDI REC "Research Project Proposal Form" completely and affix appropriate signatures. One copy of the "Research Project Proposal Form" must be attached to each packet.
2. The Investigator’s Agreement Form must be submitted. One copy should be attached to each packet.
3. Submit the required numbers of packet copies.

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| --- | --- |
|  | **Required submission items** |
|  | Completed and signed IDI REC Research Project Proposal Form |
|  | Investigator’s Agreement Form complete with required attachments |
|  | Research protocol |
|  | Informed consent document and checklist |
|  | Proposed participant instructions |
|  | Other supporting material (sample of proposed advertising, patient diaries, etc.) |
|  | Investigator Brochure or insert /device description (Required for NDA/ FDA regulated products) |
|  | Financial disclosure statement |
|  | Copy of the grant with budget |
|  | Case report form |
|  | Questionnaires & assessment instruments |
|  | Food and Drug Administration Form 1572 (IND) or signed Investigator Agreement (IDE) |
|  | Documentation that the study has been reviewed and approved by other committees charged with oversight of research. |

Comments:

Reviewed by

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date