Navicent Health IRB
Research Protocol Submission Packet
Required Documents

NOTE:

- **ALL** items must be received before a research proposal will be reviewed
- All forms must be filled out completely. No missing information.
- Spelling and grammar should be checked on all documents and are correct.
- Application has been **signed in writing** by the Principal Investigator
- There is no charge for review of a Humanitarian Use Device

Required Documents:

□ IRB Protocol Review Fee Invoice

□ Research Protocol Application

□ Investigator Information

- □ CV for each investigator
- □ Citi training certificates of completion for each investigator
- □ FDA Form 1572 for each investigator (Industry Sponsored Studies)

□ Additional Research Personnel Information

□ Conflict of Interest Disclosure for PRINCIPLE Investigator

□ Conflict of Interest Disclosure for **ALL** CO-INVESTIGATORS

□ Copy of the research protocol (refer to "How to Write a Research Protocol" document for assistance)

□ Investigator's brochure (industry sponsored research)

□ Informed Consent Information Sheet

- □ Copy of Informed Consent (if consent required)
- □ Copy of Assent *(required for study participants under the age of 18yrs of age)*
- □ A Certificate of Translation Accuracy for consents/assents used in different languages

□ Copy of Data Collection Instrument(s) (survey/questionnaire/etc.)

□ Copy of Recruitment Materials, Scripts

□ Completed Institutional Review Board Security Risk Assessment Questionnaire

List any Additional Documents Submitted.