

REQUIRED ISTAR SECTIONS BASED ON REVIEW LEVEL

| Sections | Full Board | Expedited | Exempt |
|--|------------|-----------|-----------|
| 1. Project Identification and Abstract | x | x | x |
| 2. Study Personnel | x | x | x |
| <i>2a. Collaborators from other institutions</i> | | | |
| 3. Required Department Approvals | x | x | x |
| 4. Funding Information | x | x | x |
| 5. Type of Study Review | x | x | x |
| 5a. Type of Study Review- Expedited Review | | x | |
| 5b. Type of Study Review- Application for Exempt Status | | | x |
| 6. Study Location(s) | x | x | x |
| 6a. HSC Location(s) or 6b. UPC Location(s) | x | x | x |
| <i>6c. Other Sites/Institutions</i> | | | |
| 9. Methods and Procedures-Selected Descriptors/Community Engaged Research | x | x | x |
| 10. Characteristics of the Study Subject Population | x | x | |
| 11. Study Design and Methodology | | | x |
| 11. Research Objectives and Background | x | x | |
| 12. Methods and Procedures-Prospective Studies (or retrospective if appl) | x | x | x |
| <i>13. Methods and Procedures-Retrospective Studies/Existing Data</i> | | | |
| <i>14. Biohazardous Substances</i> | | | |
| <i>17. Methods and Procedures- Drug and Biologic Information</i> | | | |
| <i>18. Methods and Procedures- Device Information</i> | | | |
| <i>21. Methods and Procedures- Surveys/Questionnaires/Psychometric Testing</i> | | | |
| 22. Special Subject Populations | x | x | x |
| <i>22a. Special Subject Populations- Normal Volunteers</i> | | | |
| <i>22d. Special Subject Populations- Non-English Speaking Subjects</i> | | | |
| <i>22e. Special Subject Populations- Minors</i> | | | |
| 23. Study Resources | x | x | |
| 24. Subject Recruitment and Informed Consent | x | x | x |
| <i>24A. Assent</i> | | | |
| <i>24P. Parental Permission</i> | | | |
| 25. Financial Obligation and Compensation | x | x | x |
| 26. Participant Privacy and Data Confidentiality | x | x | x |
| 27. Risk/Benefit Assessment- Risks | x | x | |
| 28. Risk/Benefit Analysis- Potential Benefits and Alternatives | x | x | x |
| 35. Is the HIPAA Privacy Rule Applicable? | x | x | x |
| <i>36. HIPAA Analysis</i> | | | |
| <i>38b. Full Waiver of HIPAA Authorization</i> | | | |
| 39. Conflict of Interest Information | x | x | x |
| 40. Additional Supporting Documents* | | | |
| 99. Instructions for Submission* | | | |
| TOTAL | 20 | 21 | 18 |

Note: italicized sections are triggered when specific answers on application are selected; samples listed are not all-inclusive

*sections 40 and 99 are included in all applications (not included in total count)

12.20.13