1. Main hypothesis, question or objective and brief overview of study methods
2. The study population (adults, minors, prisoners, cognitively impaired subjects)
3. Time required for research participation
4. Address the required criteria for approval, in order if possible, and then the applicable additional items further below. **Using the “comments” column is completely voluntary;** you may likewise refer to your eIRB review form, or other notes.

|  |  |
| --- | --- |
| **Criteria 1: Minimize Risks** | |
| Speak to whether study procedures are consistent with sound research design and do not expose the subjects to unnecessary risk. Address if procedures are already being performed on the subjects for diagnostic or treatment purposes and whether risks could be any further minimized, e.g. are all tests/procedures necessary; are all investigators qualified; is target enrollment justified? | Comments: |
| **Criteria 2: Risk/Benefit Ratio** | |
| Speak to whether there is adequate prior evidence that the risks in the study are outweighed by the potential benefits to the subjects and/or scientific knowledge. | Comments: |
| **Criteria 3: Selection Equitable** | |
| Speak to whether there are appropriate inclusion/exclusion criteria, and if vulnerable populations are to be enrolled (or excluded) in an appropriate and meaningful way and what safeguards are included for vulnerable populations. | Comments: |
| **Criteria 4: Seek Informed Consent** | |
| Speak to whether the informed consent document contains the required elements, and whether language is understandable (8th grade level). Address any waivers requested and whether justified. State if consent is obtained from appropriate individuals (subject, LAR, parent) and if LAR, is it clear when LAR would be used. | Comments: |
| **Criteria 5: Consenting Process** | |
| Speak to whether the consent process/timing is adequate; state any issues with document and/or process. Will the right people be obtaining consent? If LAR may consent for subject, speak to whether adequate protections for the subject are in place. If waiver of *documentation* of IC is requested, is it justified? If short form is requested, is it justified, and would subjects need reconsenting afterwards with fully translated ICF? | Comments: |
| **Criteria 6: Data Monitoring** | |
| Speak to whether the safety monitoring plan clear and adequate (may or may not be a formal DSMB). Then, whether there are adequate plans for site/data monitoring to ensure completeness and integrity of study data. | Comments: |
| **Criteria 7: Privacy and Confidentiality** | |
| Are the provisions to protect privacy of subjects adequate, and confidentiality of their information? | Comments: |

Investigation Drug/device

* Is an investigation drug or device used? Is there an IND, IDE, or is exemption requested?
* Device risk determination required? (Significant risk or non-significant risk)?
* Is this a sponsor-investigator study, and if so, have they completed training, responsibility forms?

Recruitment

* Are subject recruitment methods appropriate?

Cost and Compensation

* Does the study involve increased cost compared to the non-study alternative? If so, it is ethical?
* Does the study reimburse subjects? If so, is the level of payment reasonable in relation to study procedures?

Risk level and approval period recommendation

* Recommend a risk level (more than minimal risk, or no more than minimal risk) and a timeframe for renewal (12 months, 6 months, or other period)