**IRB Informed Consent Checklist**

Indicate whether the informed consent process provides the required basic elements of information to subjects:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| 1. Statement that the protocol involves research and includes:
	* Purpose of research
	* Expected duration of subject’s participation
	* Description of procedures to be followed and identifies those that are experimental
 |  |  |  |
| 2. A description of any reasonably foreseeable risks ordiscomforts to the subject. |  |  |  |
| 3. A description of any benefits to the subject or to otherswhich may reasonably be expected from the research. |  |  |  |
| 4. Appropriate alternative procedures, if any, that mightbe advantageous to subjects. |  |  |  |
| 1. How confidentiality of records identifying the subject will be maintained.
	* Disclose all infringements upon privacy or confidentiality which may result from

participation in the research. |  |  |  |
| 6. If research is more than minimal risk, whether anycompensation is available. |  |  |  |
| 1. Contact information for the research team to:
	* Obtain answers to questions about the research.
	* Voice concern or complaints about the research.
 |  |  |  |
| 1. Contact information for a person independent of the research team:
	* To obtain answers to questions about the research.
	* To voice concerns or complaints about the research.
	* In the event the research staff could not be reached.
	* In the event they wished to talk to someone other than the research staff.
 |  |  |  |
| 9. Statement that participation is voluntary, that there areno penalties if subject refuses to participate and that subject can withdraw at any time without penalty. |  |  |  |

If appropriate to the research, indicate whether the informed consent process provides the following 6 additional elements of information (indicate why inclusion of this element is appropriate):

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Comments** |
| 1. That some risks to subject may be unforeseeable. |  |  |  |
| 2. Outlines the circumstances where a subject’sparticipation may be terminated by PI without regard to subject’s consent. |  |  |  |
| 3. Whether there are any costs for which subjects will beresponsible. |  |  |  |
| 4. The consequences of a subject’s decision to withdraw(safety issues). |  |  |  |
| 5. That new and significant findings, which may affectsubject’s willingness to continue, will be disclosed. |  |  |  |
| 6. The approximate number of subjects involved in theresearch at the institution and nationally. |  |  |  |