**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 or  discomforts to the subject. |  |  |  |
| 3. A description of any benefits to the subject or to others  which may reasonably be expected from the research. |  |  |  |
| 4. Appropriate alternative procedures, if any, that might  be 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 any  compensation 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 are  no 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’s  participation may be terminated by PI without regard to subject’s consent. |  |  |  |
| 3. Whether there are any costs for which subjects will be  responsible. |  |  |  |
| 4. The consequences of a subject’s decision to withdraw  (safety issues). |  |  |  |
| 5. That new and significant findings, which may affect  subject’s willingness to continue, will be disclosed. |  |  |  |
| 6. The approximate number of subjects involved in the  research at the institution and nationally. |  |  |  |