

**IRB CHECKLIST FOR INFORMED CONSENT**

| <b>@ Items <u>required</u> by regulation [45 CFR 46.116(a)]</b>   |   | <b>Yes</b> | <b>n/a</b> | <b>No</b> |
|---|---|------------|------------|-----------|
| @ [(a)(1)]  | A. A clear statement that the study is " <b>research</b> "  | —          | —          | —         |
| @ [(a)(1)]  | B. <u>All</u> the research <u>purposes</u> [ <i>i.e.</i> , protocol's <u>objectives</u> ] clearly stated  | —          | —          | —         |
| [ (b)(6) ]  | C. How, why, & how many prospective volunteers are <u>selected</u>  | —          | —          | —         |
| @ [(a)(1)]  | D. Expected <u>duration</u> of the volunteer's involvement  | —          | —          | —         |
| @ [(a)(1)]  | E. <u>Procedure(s)</u> or <u>treatment(s)</u> to be done  | —          | —          | —         |
| @ [(a)(3)]  | F. Reasonably expected <u>benefits</u> to volunteer and others  | —          | —          | —         |
| @ [(a)(2)]  | G. Reasonably foreseeable <u>discomforts and risks</u>  | —          | —          | —         |
| [ (b)(1) ]  | H. Especially for experiments, a statement that the treatment(s) or procedure(s) "may involve risks that are currently unforeseeable" —                       | —          | —          | —         |
| @ [(a)(1)]  | I. Which procedure(s) or treatment(s) are <u>experimental</u>   | —          | —          | —         |
| @ [(a)(4)]  | J. The <u>alternatives</u> to the research's diagnostic method or treatment   | —          | —          | —         |
| [ (b)(4) ]  | K. Procedure for the <u>orderly termination</u> of a volunteer's participation  | —          | —          | —         |
| [ (b)(4) ]  | 1) Consequences of a volunteer's <u>withdrawal</u> from the research  | —          | —          | —         |
| [ (b)(2) ]  | 2) When may the researcher <u>terminate</u> a volunteer's participation without the volunteer's consent   | —          | —          | —         |
| [ (b)(5) ]  | L. Plans to <u>inform</u> volunteers of <u>significant research findings</u> during or after the study relevant to their continued participation or treatment | —          | —          | —         |
| @ [(a)(6)]  | M. If > minimal risk: " <u>If you are injured as a result of ...</u> "  | —          | —          | —         |
| @   | 1) Will <u>medical care for adverse affects</u> be given? who? where?   | —          | —          | —         |
| @   | 2) Is <u>compensation for adverse affects</u> available? how?   | —          | —          | —         |
| @ [(a)(6)&(7)]  | 3) <u>Whom</u> should a volunteer contact with injury or adverse affect?  | —          | —          | —         |
| @ [(a)(7)]  | N. Who will answer <u>questions about the research itself</u> ?   | —          | —          | —         |
| @ [(a)(5)]  | O. How <u>confidentiality</u> ( ) or <u>anonymity</u> ( ) are maintained  | —          | —          | —         |
| @ [(a)(7)]  | P. Which HSPO staff will answer <u>questions about the volunteers' rights</u>   | —          | —          | —         |
| [ (b)(3) ]  | Q. <u>Financial</u> factors ( <u>extra costs of</u> , or compensation for, participation)   | —          | —          | —         |
| [.109(b)]   | R. <u>Other elements</u> a reasonable person would want to know   | —          | —          | —         |
| <b><u>NOTE: If it is a FDA trial the consent must state that the FDA will have access to the records.</u></b> |   |            |            |           |

@ [(a)(8)] S. Non-coercion disclaimer. *E.G.*, "Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you receive at this institution.

**NOTE: The University of California requires that the subjects be given a copy of "The Experimental Subject's Bill of Rights." This must also be in the consent.**