**Jupiter Medical Center Checklist for Protocol Review**

Regulatory review requirement (see 45 CFR 46.11) Y N

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| 1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk. |  |  |
| 2. Risks to subjects **are reasonable in relation to anticipated benefits**, if any, to subjects, **and** the importance of knowledge that may reasonably be expected to result. |  |  |
| 3. Subject selection is equitable. |  |  |
| 4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence. |  |  |
| 5. Informed consent is obtained from research subjects or their legally authorized representative(s). |  |  |
| 6. Risks to subjects are minimized. |  |  |
| 7. Subject privacy & confidentiality are maximized. |  |  |
| Additional considerations |  |  |
| 1. Collaborative research ( NIH research, MSCCOP) |  |  |
| 2. FDA-regulated research |  |  |
| 3. Other |  |  |

Suggested Questions for IRB Discussion

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| 1. Is the hypothesis clear? Is it clearly stated? |  |  |
| 2. Is the study design appropriate to prove the hypothesis? |  |  |
| 3. Will the research contribute to generalized knowledge and is it worth exposing subjects to risk? |  |  |
| 4. What does the IRB consider the level of risk to be? (See risk assessment guide on next page) |  |  |
| 5. What does the PI consider the level of risk/discomfort/inconvenience to be? |  |  |
| 6. Is there prospect of direct benefit to subjects? (See benefit assessment guide on next page) |  |  |
| 7. Who is enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously ill persons? Healthy volunteers? |  |  |
| 8. Are these subjects appropriate for the protocol? |  |  |
| 9. Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially or economically-disadvantaged, decisionally-impaired? |  |  |
| 10. Does the informed consent document include the eight required elements? |  |  |
| 11. Is the consent document understandable to subjects? |  |  |
| 12. Who will obtain informed consent (PI, nurse, other?) & in what setting? |  |  |
| 13. If appropriate, is there a children’s assent? |  |  |
| 14. Is the IRB requested to waive or alter any informed consent requirements? |  |  |
| 15. Does the research design minimize risks to subjects? |  |  |
| 16. Would use of a data & safety monitoring board or other research oversight process enhance subject safety? |  |  |
| 17. Will personally-identifiable research data be protected to the extent possible from access or use? |  |  |
| 18. Are any special privacy & confidentiality issues properly addressed, e.g. use of genetic information? |  |  |
| 19. Is an Investigational New Drug (IND) or Investigational Device Exemption (IDE) in this protocol? |  |  |

**Risk/Benefit Assessement**

**RISK**

Regulatory definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).

Check appropriate risk category:

1.\_\_\_\_\_\_ The research involves no more than minimal risk to subjects.

2.\_\_\_\_\_\_The research involves more than minimal risk to subjects.

\_\_\_\_\_\_The risk(s) represents a minor increase over minimal risk, OR

\_\_\_\_\_\_The risk(s) represents more than a minor increase over minimal risk.

**BENEFIT**

Definition: A research benefit is considered to be something of health-related, psychological, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

1.\_\_\_\_\_\_The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject’s disorder or condition.

2.\_\_\_\_\_\_The research involves the prospect of direct benefit to individual subjects.