Pre-IRB Human Subjects & Regulatory Screen for UF COM Jax Investigator-Initiated Studies

Study Title:
Study PI:

Study Risk Level: [ ] No More than Minimal Risk [ ] Greater than Minimal Risk

Study Type: [ ] Full Board [ ] Expedited [ ] Exempt [ ] Non-Human Subjects Research
Is Study a Chart Review: Yes / No
Is Study a Data/Tissue Bank or Contact Registry: Yes / No
*Is study type appropriate: Yes / No If no, please explain and define appropriate study type:*_____
_____

Study IRB: [ ] UF IRB [ ] External IRB, please specify: _____
*Note external IRBs still go to UF IRB for local context review

Informed Consent Plan: [ ] Written [ ] Waiver [ ] Partial Waiver
If Waiver of Partial Waiver, Explain Why & if this is appropriate:_____
_____
_____

Recruitment Plan: [ ] Adequate [ ] Not Adequate
Describe subject recruitment plan and any recommendations:_____
_____
_____

Describe ALL Risks of Study for Human Subjects Participants (Examples include breach of private health data, pain from blood draws, distress while filling out surveys, etc.): _____
_____
_____

Describe how study minimizes those risks and if this is an adequate plan:_____
_____
_____
_____

If study is multicenter, is a DUA needed? Yes / No If Yes, is DUA executed? Yes / No

Other Recommendations to Study Team:_____
_____
_____

Next Action:
[ ] Approve to submit in myIRB
[ ] Make requested changes (see above) and resubmit for pre-review
[ ] Schedule meeting with IRB-01 staff to discuss
Date of Recommendation / Action:_____