**IRB Reciprocity**

**Permission to Rely on Another IRB in the State University System of Florida**

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| Instructions:* The “local/site PI” must complete this form and submit it to their “local/relying IRB” office.
* If your “local/relying IRB” approves you to rely on the other IRB indicated, forward this approved form plus other local context documents to the “Overall PI” who will submit it to the “Reviewing IRB.”
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| Section 1: General Study Information |
| Study Title  |       |
| Funding Source |       |
| Recipient of Grant (Institution Name) |       |
| Brief summary of the research project |       |
| Risk level to subjects? | [ ]  Greater than minimal risk[ ]  Minimal risk |
| Phase 1 drug study? | [ ]  No [ ]  Yes |
| Check all that apply: | [ ]  Drugs / biologic | [ ]  Medical Devices |
|  | [ ]  Radiation  | [ ]  Placebo |
|  | [ ]  Gene therapy | [ ]  Genetic Testing |
|  | [ ]  Pharmocogenomic/kinetic | [ ]  Exercise/nutrition |
|  | [ ]  Deception  | [ ]  Analysis of existing data |
|  | [ ]  Data banking | [ ]  Tissue banking |
|  | [ ]  Behavioral/social (including surveys) | [ ]  Other research only procedure (diagnostic, surgical, etc) |
| [ ]  Other. Describe:        |
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| Section 2: Overall Reviewing IRB Site Study Information |
| Overall PI Info (from the Reviewing IRB’s Institution) |
| Name (last, first) |       |
| Email address |       |
| Phone # |       |
| Name of SUS Institution that will be serving as the **Overall** **Reviewing IRB** (select one) |
|  | [ ]  Florida A&M University | [ ]  Florida Atlantic University |
| [ ]  Florida Gulf Coast University | [ ]  Florida International University |
| [ ]  Florida State University | [ ]  New College of Florida |
| [ ]  University of Central Florida | [ ]  University of Florida |
| [ ]  University of North Florida | [ ]  University of South Florida |
| [ ]  University of West Florida |  |
| Brief description of the human subject research activities that will be performed by the Overall PI and his/her study team (team members from his/her institution):       |

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| Section 3: Local/Relying Institution Site Study Information (your site) |
| Local PI Info (from the Relying Institution) |
| Name (last, first) |       |
| Address |       |
| Office Phone # |       |
| Email address |       |
| Which institution are you affiliated with (select one) |
|  | [ ]  Florida A&M University | [ ]  Florida Atlantic University |
| [ ]  Florida Gulf Coast University | [ ]  Florida International University |
| [ ]  Florida State University | [ ]  New College of Florida |
| [ ]  University of Central Florida | [ ]  University of Florida |
| [ ]  University of North Florida | [ ]  University of South Florida |
| [ ]  University of West Florida |  |
| **Attach** a listing of local study staff that will be engaged in conducting research with human subjects on this project (last name, first, ID #). |
| What human subject research activities will you and your local study team be involved with on this project? Check all that apply. |
|  | [ ]  Data analysis. Data is: [ ]  identifiable [ ]  coded [ ]  anonymous or coded with confidentiality agreement |
| [ ]  Collaborate with the Overall PI ***at their site***.Describe what you and your local study team will be doing:        |
| [ ]  Collaborate with the Overall PI ***at an outside site*** *(not your university nor their university)*. Describe what you and your local study team will be doing:       Describe where you and your local study team will be engaging in the research:        |
| [ ]  Recruit/enroll subjects at your university. **You must complete Section 4 below.** |
| [ ]  Conduct study interventions at your university. Describe:       |
| [ ]  Access/collect/release (a) PHI or (b) sensitive data at your local site or subjects from/at your university |

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| **Conflict of Interest - Personal.** Does anyone on your local study team, their spouses, or dependent children:1. hold a patent or license for any material, object, or process used in this project?
2. have a patent or license pending or under consideration, or is there any intention to file a patent application at a later date?
3. own stock or bonds (specifically, not in a mutual fund) in the company sponsoring the project?
4. give presentations for or serve as a consultant to the sponsoring company on their behalf?
5. have ownership interest (equity or stock options) of any amount where the value could be affected by the outcome of the research?
6. receive compensation of any amount where the value could be affected by the outcome of the research?
7. have any other possible conflict of interest?

[ ]  No [ ]  Yes. Attach documentation describing how the conflict is being managed and if there are any suggested restrictions on engagement in research |
| **Conflict of Interest - Institutional.** Select any that apply: |
|  | [ ]  Does your local institution or affiliated institutions hold any patents or licenses for any material, object, or process used in this project? |
|  | [ ]  Is a patent pending or under consideration, or is there any intention to file a patent application at a later date?  |
|  | [ ]  Does your local institution or affiliated institutions own any stock in the company sponsoring the project? |
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| **Section 4: Recruiting Subjects at Local Site** (only required as indicated in Section 3 above) |
|  | How many subjects will you recruit/enroll?       |
|  | How will you recruit them?[ ]  Existing patients in local/site PI practice[ ]  Referrals[ ]  Advertisements[ ]  Database of potential subjects who consented to be contacted[ ]  Other. Describe:       |
|  | Describe the recruitment process:       |
|  | Who will obtain consent:       |
|  | Where will they obtain consent:       |
|  | **Attach** a copy of the consent form that will be used to recruit subjects. |
|  | Select any vulnerable subjects who will be recruited at your site:[ ]  Children[ ]  Pregnant women[ ]  Cognitively impaired[ ]  Prisoners[ ]  Other. Describe:       |

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| Section 5: Acknowledgement by Local/Site PI |
| * I will only engage in research that is actively approved by the Reviewing IRB.
* I will follow the protocol and not implement any changes without prior approval from the Reviewing IRB.
* I will promptly report any unanticipated problems involving risks to subjects or others to the Lead PI so he/she can report it to the Reviewing IRB.
* I am aware of my local institution’s policies and procedures to conduct research at my local institution.
* I will cooperate with any monitoring oversight by the Reviewing IRB or my institutional representatives.
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| Signature of the Local/Site PI | Date |

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| Section 6: Local IRB Assessment to rely on another IRB in the State University System |
| The above request has been assessed by the local IRB Office. |
| All information is appropriate and all applicable local context is attached. Our site has determined:[ ]  We will cede review and rely on the outside reviewing IRB indicated in Section 2. The PI/research team has completed all of our local training requirements, is in good standing, and is qualified to be engaged in this project.[ ]  After reviewing the materials, review by our local IRB is necessary.[ ]  Other. Describe:       |
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| Signature of the Official Authorized by the Local Institution | Date |

**Appendix A**

**IRB Reciprocity Process Flow Charts**







