

Protocol Adherence Checklist

*This checklist is for researchers to ensure that **all** of your human research procedures are performed as indicated and approved by the UF IRB. Any changes to your research activities must be submitted and approved by the IRB **before implementation**.*

Adherence to and Documentation for the UF IRB-Approved Protocol

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| <input type="checkbox"/> IRB approval for the study was continuous (Continuing Review(s) were submitted to the IRB in time and did not expire) <ul style="list-style-type: none">• If the study was expired during a certain timeframe, no study activity can occur without IRB approval (includes but not limited to enrollment, study procedures, follow-up, data analysis)• If it is in the subject's best interest to receive study related procedures, notify the IRB immediately |
| <input type="checkbox"/> Research subjects were only enrolled on the study (signed the informed consent form) during IRB-approved study periods <ul style="list-style-type: none">• If enrollment occurred during the time a study had expired or was closed to enrollment, complete a Deviation Report form and add the event to the Deviation Tracking Log• Permission will have to be obtained from the IRB to keep the subject and data |
| <input type="checkbox"/> All Research staff have been IRB approved prior to engaging in study activities <ul style="list-style-type: none">• A revision must be submitted prior to allowing a new co-investigator/study staff member participate in any study related activities• If a co-investigator/study staff member participates in study activity prior to IRB approval, submit a Deviation Report from to the IRB and add the event to the Deviation Tracking Log |
| <input type="checkbox"/> The number of enrolled research subjects was within the total enrollment number approved by the IRB. <ul style="list-style-type: none">• If the investigator over-enrolled, complete a Deviation Report form and add the event to the Deviation Tracking Log• Permission will have to be obtained from the IRB to keep the subject and data |
| <input type="checkbox"/> The IRB-approved methods of recruiting/screening subjects were met and documented for each subject enrolled <ul style="list-style-type: none">• Examples of some recruitment/screening methods are, but are not limited to: advertisements (posting on bulletin boards, flyers, newspapers, television, and radio), referrals, IRB-approved research databases, medical records, inpatient population, clinic visits, etc. |
| <input type="checkbox"/> All inclusion/exclusion criterion were met and source documents for eligibility exist for each research subject <ul style="list-style-type: none">• If a subject does not meet all eligibility criteria but the investigator still wants to enroll them, permission from the sponsor (if applicable) and approval from the IRB must be obtained prior to enrollment (submit a Revision)• If an ineligible subject has been enrolled, complete a Deviation Report form and add the event to the Deviation Tracking Log• Permission will have to be obtained from the IRB to keep the subject and data |
| <input type="checkbox"/> IRB-approved study procedures were met and documented for each research subject <ul style="list-style-type: none">• If a procedure was not performed, a note to file should be created, signed, dated and filed with the subject's research file• Add this to the Deviation Tracking Log to report at time of CR |
| <input type="checkbox"/> Follow-up procedures (return visits, phone calls, etc.) indicated in the IRB-approved protocol were met and documented for each research subject <ul style="list-style-type: none">• If a subject does not show for clinic or return phone calls, a note to file should be created, signed, dated and filed |

<p>with the subject's research file</p> <ul style="list-style-type: none">• Add this event to the Deviation Tracking log to report at time of CR
<p><input type="checkbox"/> All revisions to your protocol were approved by the UF IRB <i>prior</i> to their implementation</p> <ul style="list-style-type: none">• Please note, if research procedures were performed different from those defined in the IRB-approved protocol, they must be reported to the UF IRB as a protocol deviation.
<p><input type="checkbox"/> Source documents were available to validate that the tests and measures specified in the IRB-approved protocol were performed.</p> <ul style="list-style-type: none">• Examples: laboratory results, pathology notes, x-rays, MRIs, psychological assessments, and questionnaires
<p><input type="checkbox"/> Adverse Events/Unanticipated Problems are reported appropriately for each subject, either on at time of CR on the Cumulative Adverse Event Table or by a Serious Adverse Event Report submitted to the IRB (and add the event to cumulative AET)</p>
<p><input type="checkbox"/> The reason(s) for subject withdrawal (per the P.I., subject choice, death, etc.) were documented in the research records and reported to the sponsor (if applicable)</p>
<p><input type="checkbox"/> Data files were complete, organized, and understandable</p>