

INDUSTRY-SPONSORED HBR STUDY MONITORING OVERSIGHT CHECKLIST

Study Information

ECOS Ref: _____

Study Title: _____

Study Site: _____

Principal Investigator (PI): _____

Sponsor: _____

Objective: The purpose of this checklist is to ensure that the Sponsor is providing adequate monitoring to guide the PI to comply with the Human Biomedical Research Act 2015 and its applicable regulations.

1. Informed Consent

Will the Sponsor's monitoring activities include oversight of appropriate informed consent processes?

(Reference: HBRA 2015, section 22(2)(c)... appropriate consent has been obtained in accordance with Part 3 prior to the research subject's participation...)

Yes, please elaborate on the monitoring activities (e.g. on-site review of signed informed consent forms, % of review):

No

2. Compliance to Research Proposal

Will the Sponsor's monitoring activities include oversight to ensure the research is conducted in accordance with the approved research proposal and protocol (e.g. site recruitment process, subjects' eligibility assessment and safety events)?

(Reference: HBRA 2015, section 22(3)(a)... the research does not deviate from the research proposal that has been reviewed and approved or exempted from review by an institutional review board unless the deviation...)

Yes, please elaborate on the monitoring activities (e.g. on-site review of subject's eligibility criteria, safety events, % of review):

No

3. Review of IRB Approval and Validity

Will the Sponsor's monitor review the IRB approval and ensure its validity throughout the study (e.g. continuing review)?

(Reference: HBRA 2015, section 22(3)(b)... any research is immediately discontinued if the institutional review board has withdrawn its approval for the research unless the immediate discontinuation will result in a risk of harm to the research subject)

Yes

No

4. Data Oversight

Will the Sponsor's monitoring activities include data integrity oversight?

Yes

No

Brief description of approach (include information such as area of Source Data Verification/ Review, % of review, review of subject withdrawal and subsequent use of data/ samples):

5. Information of Monitor

Is the Monitor independent of the research team?

Yes

No

(To be completed by the PI) Endorsement

Note: Research teams are expected to maintain still oversight of other key areas (e.g. Investigator File management, Biological specimen management) per Institutional SOPs and good documentation practices.

PI Name & Signature: _____

Date: _____