IND or IDE Checklist for Research Review Coordinator

For clinical protocols being conducted under an IND or IDE application, the IRB OSIRIS application requires that the University investigator provide the corresponding IND or IDE number.

If the clinical protocol is being conducted under an externally sponsored IND or IDE application, an evaluation must be performed by the responsible IRB Research Review Coordinator to determine whether the IND or IDE number provided by the University investigator is valid. Validation can be done by determining that the IND or IDE number provided by the University investigator matches the IND or IDE number specified in:

- the corresponding sponsor's protocol
- communication from the sponsor, or
- communication from the FDA.

(Note: the investigator's brochure should NOT be used for validation because one investigator brochure may serve multiple INDs or IDEs.)

In the case of a clinical protocol being conducted under an investigator-sponsored IND or IDE application held by a University of Pittsburgh investigator, review of the IND or IDE application, to include validity of the IND number, will be conducted by the University O3IS[1] [2] . The OSIRIS application will automatically notify the O3IS of any submitted clinical protocol meeting this criterion, and the O3IS will notify the IRB should any problem be identified.

[1] For University investigator-sponsored IND or IDE applications that were submitted to the FDA prior to the issuance of the O3IS policies and procedures, and which remain active, the investigator-sponsor should submit copies of the following to the O3IS: 1) the initial IND or IDE application; 2) notification of the IND or IDE number assigned to the application and documentation of the date of FDA-acceptance of the application; 3) all subsequent correspondence from the FDA regarding any deficiencies or problems related to the IND or IDE application and all investigator-sponsor responses corresponding to these FDA concerns; 4) adverse event reports (i.e, Safety Reports); 5) protocol amendments or supplemental IDE applications, if applicable, that correspond to the current version(s) of the clinical study(ies) in progress; and 6) the most recent Annual Report. These documents will be reviewed by the O3IS and should any concerns be identified, the O3IS will work with the investigator-sponsor to address them. The O3IS must be copied on all written correspondence between the investigator-sponsor and the FDA that occurs after the date of issuance of these policies and procedures.

[2] The University Institutional Review Board (IRB) shall verify, upon its initial receipt of a proposed clinical trial being conducted under an investigator-sponsored IND or IDE, that the IND or IDE was submitted to the FDA by the O3IS.

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Criteria	Yes	No	N/A
For industry sponsored protocols, ensure the investigator has uploaded: • The sponsor's clinical protocol • The investigator's brochure	_____ _____	_____ _____	_____ _____
For multi-center protocols where an investigator outside of the institution holds the IND or IDE, ensure the investigator has uploaded: • The sponsor's clinical protocol	_____	_____	_____
Does the IND / IDE number provided in the OSIRIS application match the IND/IDE number specified in the sponsor's clinical protocol or other submitted information (i.e FDA correspondence or sponsor correspondence)?			
For investigator – sponsored INDs or IDEs, has the PI uploaded in OSIRIS, the following documents? • The initial IND or IDE application • FDA notification of the assigned IND or IDE number • Subsequent correspondence from the FDA • Safety reports • The most recent annual report	_____ _____ _____ _____ _____	_____ _____ _____ _____ _____	_____ _____ _____ _____ _____

_____ _____

Signature of RRC Date