# OnCore Communication Memo

**Memo #: 26 – IND/IDE Tab Re-tool**

**To:** All Research Managers, Regulatory Coordinators
**From:** System Administrator
**Original Effective Date:** July 17, 2016
**Update Effective Date:** August 3, 2016

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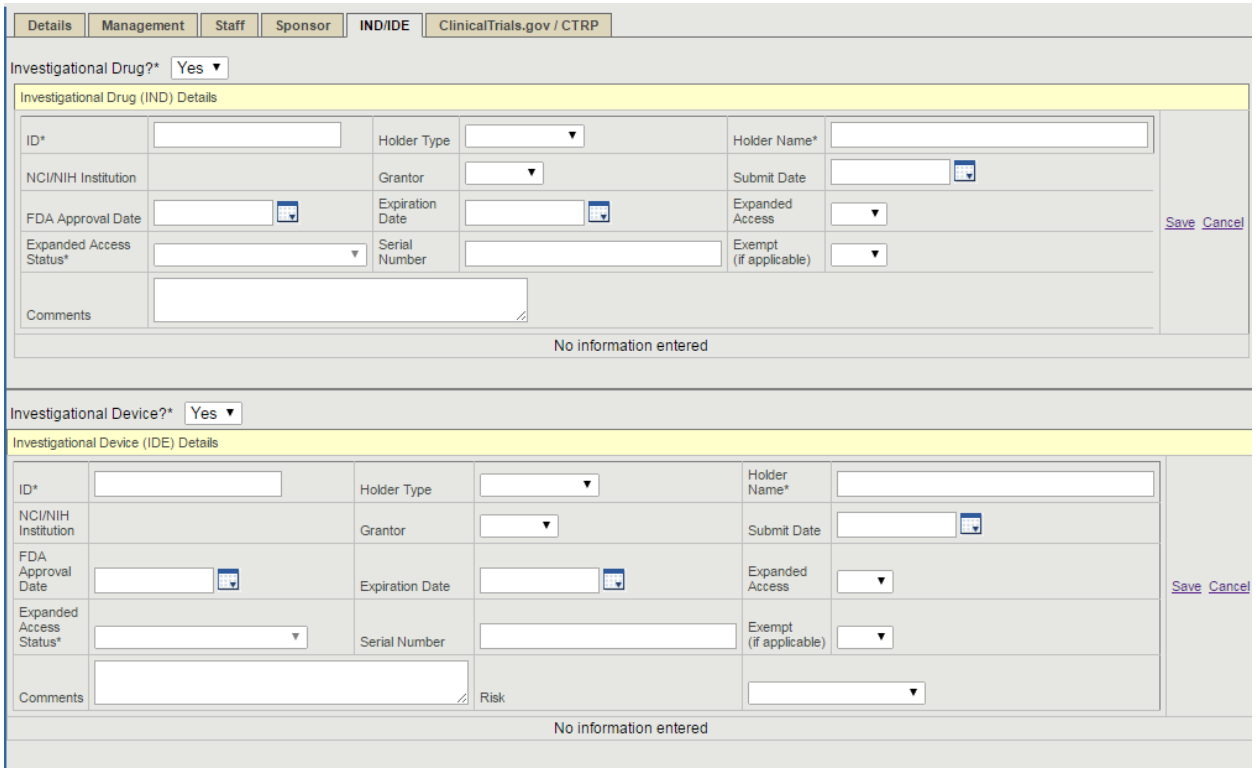
**Purpose:** In order to more easily track MCW Physicians held IND/IDE studies and expiration dates, the IND/IDE tab will need to be re-tooled so it reflects ONLY those studies that have an MCW/MCW Physician held IND/IDE. Starting July 18, 2016, all existing records in the IND/IDE tab will be wiped out of OnCore and staff should please go ahead and update those studies that have an existing MCW held IND/IDE with the information listed below. The indication that a study contains and IND/IDE may still be selected as 'Yes' on the Protocols>PC Console>Main>Details Tab for non-MCW held studies, but the IND/IDE Tab should ONLY be completed for studies with MCW held IND/IDEs.



**Field Descriptions:**

**ID**

The drug/device identification number. This is a required field. The value entered may be used to search for a protocol in any of the Select Protocol find-as-you-type fields throughout OnCore.

**Holder Type**

Limited to values provided by CTRP, and determine the values available in the NCI/NIH Institution field. (Industry, Investigator, NCI, NIH, Organization)

**Holder Name**

A free text field to capture the name of the holder. This is a required field.

**NCI/NIH Institution**

Active if the Holder Type selected is 'NCI' or 'NIH'. The values presented are dependent on the Holder Type value, and are limited to values provided by CTRP.

**Grantor**

The values for this field depend upon whether an IND or IDE is being added. Values are limited to values provided by CTRP.

**Submit Date**

The date that the IND/IDE application was submitted.

**FDA Approval Date**

The date of FDA approval for the IND/IDE. This is found on the Letter to Proceed, and is the Electronic Signature Date.

**Expiration Date**

Usually used to hold the date of the last required yearly report. On the original entry this is one year from the Approval Date. This date must be updated every year, using the date the letter of renewal was submitted, in order to search for the next renewal date.

**Expanded Access**

Indicates whether the IND/IDE has "expanded access" (similar to compassionate use).

**Expanded Access Status**

Active if the Expanded Access field is marked as 'Yes'. Values are limited to values provided by CTRP.

**Serial Number**

The drug/device serial number.

**Exempt (if applicable)**

When the record is marked as exempt, the ID field is mandatory.

**Comments**

This is an information-only free text field.  Add comments yearly documenting the date the annual report was submitted, as this appears in the report.

**Risk (IDE only)**

Indicate if Significant or Non-Significant Risk.

**Notes:** An IND/IDE Lapse Report is available under Reports>Reports>Regulatory that will list all studies with IND/IDE's associated and give the expiration date in order to keep track of all studies with IND/IDEs.