QC ONCORE PROTOCOL IN PC CONSOLE

Description: At UF, OnCore protocols are created either by the UF Cancer Center (for cancer-relevant studies) or the Office of Clinical Research. For details about this process, see the OnCore Protocol Creation & Set-Up user guide.

Once a protocol "shell" has been built, the study team will be asked to review the protocol via the PC Console and confirm that all required OCR "minimum footprint" data fields are correct.

LOGIN TO ONCORE

- You must have an OnCore account to use OnCore. For details, see the Obtain OnCore Access user guide.
- For details about login, see the Login to OnCore user guide.
- If you are new to OnCore, please review the online OnCore user guides and/or take OnCore Training.

FIND YOUR STUDY

Note: For detailed instructions, see the Find Your Study user guide.

1. Navigate to **Menu > Protocols > PC Console**.
2. In the **Select Protocol** field, type in any of the following study identifiers:
   - OnCore Protocol No.
   - IRB No.
   - Short Title
   - Sponsor Protocol No.
   - FDA IND No. *(IND drug studies only)*
   - FDA IDE No. *(IDE device studies only)*
   - ClinicalTrial.gov NCT No. *(if applicable)*
   - Study "Nickname" or acronym *(See **Note** below)*
3. Select the study protocol number hyperlink to open your study.

> ***Note:*** *Currently, there is not a designated field in OnCore for a study **Nickname** or **acronym.***
>
> *During set-up, OCR staff will add your study **Nickname** or **acronym** (if known) to the **Sponsor Protocol No**. field, which will enable you to use this as an additional searchable identifier.*
>
> *The **Sponsor Protocol No**. and the **Nickname** will be separated by a semicolon (;).*
>
> *If your **Sponsor Protocol No**. field does not include a **Nickname** or **acronym**, and you would like it added, please contact **OCR-Intake@ahc.ufl.edu***

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REVIEW **DETAILS** TAB DATA

Follow your **internal departmental workflow** to determine the proper study staff member(s) who should review and confirm the following data.

1. Navigate to **Protocols > PC Console > Main > Details** and make sure the following data fields are correct:

Protocol No.	*A unique, automatically generated OnCore protocol identifier*
NCT Number	*The NCT ID from clinicaltrials.gov as available, when the study is in clinicaltrials.gov*
Library	***Oncology*** *for cancer studies and* ***Academic Health Center*** *for non-oncology studies*
Department	*Principal Investigator's UF Department*
Organizational Unit	***Cancer Center*** *for cancer studies and* ***Academic Health Center*** *for non-oncology studies*

IMPORTANT!

- *If Library =* ***Oncology****, Organizational Unit should be* ***Cancer Center***
- *If Library =* ***Academic Health Center****, Organizational Unit should be* ***Academic Health Center***
- *If Library does* ***NOT*** *align with Organizational Unit, contact OCR-Intake@ahc.ufl.edu before proceeding!*

Title	*Should EXACTLY match the full title on the protocol document submitted/approved by the IRB*
Short Title	*As available, the BRIEF TITLE from clinicaltrials.gov entry. If the study is not in clinicaltrials.gov, you may see an abbreviated version of the protocol title that includes the phase, drug or treatment, and disease*
Phase	*The phase of the protocol, or "NA", as applicable*
Age	***Adults*** */* ***Children*** */* ***Both*** *per the appropriate age category*
Investigator Initiated Protocol	*"Yes" if the protocol was written by a UF investigator, regardless of sponsorship. Otherwise, "No"*
Summary Accrual Info. Only	*"Yes" = Observational studies with no clinical services, "No" = Interventional studies or observational with clinical services*
Protocol Type	*"Interventional" = If any part of the study involves manipulation of the subject or environment to change health related biomedical or behavioral processes or outcomes* *"Observational" = No manipulation of the subject or environment intended to change outcomes/processes. *Oncology studies will list NCI protocol type*
Investigational Drug	*"Yes" if an investigational drug is being used in the protocol. Otherwise, "No"*
Investigational Device	*"Yes" if an investigational device is being used in the protocol. Otherwise, "No"*
RC Total Accrual Goal (Lower)	*The TARGET number of participants to enroll at UF - This is the number of participants you need to complete the study to either: (1) conduct your analysis and answer your scientific question, or (2) meet a contractual obligation to the study sponsor.*
RC Total Accrual Goal (Upper)	*The MAXIMUM number of participants to enroll at UF (including screen failures) - This is the maximum number of participants that are (or will be) IRB-approved to consent.*
Accrual Duration (Months)	*The number of months this study will be open to accrual/actively recruiting subjects at UF*

If any of these data fields are incorrect, do ***NOT*** *try to correct yourself.*

Email OCR-Intake@ahc.ufl.edu and ask OCR staff to correct.

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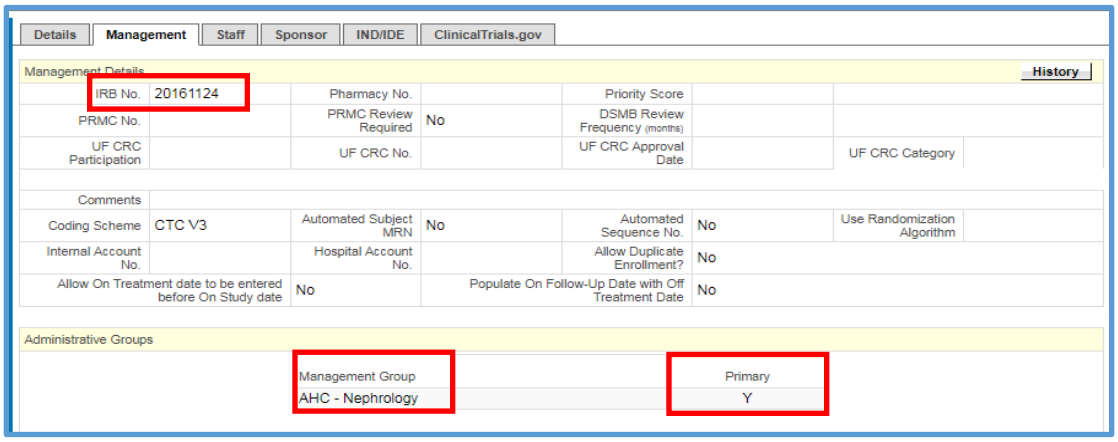
REVIEW **MANAGEMENT** TAB DATA

Follow your **internal departmental workflow** to determine the proper study staff member(s) who should review and confirm the following data.

1. Navigate to **Protocols > PC Console > Main > Management.**
2. If the study already has an IRB number assigned, confirm that the IRB No. field is correct.



3. If the study will be managed by any established OnCore management groups, review and confirm that the **Management Groups** are correct and that the correct **Primary** management group is marked with a **"Y"**.
4. Confirm additional required management groups:
   - **Investigational Drug Pharmacy** - required if study involves drugs dispensed by UF Health Investigational Drug Service (IDS).
   - **CTSI Biorepository -** required if study involves any study UF CTSI Biorepository services.
   - **Research Billing Office** - required if study involves any UF Health patient-based billable services (e.g. Epic charges).

*If any of these data fields are incorrect, do **NOT** try to correct yourself.*

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REVIEW **STAFF** TAB DATA

UF study teams **MUST** keep OnCore study staff data current. This is even more important for OnCore studies that are also in **Epic** and/or IDS Vestigo; many Epic and/or Vestigo staff records are automatically updated from OnCore.

Study team members with either the PC or CRA role are allowed to update protocol staff records. Follow your **internal departmental workflow** to determine the proper OnCore study staff member(s) who should review, confirm, and update this data.

1. Navigate to **Protocols > PC Console > Main > Staff**.
2. Sort the staff table by clicking on the **Role** column header.
3. Make sure there is **at least one person** assigned to each of the following **REQUIRED** staff roles:

Authorized Prescriber	*Only required for studies that involve investigational drugs dispensed by the UF Health Investigational Drug Service (IDS)*
Billing Coordinator	*Person responsible for paying patient care costs invoices (e.g. from Epic)*
Epic Charge Reviewer	*Only required for studies that are/will be in Epic*
Financial Coordinator	*Person who negotiates the budget, and/or performs coverage analysis on the billing grid, and/or is responsible for invoicing sponsor*
IRB Coordinator	*Person responsible for IRB submissions and consents*
Primary Study Coordinator	
Principal Investigator	
Study Site Contact	*Only required if information about this study will be published on a public UF website (e.g. Study Connect) using data from OnCore.*

If any of the required roles are missing, you must add the missing staff.

For instructions on how to add study staff, see the Assign Study Staff user guide.

OCR Staff Assignments

*You might see several assigned roles that start with "**OCR**".*

These are OCR staff members who have been assigned to this protocol by the OCR office.

DO NOT EDIT OR DELETE THE OCR ROLES.

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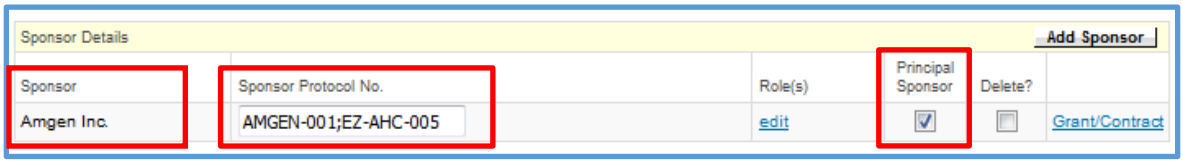
REVIEW **SPONSOR** TAB DATA

Multiple sponsors can be assigned to a protocol, but only one can be the **Principal Sponsor**. All sponsors can be invoiced for procedures or visits for the protocol.

Follow your **internal departmental workflow** to determine the proper OnCore study staff member(s) who should review and confirm this data.

1. Navigate to **Protocols > PC Console > Main > Sponsor.**



2. Review and confirm that the **Sponsor** information is correct.
3. Confirm that the **Principal Sponsor** is set to "Y" on the correct sponsor line.

Note:** Currently, there is not a designated field in OnCore for a study **Nickname** or **acronym.

*During set-up, OCR staff will add your study **Nickname** or **acronym** (if known) to the **Sponsor Protocol No**. field, which will enable you to use this as an additional searchable identifier.*

*The **Sponsor Protocol No**. and the **Nickname** will be separated by a semicolon (;).*

*If your **Sponsor Protocol No**. field does not include a **Nickname** or **acronym**, and you would like it added, please contact **OCR-Intake@ahc.ufl.edu.***

*If any of these data fields are incorrect, do **NOT** try to correct yourself.*

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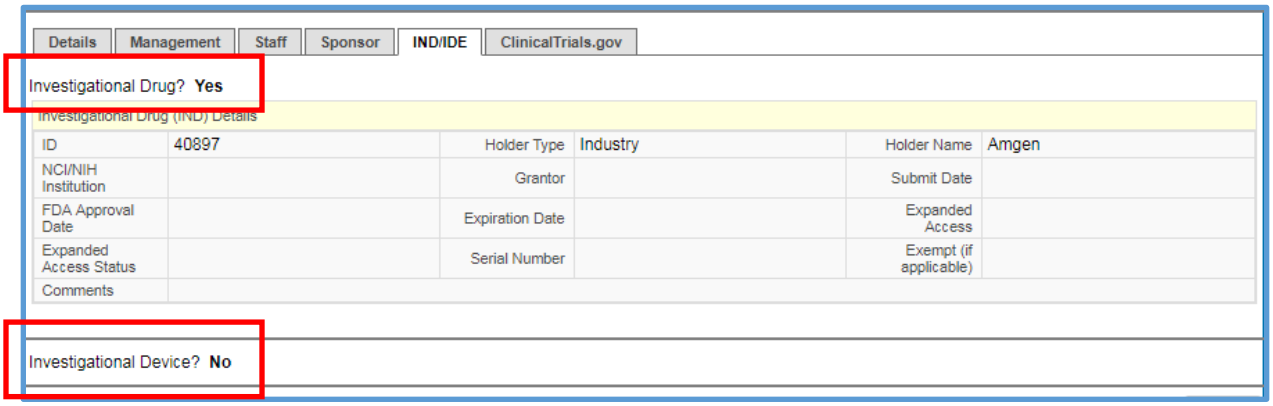
REVIEW **IND/IDE** TAB DATA

Follow your **internal departmental workflow** to determine the proper OnCore study staff member(s) who should review and confirm this data.

1. Navigate to **Protocols > PC Console > Main > IND/IDE.**



2. This screen has pulled the values for **Investigational Drug** and the **Investigational Device** from the Details tab for this study.
3. Review and confirm that the IND/IDE "**Yes**" and "**No**" information is correct.
4. No other fields are required at this time.

*If any of these data fields are incorrect, do **NOT** try to correct yourself.*

Email OCR-Intake@ahc.ufl.edu and ask OCR staff to correct.

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REVIEW **INSTITUTION** TAB DATA

Follow your **internal departmental workflow** to determine the proper OnCore study staff member(s) who should review and confirm this data.

1. Navigate to **Protocols > PC Console > Main > Institution.**

Participating Institutions

Institution • Study Sites	Uses Research Center IRB	IRB Initial Approval Date	IRB Last Renewal Date	IRB Next Review Date	Current Status	Status Date	Total Accrual	Pending Amendment	Expired Items	Calendar Version
University of Florida • UF Jacksonville • UF Gainesville					NEW	09/29/2017	0			0

2. Confirm that the **Institution** is University of Florida.
3. The UF **Study Sites** list will include
    - UF Jacksonville
    - UF Gainesville
    - No UF Health MRN

*If any of these data fields are incorrect, do **NOT** try to correct yourself.*

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WHAT COMES NEXT?

After the Protocol QC has been completed, if your study will involve any of the OCR services listed below, you can Track Your OCR Submission with the OnCore Task Lists:

- Contracting
- Billing Compliance Review
- OnCore Calendar
- OnCore Milestone-Based Budget

As applicable to your study and OCR submission, OCR staff will contact you when:

- OCR Contracting gets underway
- OCR Billing Compliance Reviewer has questions
- OnCore Calendar and/or Budget build has been completed

HOW TO GET HELP

ONCORE **WEB PAGES**

- https://clinicalresearch.ctsi.ufl.edu/oncore/
- Includes web-based **User Guides**, **Tip Sheets, Videos**, **OnCore Dictionary**, and **Support Desk Information.**

ONCORE **USER GUIDES**

- UF OnCore User Guides

ONCORE **SUPPORT DESK**

- Phone: (352) 273-5924
- Email: OnCore-Support@ahc.ufl.edu

ONCORE **ONLINE HELP DESK TICKET SYSTEM**

The UF OnCore Support webpages provide a way for UF OnCore users to easily create trackable help desk tickets for:

- Adding or Updating Staff Contacts in OnCore
- Requesting an OnCore User Account
- Other Support Requests (technical support, report requests, etc.)

ONCORE **SUPPORT CONSULTS**

The UF OnCore support staff love to work "face-to-face" with new UF OnCore users, especially when they need help with their first "real study". Our most popular consults involve showing new users how to:

- Review the protocol calendar and budget
- Enter an IRB review
- Upload approved study consents
- Open the study to accrual
- Register new subjects
- Check-in visits
- Enter visit variations and deviations

To schedule a consult, please complete an OnCore Request Form.