Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

Melanie Wiggins, Director, OSP-Industry and Clinical Trials, Virginia Commonwealth University, Richmond, VA USA
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

• Learning objective

(1) Analyze the impact of subject injury language review on Institution's risk assessment and the ability to ensure compliance with Institutional policies and federal regulations.

(2) Establish a system for tracking subject injury language review.
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

• Virginia Commonwealth University (VCU) is an urban, public research university located in Richmond, Virginia. VCU conducts clinical trials at its affiliated hospital, the VCU Health System Authority (AKA VCU Medical Center).
Virginia Commonwealth University (VCU) is an urban, public research university located in Richmond, Virginia. VCU conducts clinical trials at its affiliated hospital, the VCU Health System Authority (AKA VCU Medical Center).

VCUHS is a separate legal entity which was established pursuant to Va. Code § 23.1-2401, for the purpose of conducting and facilitating research in the medical field and related disciplines, and to provide a site for VCU faculty members to conduct medical and biomedical research.
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

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- Under an Affiliation Agreement between VCU and VCUHS, VCU is responsible for contracting with outside entities for the conduct of clinical trials.
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Under an Affiliation Agreement between VCU and VCUHS, VCU is responsible for contracting with outside entities for the conduct of clinical trials.

In conjunction with the review of clinical trial contracts, VCU is responsible for the review and negotiation of the associated subject injury language (SIL) in the informed consent form prior to submission to the appropriate institutional review board.
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

- What is “subject injury language”?
- AKA research-related injury language
  - Language found in the informed consent form and in the contract that addresses responsible party for payment of costs associated with diagnosis/treatment of an illness or injury to a study participant as a result of their participation in the research.
  - Responsible party could be the Sponsor, insurance or the study participant depending on the type of study and compliance considerations.
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

VCU Compliance Considerations:

1. **VCU is accredited by** the Association for the Accreditation of Human Research Protection Programs (**AAHRPP**) and as such must comply with **Element I.8.A.** which stipulates “The Organization has a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate.”
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2. **VCU has a Corporate Research Agreement policy** that stipulates “in accordance with [21 CFR §50.25 (6-7)], VCU agreements with corporate sponsors of corporate-initiated clinical research involving greater than minimal risk must include clear and appropriate provisions for ensuring adequate compensation for medical care in the case of research-related injury. Corporate Agreements for clinical research studies where the Corporate Entity holds the Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) and controls the study protocol should stipulate that the Corporate Entity will fund medical care costs for research-related injury”
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3. **VCU Compliance Notices – Cost Coverage Requirement**
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

NOTICE: CLINICAL RESEARCH COVERAGE ANALYSIS

In accordance with previously published VCU procedures, a Clinical Research Coverage Analysis is required for all clinical research studies involving clinical services or items. Requisite forms must be reviewed and approved by an Institutionally-designated Coverage Analysis Specialist.

This requirement applies to all clinical research, regardless of funding source (i.e. external sponsor type, internal funds, or any combination thereof).

About Coverage Analysis:
The VCU Coverage Analysis process supports clinical research teams:

1. Determining if a clinical study qualifies for coverage of ‘routine care’ costs in accordance with the requirements of Medicare and the U.S. Patient Protection and Affordable Care Act;
2. Documenting a plan for managing costs of clinical services/items by cost type and by appropriate responsible payer; and
3. Complying with essential reporting requirements which support billing compliance over the course of the clinical study.

VCU’s qualification process for clinical research studies harmonizes requirements found within:

- The Patient Protection and Affordable Care Act (42 United States Code 300GG-8 – Coverage for Individuals Participating in Approved Clinical Trials);
- The U.S. CMS National Coverage Determination for Routine Costs in Clinical Trials §310.1; and
- The Code of Virginia §38.2-3418.8 – Coverage for Clinical Trials for Treatment Studies on Cancer and §38.2-3453 – Clinical Trials.

For qualified clinical studies the (i) study specific ‘routine care’ costs must be identified with the responsible payer; (ii) the responsible payer must be identified consistently for all research participants; and (iii) all study specific costs not deemed ‘routine care’ must be borne by the study sponsor. For Non-Qualified Studies, all study specific costs, including anticipated ‘routine care’ must be accounted for within the study budget (e.g., no third-party/participant billing) and should be borne by the study sponsor.
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- Determines if study qualifies for ‘routine care’.
- Documents a plan for managing costs.
- Ensures compliance with appropriate laws.
- At VCU, process managed by specialists at the School level (e.g. School of Medicine and Massey)
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trial

1. VCU is accredited by AAHRPP
2. VCU has a Corporate Research Agreement policy
3. VCU Compliance Notices – Cost Coverage Requirement
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trial

1. VCU is accredited by AAHRPP
2. VCU has a Corporate Research Agreement policy
3. VCU Compliance Notices – Cost Coverage Requirement
4. Applicable laws, regulations, National Coverage Decisions (i.e., 310-1, Routine Costs in Clinical Trials) and the Medicare Secondary Payer rule
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trial

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2. VCU has a Corporate Research Agreement policy
3. VCU Compliance Notices – Cost Coverage Requirement
4. Applicable laws, regulations, National Coverage Decisions (i.e., 310-1, Routine Costs in Clinical Trials) and the Medicare Secondary Payer rule

5. **External Institutional Review Boards** – Western IRB and Advarra are two of VCU’s contracted external IRB’s to review industry supported research and requires documentation from VCU at the time of IRB submission of the VCU/Sponsor approved subject injury language for the informed consent form.
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trial

• NCD 310-1 stipulates “Original Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in MA plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials. All other original Medicare rules apply.
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

VCU’s position regarding a clinical trial sponsor’s responsibility for reimbursement of costs associated with a subject injury in a clinical trial in part stems from the Lutz Letter referred to here:

“CMS’ 2004 Informal Position in the “Lutz Letter”: – “The clinical trial sponsor’s agreement with participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such an injury occurs.” – “

“[CMS] believes that Medicare would not be the primary payor in such a situation.” Remember: Medicare is secondary to any liability insurance plan that is required or responsible to pay based on “legal liability for injury or illness or property damage.” (42 C.F.R. § 411.50) CMS Rationale: – Sponsor promise = liability insurance policy or plan (sponsors may be self insured) – Sponsor’s “agreement to pay for RRI” = de facto “demonstration” of Sponsor’s responsibility to pay June 10, 2010, CMS issued a three-sentence alert (dated May 26, 2010) related to MMSEA § 111, that “clarifies” that Sponsors paying for RRI are considered to be payments from liability plans, and must be reported to CMS.

Source: The above information is from excerpt from a presentation entitled MSP in the Clinical Trial Context and Other Thorny Issues by Holly Lutz and Lisa Murtha (SNR DENTON) June 12, 2011)
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

• Medicare will cover costs for subject injury as outlined in NCD 310.1.
• Many times subject injury language found in industry consent forms and in contracts stipulate that industry clinical trial sponsors will pay but only to the extent not covered by insurance.
• This represents a conflict with the MSP rules as the Sponsor would be viewed as the primary payer and Medicare could not be billed first.
• VCU vetted and developed template language specifically to address the applicable situation.
VCU establishes a process to review subject injury language (SIL) found in consents and contracts and determine payer

- Guidelines were developed based on scenarios
  - Unconditional compensation for research related injury (RRI)
  - Conditional reimbursement (billing to insurance)
- Training was provided to reviewers
- ICF language and contract language is compared to determine if:
  - the Sponsor will agree to pay for costs either outright or conditionally
  - the SIL in the contract differs from the SIL in the informed consent form
  - the language is appropriate based on the type of study/subject population
- The reviewer works with the Study Team, as appropriate, to determine which language prevails in the event of a conflict in terms or if additional info is needed about the type of study.
- The reviewer negotiates the appropriate language with the Sponsor/CRO
- The reviewer reviews the IRB approved language prior to contract award.
Institutional Risk Assessment and the Review of Subject Injury Language for Clinical Trials

**SCENARIO 1: Sponsor agrees to pay for RRI (Unconditional RRI injury compensation)**

- If you are injured by or become ill from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System Facilities (VCU Health). Your study doctor will arrange for short-term emergency care at VCU Health or for a referral if it is needed. If medical treatment is provided at a location other than VCU Health, please contact your study doctor immediately.

- The Sponsor will pay for costs associated with the diagnosis and treatment of a research injury. A research injury is an illness or injury directly caused by the study product (drug/device) or study procedures required by the study protocol and would not have been expected from the standard treatment for your condition. If you are injured by a medical treatment or procedure that you would have received even if you weren’t in the study, that is not a research injury. Any medical treatment you need for other reasons unrelated to the study will be billed to you or your insurance...
SCENARIO 2: (Conditional RRI injury compensation)

Sponsor requests and VCU agrees that a sponsor is to pay for RRI only after billing “private or commercial” insurance. It should be clear that we will not bill any governmental insurance in violation of the law. If the Sponsor agrees to pay on a conditional basis, they are considered to be the primary payor by Medicare and responsible for costs which would be otherwise borne by Medicare/Medicaid.

- If you are injured by or become ill from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System Facilities (VCU Health). Your study doctor will arrange for short-term emergency care at VCU Health or for a referral if it is needed. If medical treatment is provided at a location other than VCU Health, please contact your study doctor immediately.

- The sponsor will pay for costs associated with the medical diagnosis and treatment of any research injury to the extent that such costs are not paid by your private/commercial insurance. A research injury is an illness or injury directly caused by the study product (drug/device) or study procedures required by the study protocol and would not have been expected from the standard treatment for your condition. If you are injured by a medical treatment or procedure that you would have received even if you weren’t in the study, that is not a research injury. Any medical treatment you need for other reasons unrelated to the study will be billed to you or your insurance.
Institutional Risk Assessment and the Review of Subject Injury Language (SIL) for Clinical Trials

Challenges of SIL Review

1. Prolonged negotiation which delays IRB submission
   a. Informed consent form (ICF) and contracting points of contact are different – don’t always coordinate internally
   b. CRO/Sponsor coordination - US/foreign – time delays
   c. Sponsor will not review SIL until contract is finalized or alternately until all ICF changes have been submitted.

2. VCU External IRB approves an alternate version of ICF without VCU approval and conflicts with executed contract.

3. Lack of understanding of the process by internal reviewers and conflicting language is agreed upon.

4. Difference of opinion with the Study Team

5. Tracking of the entire process
Background Information about Systems used in tracking Subject Injury Language Review

• **SPOT** – Sponsored Projects Online Tracking, a VCU customized Click Commerce platform for electronic submission of funding proposals and tracking of associated sponsored project contracts and awards.

• **OnCore** – Forte platform – enterprise clinical trial management system used by VCU for clinical research

• [https://forteresearch.com/enterprise-research-oncore/](https://forteresearch.com/enterprise-research-oncore/)
Begin process by logging in to Oncore, Under Protocol Tab, Click on PC Console.

Select the appropriate Protocol

Click on Status, Task Lists. Then find the OSP Subject Injury Language Review Task List.

Click on the Task List.
Complete Task#1 *(Draft Consent Uploaded to OnCore)* as follows:

- Attach a copy of the draft ICF which needs OSP subject injury language review.
- Add a comment to the *Communications Section* indicating ICF has been updated.
- Select contact name in the *Owner Section*.
- Enter the date in the *Completed Date Section*.

Upload the contract in SPOT through the *Submit Document for Review* mechanism and link to the funding proposal. *(Note: The review record should include the contact information for the Sponsor and the CRO, to include email address, for review of the ICF and contract.)*

Log a *Public Comment* in SPOT in the *Funding Proposal* that consent form is available through OnCore for review.
Complete **Task 2 (Draft Contract Uploaded to SPOT)** as follows:

- Indicate the date in *Completed Date Column* that contract was uploaded in SPOT.
- Select contact name in the *Owner Section* and provide a comment in the *Communications Section* that contract has been uploaded.
- Please provide the associated funding proposal number in the comment.

OSP completes **Task #3, OSP Review Start**. A report is generated and sent to school when OSP completes **Task #4, OSP Approval and Upload of Approved Injury Language ICF and Memo**, and the approved subject injury review forms (Redline ICF and External IRB Memo) have been uploaded to OnCore.
Under Task #5, Study Team Notified of SIL Approval and Availability of Documents, School enters date in Completed Date column and select contact name in the Owner Section. School notifies Study team of availability of documents.

Study team downloads consents for further processing (as required) and regulatory submission and marks the record as complete.

Process Complete
OSP Subject Injury Review Process
Study Team / School Administrator Guidelines

Introduction
The following guide is to outline key functions for the study team/school administrator related to the OSP Subject Injury Review Process.

Oncore Navigation

1) Begin by logging into OnCore and selecting PC Console from the Protocols menu.

2) Select the appropriate Protocol.

3) Select Task Lists from the Status Tab menu.

4) Select the OSP Subject Injury Language Review Task List.

5) Under Task #1:
(Draft Consent Uploaded to OnCore)
- Attach a copy of the draft ICF which needs OSP subject injury language review.
- Add a comment to the Communications Section indicating ICF has been uploaded.
- Select contact name in the Owner Section, and enter the date in the Completed Date Section.

6) In SPOT, click on Submit Document for Review.

7) Log a Public Comment in SPOT in the Funding Proposal stating that the consent form is available through OnCore for review.

9/8/2017
OSP Subject Injury Review Process
Study Team / School Administrator Guidelines

OnCore Processing – Task #2

8) Under Task#2, Draft Contract Uploaded to SPOT,
   2 Draft Contract Uploaded to SPOT

- Indicate the date in Completed Date column that contract was uploaded in SPOT.

   Completed Date
   07/31/2017

- Select contact name in the Owner Section.

   Owner
   - Virginia Commonwealth University

- Provide a comment in the Communications Section that the contract has been uploaded.

   Date | Communication
   07/11/2017 | Contract uploaded to SPOT. FP000006715

- Note: Please provide the associated funding proposal number in the comment.

OnCore Processing – Task #3/#4

9) OSP completes Task #3, OSP Review Start. A report is generated and sent to school when OSP completes Task #4, OSP Approval and Upload of Approved Injury Language ICF and Memo, and the approved subject injury review forms (Redline ICF and External IRB Memo) have been uploaded to OnCore.
   3 OSP Review Start
   4 OSP Approval and Upload of Approved Injury Language ICF and Memo

OnCore Processing – Task #5

10) Under Task #5, Study Team Notified of SIL Approval and Availability of Documents, School enters date in Completed Date column and select contact name in the Owner Section. School notifies Study team of availability of documents.
   5 Study team notified of SIL approval and availability of documents.

OnCore Processing – Completion

11) Study Team downloads consents for further processing (as required) and regulatory submission and marks the Task Record as Completed.

   Update Status
   Move to 'Complete' Status

Summary / Example (Tasks 1 – 5)

See example below (Tasks 1 – 5 complete):

Tasks
- Draft Consent Uploaded to OnCore
- Draft Contract Uploaded to SPOT
- OSP Review Start
- OSP Approval and Upload of Approved Injury Language ICF and Memo
- Study team notified of SIL approval and availability of documents

Contact Information

For questions or further assistance with the OSP Subject Injury Review Process, please contact:

Office of Sponsored Programs – Red Team:
Industry Support
Tel: (804) 828-6772
E-mail: ospred@vcu.edu

For questions regarding OnCore, please reference the OnCore Wiki or email OnCore help (oncore@vcu.edu)

9/8/2017 2
## OSP Subject Injury Task List – OnCore Screenshot

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>NA</th>
<th>Target Date</th>
<th>Completed Date</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Draft Consent Uploaded to OnCore</td>
<td></td>
<td></td>
<td></td>
<td>Owner</td>
</tr>
<tr>
<td>2</td>
<td>Draft Contract Uploaded to SPOT</td>
<td></td>
<td></td>
<td></td>
<td>Owner</td>
</tr>
<tr>
<td>3</td>
<td>OSP Review Start</td>
<td></td>
<td></td>
<td></td>
<td>Owner</td>
</tr>
<tr>
<td>4</td>
<td>OSP Approval and Upload of Approved Injury Language ICF and Memo</td>
<td></td>
<td></td>
<td></td>
<td>Owner</td>
</tr>
<tr>
<td>5</td>
<td>Study team notified of SIL approval and availability of documents.</td>
<td></td>
<td></td>
<td></td>
<td>Owner</td>
</tr>
</tbody>
</table>
OSP Subject Injury Task List – OnCore Screenshot

Task 1 - Consent Uploaded

<table>
<thead>
<tr>
<th>Description</th>
<th>Version Date</th>
<th>Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent</td>
<td>06/27/2019</td>
<td>EAP CON...NT.docx</td>
</tr>
</tbody>
</table>

Task 2 - Contract upload verified

<table>
<thead>
<tr>
<th>Date</th>
<th>Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/28/2019</td>
<td>RV00013277 was created by Melanie Wiggins on 06/27/2019</td>
</tr>
</tbody>
</table>
**OSP Subject Injury Task List – OnCore Report generated**

<table>
<thead>
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<th>Consent and Contract Uploaded</th>
<th>Department</th>
<th>FP Number</th>
<th>Protocol Number</th>
<th>Sponsor</th>
<th>PI</th>
<th>Study Site Contact</th>
<th>Consent Uploaded</th>
<th>Contract Uploaded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neurology</td>
<td>FP0000000</td>
<td>EAP</td>
<td>Company</td>
<td>Harper</td>
<td>Coordinator</td>
<td>6/28/19</td>
<td>6/27/19</td>
</tr>
</tbody>
</table>
OSP Subject Injury Task List – System generated email when Documents are uploaded

OnCore - Subject Injury Language Report - Document Upload
1 message

rbmoulden@vcu.edu <rbmoulden@vcu.edu>
To: rbmoulden@vcu.edu, ospred@vcu.edu

This report lists studies that have had their draft consent uploaded in OnCore and their contract uploaded in Spot.

Download the consent from OnCore and mark this study as Under Review (Task 3).

Task Lists are found in OnCore under Protocols - PC Console - Status - Task List

2K
Communications for 'OSP Review Start'

<table>
<thead>
<tr>
<th>Date</th>
<th>Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/28/2019</td>
<td>Emailed study team to let them know an ICF has not been uploaded.</td>
</tr>
<tr>
<td>06/29/2019</td>
<td>Reviewed ICF and added language to ICF and contract to send to ReveraGen for their review/approval</td>
</tr>
<tr>
<td>Department</td>
<td>FP Number</td>
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<td>School of Medicine</td>
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</tbody>
</table>
OnCore Subject Injury Language Report - Studies Under Review

These studies are currently listed as Under Review in OnCore. Once the review is completed, upload the redline consent and memo of approval to OnCore.

OSP Task List can be accessed in OnCore by going to Status then Task Lists.

Subject Injury Language Report - Studies Under Review.pdf

2019 ANNUAL MEETING
OCTOBER 19 - 23
## OSP Subject Injury Task List – OnCore Screenshot – Task #4 – OSP Approval and Upload of Approved Injury Language ICF and Memo

### Attachments for 'OSP Approval and Upload of Approved Injury Language ICF and Memo'

<table>
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<td>EAP CON….19.docx</td>
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<tr>
<td>Email approval of SIL 7.8.19</td>
<td>07/08/2019</td>
<td>Email fr….19.pdf</td>
</tr>
</tbody>
</table>
Western IRB
1019 39th Avenue SE, Suite 120
Puyallup, WA 98374-2115

**Sponsor:** Name of Sponsor (Approved by Contact at Company)

**Study:** Protocol No: EAP#
“Title of Protocol”

**HM#:** Internal IRB Number

**PI:** Dr. Amy Harper

Dear WIRB Intake:

Office of Sponsored Programs at Virginia Commonwealth University has reviewed the informed consent subject injury language. The subject injury language in the included informed consent form version highlighted below has been approved by VCU and the Sponsor, and should read as follows:

```
Insert text of the compensation for injury section in the ICF as approved by VCU and Sponsor
```

If WIRB approved ICF version exists, please replace the subject injury language with this version.

Please contact me with any questions or concerns.

Melanie Wiggins
Virginia Commonwealth University
Director, Office of Sponsored Programs - Industry & Clinical Trials

7/8/19
## OSP Subject Injury Task List – OnCore Screenshot

### OSP - Subject Injury Language Review – EAP

**Status:** Complete

### Tasks

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<td></td>
<td></td>
<td>06/29/2019</td>
<td>Brittany A Holmberg - Virginia Commonwealth University</td>
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<td>Draft Contract Uploaded to SPOT</td>
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<td>06/27/2019</td>
<td>Letitia M Rivers - Virginia Commonwealth University</td>
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<td>3</td>
<td>OSP Review Start</td>
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<td>06/29/2019</td>
<td>Melanie A Wiggins - Virginia Commonwealth University</td>
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<td>4</td>
<td>OSP Approval and Upload of Approved Injury Language ICF and Memo</td>
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<td>07/03/2019</td>
<td>Melanie A Wiggins - Virginia Commonwealth University</td>
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<td>Study team notified of SIL approval and availability of documents.</td>
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<td>07/09/2019</td>
<td>Letitia M Rivers - Virginia Commonwealth University</td>
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OSP Subject Injury Task List – OnCore and other Challenges

- Report doesn’t generate due to incomplete information – delay in review
- Annotating when a review has been put on hold
- Ensuring that the responsible person/department enters all required/correct information (e.g., dates not completed, ICF not uploaded)
- Additional/different requirements from external IRB (e.g., WIRB, Advarra)
QUESTIONS

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