Commercial IRB Submissions: Lessons Learned

Catherine Jahrsdorfer, R.N., B.S.N.

Director of Clinical Services

Office of Clinical Research

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Referring to the IRBs as Commercial IRBs for this training and not Central IRBs because the central IRB for a study may or may not be a commercial IRB. This training is specific to the commercial IRBs that USF PIs may use – WIRB, Quorum and Schulman.

This talk was developed using 100% real world examples as experienced over the past 2 months. Many problems identified are not unique to one individual and they provide an excellent opportunity to help others avoid the same mistakes.

Learning Objectives

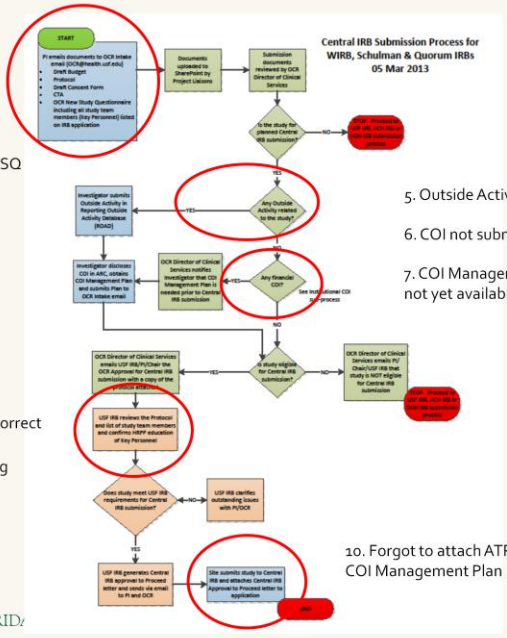
- Review Commercial IRB (CIRB) Submission Process Flow
- Identify common bottlenecks
- Discover measures to avoid submission problems
- Learn how to pay for CIRB services
- Review steps to submit to CIRBs

CIRB Process Flow - Bottlenecks

1. Incomplete document submission

2. Sending documents to the wrong email address

3. Incomplete or incorrect NSQ



5. Outside Activity not yet reported

6. COI not submitted in ARC

7. COI Management Plan not yet available

8. Names misspelled or incorrect

9. Expired HSP/CITI training

10. Forgot to attach ATP letter or COI Management Plan

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Getting Started

- New Study Questionnaire (NSQ) is sent to OCR@health.usf.edu with the four essential documents
  - Protocol
  - Draft consent form
  - Draft contract
  - Draft budget
- See process flow diagram handout:

  CIRB Submission Process

Getting Started: Lessons Learned

- Can send 4 essential documents and NSQ under separate cover, but processing may be enhanced when submitted as a package
- Sending the four essential documents to OCRFM@health.usf.edu instead of OCR@health.usf.edu may cause delays
- Complete *at a minimum* page 1 of the NSQ; Study Demographics

Lessons Learned: NSQ

- Site must provide full names of study team members on NSQ.
  - Reference any name changes/aliases if the current HRP/CITI training is registered under a prior name, uses a nickname, or if the first initial and full middle name is used.
- *Misspelled or incomplete names will cause delays.*
- COI and Outside Activity boxes must be checked yes or no for each study team member

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The USF IRB is responsible for confirming HSP training is current. The IRB staff do not know if you got married, divorced or adopted or that you used a nickname when registering for training.

Lessons Learned: NSQ, cont.

- Outside Activity must be reported prior to the activity occurring
  - COM Faculty report in ROAD: https://hsccf.hsc.usf.edu/road2/
  - A&P and Staff report using form found on Academic Affairs website: http://www.acad.usf.edu/resources/forms/
- Financial COI must be disclosed in ARC
- ATP letter cannot be requested without required disclosures and COI Management Plan if necessary

Lessons Learned: NSQ, cont.

- Ask every person on the study team if they have outside activity or a financial COI with the sponsor, not just the PI
- Cannot rely on FDF because it's not asking the same questions
  - USF threshold for reporting financial COI is anything above $0
  - FDF does not capture uncompensated outside activity
- Ask about consulting services, speaker's bureaus, advisory boards, etc.

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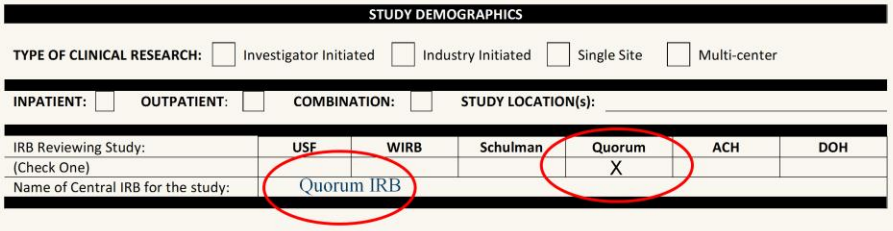
Lessons Learned: NSQ, cont.

- Name of Central IRB for the study must be completed
  - Notifies PLs to stipulate in the contract that sponsor will pay the CIRB directly instead of flowing payments through USF



STUDY DEMOGRAPHICS

TYPE OF CLINICAL RESEARCH: ☐ Investigator Initiated ☐ Industry Initiated ☐ Single Site ☐ Multi-center

INPATIENT: ☐ **OUTPATIENT:** ☐ **COMBINATION:** ☐ **STUDY LOCATION(s):**

IRB Reviewing Study:	USF	WIRB	Schulman	Quorum	ACH	DOH
(Check One)				X		
Name of Central IRB for the study:	Quorum IRB					

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Note that this question is asking the name of the **Central IRB for the multicenter study**, and the Central IRB may or may not be a commercial IRB.

CIRB Fees Not Paid Directly by Sponsor

- Notify your Departmental Research Administrator that you will be incurring CIRB fees (or any outside vendor fees) *prior* to the service occurring
- To avoid After-the-Fact POs
  - Enter a Requisition for the services in FAST, or
  - Enter a Blanket PO for lump sum, or
  - Pay fees on a P-Card
- OCR copies DRA on request for ATP emails but CRCs must communicate with DRAs throughout study

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If the central IRB for the study is not a USF relied upon IRB, USF will need to pay the fees to the commercial IRB directly. These fees are paid to the CIRB by the department.
If choose to enter a blanket PO to cover CIRB fees, it will encumber the entire amount of the blanket PO so it is not recommended to use the entire initial budget released or will not have funds available to pay other vendors, salary, etc. Can increase the blanket PO as needed during the study.
USF Purchasing has notified that may begin charging $5K to the College for each after the fact PO.

Get Reimbursed for CIRB Fees

- First, pay the vendor for services rendered in a timely manner
- Read your contract
  - Does it require the sponsor to be invoiced for reimbursement of IRB fees paid by the site?
  - If yes, note the item to be invoiced on your SSL *and*
  - Send the supporting IRB invoice with your SSL to OCRFM@health.usf.edu by COB on the 5th day of the month
- Do not send CIRB statements, OCR must have the invoice

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Western IRB (WIRB) Submissions

- Insert WIRB approved USF consent language excerpts into sponsor's consent template
- Submit consent to your PL for review prior to sending to sponsor
  - PLs confirm sponsor payment for subject injury language aligns with contract and participant compensation agrees with budget
- Submit consent to sponsor for approval prior to WIRB submission
- Attach Approval to Proceed letter to all initial submissions
- Attach COI Management Plan, prn

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WIRB approved consent language excerpts are located on the OCR website Forms page. Your Project Liaisons do confirm the sponsor payment for subject injury language in the consent is aligned with the contract language and they also confirm the participant compensation agrees with the budget but they do not engage in the other regulatory aspects of the consents such as HIPAA and privacy and confidentiality. That language is up to the site to insert and the CIRB is to verify that the language has been inserted prior to approving the consent.

Quorum Review IRB Submissions

- Insert Quorum approved USF consent language excerpts into sponsor's consent template
- Submit consent to your PL for review prior to sending to sponsor
  - PLs confirm sponsor payment for subject injury language aligns with contract and participant compensation agrees with budget
- Submit consent to sponsor for approval prior to Quorum submission
- Attach Institution Cover Sheet to all initial site submissions
- Attach Approval to Proceed letter to all initial submissions
- Attach COI Management Plan, prn

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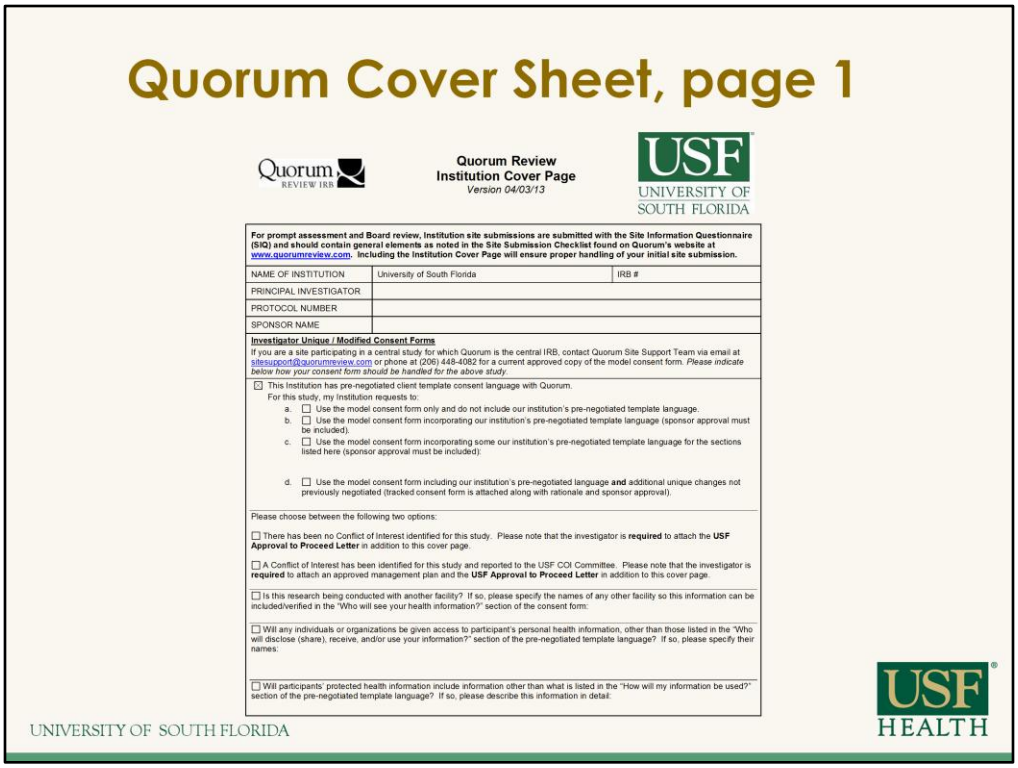
The Cover Sheet identifies the special handling requirements for USF studies.
Quorum approved consent language excerpts are located on OCR website Forms page

Quorum Cover Sheet, page 1



Quorum Review
Institution Cover Page
Version 04/03/13

For prompt assessment and Board review, Institution site submissions are submitted with the Site Information Questionnaire (SIQ) and should contain general elements as noted in the Site Submission Checklist found on Quorum's website at www.quorumreview.com. Including the Institution Cover Page will ensure proper handling of your initial site submission.

NAME OF INSTITUTION	University of South Florida	IRB #
PRINCIPAL INVESTIGATOR		
PROTOCOL NUMBER		
SPONSOR NAME		

Investigator Unique / Modified Consent Forms

If you are a site participating in a central study for which Quorum is the central IRB, contact Quorum Site Support Team via email at sitesupport@quorumreview.com or phone at (206) 448-4082 for a current approved copy of the model consent form. *Please indicate below how your consent form should be handled for the above study.*

☑ This Institution has pre-negotiated client template consent language with Quorum.

For this study, my Institution requests to:

a. ☐ Use the model consent form only and do not include our institution's pre-negotiated template language.

b. ☐ Use the model consent form incorporating our institution's pre-negotiated template language (sponsor approval must be included).

c. ☐ Use the model consent form incorporating some our institution's pre-negotiated template language for the sections listed here (sponsor approval must be included):

d. ☐ Use the model consent form including our institution's pre-negotiated language **and** additional unique changes not previously negotiated (tracked consent form is attached along with rationale and sponsor approval).

Please choose between the following two options:

☐ There has been no Conflict of Interest identified for this study. Please note that the investigator is **required** to attach the **USF Approval to Proceed Letter** in addition to this cover page.

☐ A Conflict of Interest has been identified for this study and reported to the USF COI Committee. Please note that the investigator is **required** to attach an approved management plan and the **USF Approval to Proceed Letter** in addition to this cover page.

☐ Is this research being conducted with another facility? If so, please specify the names of any other facility so this information can be included/verified in the "Who will see your health information?" section of the consent form:

☐ Will any individuals or organizations be given access to participant's personal health information, other than those listed in the "Who will disclose (share), receive, and/or use your information?" section of the pre-negotiated template language? If so, please specify their names:

☐ Will participants' protected health information include information other than what is listed in the "How will my information be used?" section of the pre-negotiated template language? If so, please describe this information in detail:

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Quorum cover sheet is also located on the OCR website Forms page

Quorum Cover Sheet, page 2

Acknowledgement by University of South Florida

The Investigator(s) named at the beginning of this form are authorized to conduct the above referenced investigational research study in this institution under the jurisdiction of Quorum Review.

Signature of Institution Official or authorized Designee: See USF Approval to Proceed letter attached

_____Date: _____

Please give portal account access to the following individuals:

Name: Julie Martin
Email address: jtmartin@usf.edu

Name: Brandy Hutchinson
Email address: bhutchin@usf.edu

Name: Catherine Jahrsdorfer
Email address: cjahrsdo@usf.edu

Name: Monique Green
Email address: tgreen2@health.ust.edu

THIS SECTION DESCRIBES CURRENT HANDLING REQUIREMENTS FOR THE INSTITUTION ABOVE AND IS FOR QUORUM USE ONLY

See University of South Florida account for handling requirements. CFD: Please see instructions related to client template language above.

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The USF Institutional Contacts are already filled in.
In lieu of a signature in the acknowledgement section, please note that the Approval to Proceed letter will be attached to the submission.

Schulman Associates IRB (SAIRB) Submissions

- Insert USF consent language excerpts for SAIRB into sponsor's consent template
- Submit consent to your PL for review prior to sending to sponsor
  - PLs confirm sponsor payment for subject injury language aligns with contract and participant compensation agrees with budget
- Submit consent to sponsor for approval prior to SAIRB submission
- Attach Approval to Proceed letter to all initial submissions
- Attach COI Management Plan, prn

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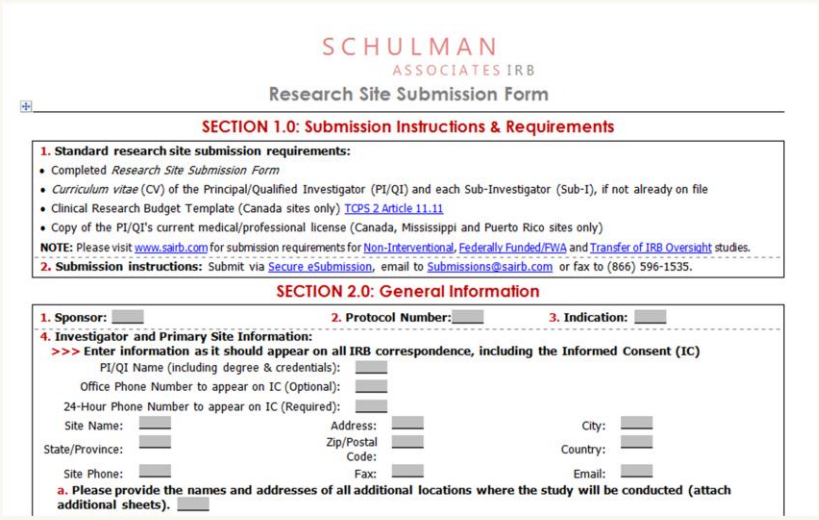
Schulman does not pre-approve the consent language excerpts. Rather the consent language, including the USF consent language excerpts, is reviewed in totality with each individual submission.
USF consent language excerpts for Schulman IRB are located on the OCR website Forms page

SAIRB Submissions, cont.

- Add the USF Institutional Contacts to the Research Site Submission Form in Section 3, Question 3: Academic Medical Center / Institution Contact Information
  - Section accommodates only one AMC contact, so a separate sheet with the additional contacts must also be attached
  - Designate that AMC contacts will have a CC role to ensure cc'd on all correspondence to site
- PENDING: SAIRB is developing a USF Institution Cover Sheet that will be attached to all initial site submissions

SAIRB Research Site Submission Form



SCHULMAN
ASSOCIATES IRB

Research Site Submission Form

SECTION 1.0: Submission Instructions & Requirements

1. Standard research site submission requirements:

- Completed *Research Site Submission Form*
- *Curriculum vitae* (CV) of the Principal/Qualified Investigator (PI/QI) and each Sub-Investigator (Sub-I), if not already on file
- Clinical Research Budget Template (Canada sites only) TCPS 2 Article 11.11
- Copy of the PI/QI's current medical/professional license (Canada, Mississippi and Puerto Rico sites only)

NOTE: Please visit www.sairb.com for submission requirements for Non-Interventional, Federally Funded/FWA and Transfer of IRB Oversight studies.

2. Submission instructions: Submit via Secure eSubmission, email to Submissions@sairb.com or fax to (866) 596-1535.

SECTION 2.0: General Information

1. Sponsor: **2. Protocol Number:** **3. Indication:**

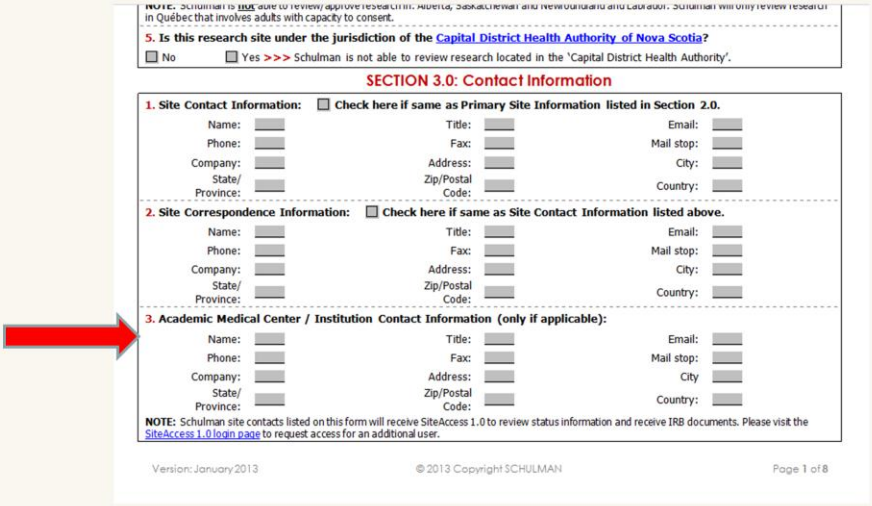
4. Investigator and Primary Site Information:

>>> Enter information as it should appear on all IRB correspondence, including the Informed Consent (IC)

PI/QI Name (including degree & credentials):
Office Phone Number to appear on IC (Optional):
24-Hour Phone Number to appear on IC (Required):
Site Name: Address: City:
State/Province: Zip/Postal Code: Country:
Site Phone: Fax: Email:

a. Please provide the names and addresses of all additional locations where the study will be conducted (attach additional sheets).

SAIRB RSS Form, Section 3 Question 3



in Québec that involves adults with capacity to consent.

5. Is this research site under the jurisdiction of the Capital District Health Authority of Nova Scotia?

☐ No ☐ Yes >>> Schulman is not able to review research located in the 'Capital District Health Authority'.

SECTION 3.0: Contact Information

1. Site Contact Information: ☐ **Check here if same as Primary Site Information listed in Section 2.0.**

Name:		Title:		Email:	
Phone:		Fax:		Mail stop:	
Company:		Address:		City:	
State/ Province:		Zip/Postal Code:		Country:	

2. Site Correspondence Information: ☐ **Check here if same as Site Contact Information listed above.**

Name:		Title:		Email:	
Phone:		Fax:		Mail stop:	
Company:		Address:		City:	
State/ Province:		Zip/Postal Code:		Country:	

3. Academic Medical Center / Institution Contact Information (only if applicable):

Name:		Title:		Email:	
Phone:		Fax:		Mail stop:	
Company:		Address:		City	
State/ Province:		Zip/Postal Code:		Country:	

NOTE: Schulman site contacts listed on this form will receive SiteAccess 1.0 to review status information and receive IRB documents. Please visit the SiteAccess 1.0 login page to request access for an additional user.

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Until the SAIRB Cover Sheet is launched, may also note “See attached USF Institutional Contacts and provide CC role to all” in Section 3, Question 3 and attach contact information on a separate sheet.

Contacts

- WIRB:
  - Devin Krug, CIP Account Manager – Institutions
    Office: (360) 252-2550 | Fax: (360) 252-2498
    Email: dkrug@wirb.com
  - Website: www.wirb.com

WIRB Global Leader | Proven Expert

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Contacts

- Quorum:
  - Rachael Birge | Study Manager

    T 206-448-4082 x338 | F 206-448-4193

    Email: rbirge@quorumreview.com
  - Website: www.QuorumReview.com

Quorum REVIEW IRB

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Contacts

- Schulman:
  - Kristian Figueras, MS | Operations Coordinator I

    Office: 954-327-0778 | FAX: 866-258-6674

    Email: KFigueras@sairb.com
  - Bette Bayne | Director, Institutional and Phase I Services

    Office: 513-794-5777 | Mobile: 512-431-9630
    Email: bbayne@sairb.com
  - Website: http://www.sairb.com

SCHULMAN ASSOCIATES IRB
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**Contacts

- USF OCR:
  - Monique Green, B.S. | Regulatory Coordinator
    Phone: 813.974.5489 | Fax: 813.905.9997
    Email: tgreen2@health.usf.edu
  - Catherine Jahrsdorfer, RN, BSN | Assistant Director
    Phone: 813.396.9172 | Fax: 813.905.9997
    Email: cjahrsdo@health.usf.edu
  - Website: USF Health Office of Clinical Research

**Institutional Contacts for Central IRBs

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**Contacts

- USF DRIC:
  - Brandy Hutchinson | Assistant IRB Manager - Biomedical
    Phone: 813.974.8553 Fax: 813.974.7091
    Email: bhutchin@usf.edu
  - Julie Martin | Assistant Director for Regulatory Affairs
    Phone: 813.974.8360 | Fax: 813.974.7091
    Email: jtmartin@usf.edu
  - Website: http://www.research.usf.edu/dric/default.asp

USF RESEARCH & INNOVATION UNIVERSITY OF SOUTH FLORIDA

**Institutional Contacts for Central IRBs

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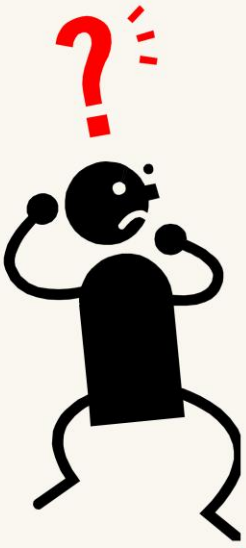
Questions, Concerns, Comments?



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