

Submitting to the IRB: Prospective and Retrospective Studies

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What is the IRB?

An **Institutional Review Board** (**IRB**), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral <u>research</u> involving <u>human subjects</u>.

- #1 Priority: Protect subjects from physical or psychological harm
 - Even retrospective chart reviews carry risks: invasion of privacy; confidentiality breach
- #2 Priority: Protect Temple's research program
 - Federal penalties, less funding, damage to Temple's image



My job: Designated reviewer

I review minimal risk <u>Human Subjects</u> <u>Research</u> for:

- Regulatory compliance
 - HIPAA, FDA, consent, FERPA, etc.
- Temple's Policies
 - CITI training, approval routes, etc.





Human subjects research (HSR)

• A systematic investigation—designed to develop/contribute to <u>generalizable knowledge</u>—involving living individuals about whom an investigator conducting research obtains: 1. <u>Identifiable private information</u> or 2. Data through <u>intervention or interaction</u> with the individual.

 If a project is Human Subjects Research, it must be reviewed/approved by the IRB.



NHSR examples

- Case study Not human subjects research > not "generalizable"
- Research on a de-identified (prior to being obtained) dataset Not human subjects research > not "human subjects"
- QI / QA that is specific to Temple's operations Not human subjects research > not "generalizable"
- Unsure? Contact the IRB (email IRB@temple.edu or call a coordinator)
- <u>A NHSR determination does not = bad project</u>



Common misconceptions

• Human subjects research must always involve direct intervention or interaction with individuals.

FALSE

- Analyses of identifiable data sets.
- A project must be Human Subjects Research in order for results to be published.

FALSE

- IRB considers whether or not a project is designed to contribute to "generalizable knowledge" not whether or not the results will be presented or published.
- IRB considers design not intent.



So your protocol is Human Subjects Research...

What's Next?



Submit to the IRB to be reviewed as follows...

- Exempt: A designated reviewer determines that the research is exempt from certain rules and regulations.
 - The IRB <u>must</u> review the initial protocol and modifications that may change the category.
 - Use the **Minimal Risk** protocol and consent templates.
- Expedited: A designated reviewer approves the research initially, annually (in some cases), and any modifications.
 - Does not mean faster.
 - Use the **Minimal Risk** protocol and consent templates.
- Full Board: A fully convened IRB committee reviews the research initially, annually (at minimum), and any modifications.
 - For research that doesn't fit into the above categories or is greater than minimal risk.
 - Use the **Main** protocol and informed consent templates.



Exempt Categories

- Exempt 1 Research on educational practices
- Exempt 2 Surveys, interviews, educational tests, or observation of public
 - No minors
- Exempt 3 Benign (and short) behavioral intervention, collecting data solely via verbal or written responses or audiovisual recording
 - No minors
- Exempt 4 Secondary data analysis of (at least) initially identifiable information
- Exempt 5 (Federal demonstration project), 6 (Taste and food testing), 7 (Collecting identifiable data for future research with Broad Consent), and 8 (Using data collected under 7) are either not relevant or not happening at Temple



Expedited Categories

- Expedited 1 Research on drugs or devices that don't need specific FDA approvals (INDs or IDEs)
- Expedited 2 Collection of blood from healthy adults (<550 ml/8 wk; up to 2x/wk) or other adults and children (<50ml or 3 ml/kg/8 wk; up to 2x/wk)
- Expedited 3 Noninvasive collection of biological specimens
- Expedited 4 Noninvasive collection of data (e.g., MRI, EEG, hr, bp, etc.)
- Expedited 5 Secondary analysis of identifiable data that isn't under HIPAA
- Expedited 6 Data collected from video/audio recordings
- Expedited 7 Surveys, interviews; research on cognition, perception, language, and other individual/group characteristics and behaviors



Exempt, Expedited, and Full Board...

- Cannot begin before the IRB approves the research.
- The IRB will stamp the consent form(s), and those are the ones that should be used.
 - Stamped consents can be found in the Attachments tab for every approved submission in which a consent was submitted.
- Changes to the study (recruitment methods, data collection/storage, N, tasks, personnel, etc.) should be submitted as Modifications.
- Problems (over-enrollment, unsigned consent, protocol deviation, confidentiality breach, adverse event, etc.) need to be reported to the IRB.



A couple of notes...



Retrospective vs prospective studies

- Retrospective = exists at the time that the IRB receives the submission.
 - Waiver of consent and HIPAA authorization is fairly simple.
 - Use the IRB's Chart Review Protocol Template.
- Prospective = exists after the time that the IRB receives the submission.
 - Waiver of consent or HIPAA authorization may not be granted.
 - Collecting patient follow-up data that extends beyond the date of submission introduces a prospective element to the study.
 - The Chart Review Protocol Template may still apply, but if waivers of consent and HIPAA aren't sought / granted, the Minimal Risk Protocol Template is preferred.



Funding matters

- Federally-funded studies:
 - May require Single IRB.
 - Require additional language in the consent.
 - Consult with the IRB prior to submitting the protocol (and grant if multi-site).
- Industry-initiated studies:
 - Must be reviewed by WIRB, but will be submitted to the Temple IRB prior to WIRB review.
 - Must include the WIRB Initial Submission Form in the submission to the Temple IRB.



General IRB tips

- When planning, give at least 2 months for a submission to be approved.
 - The first review can take up to a month and there may be Mods Required.
 - Check in with a coordinator if you haven't heard from us after a month.
- Read HRP-070, -071, -802, and -803.
 - <u>https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-forms-standard-operating-procedures</u>
- An hour of checking your work can save a week in time-to-approval.
- The IRB approves and stamps all consents forms and consent scripts.
- Use ERA as your repository for clean protocols, consents, and recruitment materials
 - That way you are always using / modifying the approved documents.
- If you have questions, reach out to a coordinator.
 - <u>https://research.temple.edu/research-compliance/meet-our-staff#IRB</u>



Submitting to the IRB: Basics

- CITI training
 - First time: research.temple.edu > Research Compliance > Institutional Review Board (IRB) > IRB Trainings and Resources
 - <u>https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-trainings-and-resources</u>
 - Subsequent visits: <u>citiprogram.org</u>
- IRB template documents
 - research.temple.edu > Research Compliance > Institutional Review Board (IRB) > Investigator Quick Links
 - <u>https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links</u>
- ERA
 - era.temple.edu
 - User guide at research.temple.edu > ERA > Training Tutorials & Documentation
 - <u>https://www.temple.edu/research/researchadmin/era/era_login.asp</u>



CITI training

- Be sure to affiliate with Temple University, **not** Temple Hospital
 - Easiest way is signing in via the IRB website linked on previous slide
- Two required courses:
 - Biomedical Research 18 modules, takes ~1-4 hours
 - Practice Runs Training 1 module, takes ~5 minutes
- Does not need to be completed prior to submitting to the IRB but...
- Needs to be completed by everyone on the study before the IRB will approve the study



Protocol and consent templates

- Download the Word docs from the website.
- Don't leave in the instructional language.
- The IRB focuses on the abstract, title, investigator, and study design
 - Particularly: timing, inclusion/exclusion, what data will be accessed / collected, privacy & confidentiality, recruitment, study methods, and consent methods
- Make sure the IRB knows what you're doing, why you're doing it, and can grant a waiver of HIPAA authorization (consult HRP-428 for the requirements) if doing a retrospective chart review.
- To the website! (https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links)



Protocol and consent tips

- Provide Word docs and tracked changes in Word (if a response)
- Be consistent across all study documents.
 - Participant duration, N, if identifiers are linked to data via a key, etc.
- Don't describe durations with dates, use months / weeks / years.
 - Bad: Recruitment completed by December 2019.
 - Good: Recruitment completed 3 months after IRB approval.
- If recording (video or audio), it must be in the consent.
- Minimal risk research usually does not require signed consent.
 - If you need signed consent (research with minors, HIPAA, etc.), the signature blocks are in the Main Informed Consent Template.
- Only include the consent summary if the study is federally funded <u>and</u> the consent body is longer than 4 pages.
- Double-check you're using the approved document as the base for any Modifications.
- Unless you are accessing medical records, you do not need HIPAA Authorization.

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ERA

- ERA is the portal through which Investigators and the IRB communicate (submissions and responses) officially.
- The IRB / ERA User Guide is helpful and has screen shots, but you will waste time and effort if you don't use the table of contents.
 - <u>https://www.temple.edu/research/researchadmin/era/era_login.asp</u>
- era.temple.edu > sign in > My Human Subjects
- Before going to the website, some tips.



ERA tips

- Make sure that you're in My Human Subjects, not My Proposals.
- Only full-time faculty can be the PI.
 - The 3rd prompt will ask for the PI, but will automatically have your name in it. Change to the correct PI.
- Immediately add the Application for Human Research (see User Guide pages 13-15).
- Immediately add yourself to the Application for Human Research (eForm).
 - If you don't you won't be able to access the record in the future.
- When all documents (minimum eForm and protocol) are uploaded, click submit, I agree, and continue.
 - Ensure it says "Electronic Submission Pending" on the Submissions page.
 - Emails are generally sent to your / your PI's @temple.edu address.
- The Department Head needs to be in the approval route for initial subs.
 - If your PI is the DH, then add the Dean.
- Upload docs via "Add" button, Not the Attachments tab.



Screenshot notes

- This is not a 1 slide, 1 click format. There are some gaps and some steps that are combined within 1 screenshot.
- Pop-up windows that are in the screenshot will not exist until a button (like "Add") on the main page is clicked.
- The pop-ups may appear in a different part of the screen or not be fully visible as they are in the screenshots.
- Use the red arrows to denote the button/clicking sequence.



Add documents by clicking the "Add" button

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Always create the Application for Human Research eForm first

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"Name" should be succinct and informative; It's what the IRB will see

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Clicking "Close" will refresh the main page and show all uploaded documents

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Click "Submit" when all documents are uploaded; Note it's not actually submitted yet

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Status will change from "Under Development" to "Electronic Submission Pending" once it's submitted

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Status can be viewed on the "Submissions" page as well; "Under Development" means not submitted

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Modification	26289-0003	08-Nov-2019	08-Nov-2019	N/A	Workflow Step 2 (Prep for Review)	N/A	N/A	N/A	Log	Delete
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Modifications Required to Secure Approval	26289-0002	N/A	N/A	N/A	Approved	12-Nov-2019	N/A	N/A	Log	Delete
Reportable New Information	26289-0004	N/A	N/A	N/A	Under Development		N/A	N/A	Log	Delete

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If something is "Electronic Submission Pending," Then it's been submitted to—but not brought into—the IRB

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"Workflow Step 2" reflects that the IRB has the submission, but has yet to review it

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You will get an email after the person ahead of you (as indicated in the previous approval route pop-up) has acknowledged the submission

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Open the Acknowledge email (from OFFICE_OLD, IRB); click "Reviewer Dashboard"

An Initial Application For Your Review Σ Index x

OFFICE_OLD, IRB

to me 👻

An Initial Application has been submitted to the Institutional Review Board. Your Approval is required for this submission.

Please click the link below to review and comment on the following application

IRB #:26289 Principal Investigator: DAVID_COMALLI Department:RESEARCH: EXECUTIVE LEADERSHIP (24010) Title:My example protocol for the talk that I'm giving right now Sponsor:NO EXTERNAL SPONSOR

Your approval is required for this submission.

Click here for a short version of instructions on how to review this submission.

REMEMBER TO SAVE YOUR WORK BY CLICKING ON "SAVE" IN THE UPPER RIGHT-HAND SIDE OF THE REVIEWER'S DASHBOARD!!!!!

To add your review, click here Reviewer Dashboard

To review the entire submission, click here Open Submission Package

If you have questions about the approval process, please contact the IRB Office at (215) 707-3390.

You may need to sign into ERA; Click the "Review" tab

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Review documents by clicking on them

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If you notice an error, you can stop the approval route (so the error can be fixed) by adding a Comment and clicking "PI Clarification"; Re-submit after fix(es)

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If the contents are acceptable, click "Acknowledge" and agree to the subsequent attestation

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Respond to "Modifications Required to Secure Approval" by clicking the "Respond..." link; Don't create a "Modification" to respond to requested changes

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Select "Modifications Required to Secure Approval" from the dropdown (or "Deferred" if appropriate)

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Submission	Modifications Required to Secure Approval		Submission Number: 26289-0002	Created on: 08-Nov-2019	Status: Under Development
Reviews					
IC Checklist	Document/Form Add	Туре	Status		Submit
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Personnel (2)	Medical Record Abstraction Sheet	Attachment	Completed	Modify	Remove

Protocol

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Attachments (7) Show Existing Protocol Attachments

Protocol

Survey

Recruitment email

Status History (1)

Departments (1)

Centers / Programs

Assignments

Locations

Add the new (Tracked Changes and Clean versions) documents

du/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E0538510600A57C3&ObjectID=96D84568D867134AE0538510600AC3CF&Page=SubmissionDetail - Google Chrome EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail Record Number 👧 Human Subjects My example protocol for the talk that I'm giving right now 26289 DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR) Edit Mode Done Save Change Project Info ? Submissions (2) Linkages Attachments (14) Communications (3) Approved Docs Summaries Home > Submissions > Modifications Required to Secure Approal > Submission Modifications Re uired to Secure Approval Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Under Development Submission Reviews Document/Form Add Status Submit Type IC Checklist Application for Human Research IRB Application Completed PDF Remove Codicils Consent Form Consent Completed Modify Remove Communications Flyer Attachment Completed Modify Remove Personnel (2) Medical Record Abstraction Sheet Attachment Completed Modify Remove Departments (1) Protocol Protocol Completed Modify Remove Centers / Programs Recruitment email Attachment Completed Modify Remove Survey Attachment Completed Modify Remove Locations Attachments (7) Show Existing Protocol Attachments Status History (1) Assignments

Click "Submit" once all updated documents are submitted; Don't remove unchanged documents

du/EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F888E59712A3E0538510600A57C3&mark=3283227&WFTabID=16&rand=0.16045401324682573&Mode=EDIT&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail - Google Chrome EnableWeb/Compliance/SubmissionDetail.aspx?ProjID=96C7F8B8E59712A3E053B510600A57C3&mark=3283227&WFTabID=16&rand=0.16045401324682573&Mode=EDIT&ObjectID=96D84568D867134AE053B510600AC3CF&Page=SubmissionDetail Record Number N Human Subjects My example protocol for the talk that I'm giving right now 26289 DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR) Edit Mode Done Save Change Project Info ? Submissions (2) Linkages Attachments (16) Communications (3) Approved Docs Summaries Home > Submissions > Modifications Required to Secure Approval > Submission Modifications Required to Secure Approval Submission Number: 26289-0002 Created on: 08-Nov-2019 Status: Under Develo Submission Reviews Submit Document/Form Add Type Status IC Checklist Application for Human Research IRB Application PDF Completed Remove Codicils Consent Clean 11.11.19 Attachment Completed Modify Remove Communications Consent Tracked 11.11.19 Attachment Completed Modify Remove Personnel (2) Modify Flyer Attachment Completed Remove Departments (1) Medical Record Abstraction Sheet Attachment Completed Modify Remove Protocol Protocol Completed Modify Remove Centers / Programs Recruitment email Attachment Completed Modify Remove Locations Survey Attachment Completed Modify Remove Attachments (8) Status History (1)

Show Existing Protocol Attachments

Assignments

After the submission is approved, retrieve stamped consent forms by going to the "Approved" submission

Muman Subjects

Change Project Info

Edit Mode

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 Record Number
 My example protocol for the talk that I'm giving right now

 26289
 DAVID COMALLI

 Done
 Save

 Submissions (5)
 Linkages

 Submissions (6)
 Attachments (20)

 Communications (6)
 Approved Docs

Home > Submissions

Submissions										▼ Add
Туре	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination	Determination Date	Date From	Date To	Access Log	
Close Protocol	26289-0005	08-Nov-2019	08-Nov-2019	N/A	Electronic Submission Pending	N/A	N/A	N/A	Log	Delete
Modification	26289-0003	08-Nov-2019	08-Nov-2019	N/A	Workflow Step 2 (Prep for Review)	N/A	N/A	N/A	Log	Delete
Initial Submission	26289-0001	08-Nov-2019	08-Nov-2019	N/A	Modifications Required to Secure Approval	09-Nov-2019	N/A	N/A	Log	Delete
Modifications Required to Secure Approval					Approved	12-Nov-2019	N/A	N/A	Log	Delete
Reportable New Information	26289-0004	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	Log	Delete

Click on the "Attachments" link within the submission

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Communications	Consent Tracked 11.11.19	Attachment	Completed	Modify
Personnel (2)	Flyer	Attachment	Completed	Modify
Departments (1)	Medical Record Abstraction Sheet	Attachment	Completed	Modify
Centers / Programs	Protocol	Protocol	Completed	Modify
Locations	Recruitment email	Attachment	Completed	Modify
Attachments (9)	Survey	Attachment	Completed	Modify
Status History (2)	Show Existing Protocol Attachments			
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Find the IRB Approved and Stamped consent(s)

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They should be sortable by "Category," labeled as " Stamped Consent "

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Clicking "Category" will sort alphabetically; Clicking again sorts in the opposite direction

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Create another submission by clicking the dropdown menu on the "Submissions" page

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Select the desired submission type; This example is creating a "Modification"

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Click and then complete the "Modification of Approved Human Research" eForm

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Submission Reviews IC Checklist Codicils Communications Personnel (1) Departments (1) Centers / Programs Locations Attachments (1) Status History (1) Assignments	Modification Document/Form Add Modification of Approved Human Research Show Existing Protocol Attachments	Section I IRB Project #: 26289 Study Title: My example protocol for the talk that I'm giving right now Investigator: COMALLI, DAVID * Department: RESEARCH: EXECUTIVE LEADERSHIP (24010) * Physical Address: 3340 N. Broad St. * Phone Number: 215-707-7792 Section II * Summarize the modification: Adding Dr. Henry Parkman as a Co-Investigator.	
		Section III Were any of the documents below affected by the modification(s)? * This modification request includes the addition of any radiation imaging; or a change in sponsored imaging requirements; or a change in number of radiation imaging or radiation therapies; or a change in type of radiation; or a change where the radiation is going to be Yes No Yes No * Investigator Protocol Yes No * Research tools Yes No * Data collection instruments (questionnaires, etc.; do not submit case report forms). All written materials to be provided to or meant to be seen or heard by subjects, including:	•

Click "Add" to add any additional documents; If changing approved documents, include tracked changes and clean versions

edu/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F888E59712A3E0538510600A57C3&ObjectID=96D88E38E0D424CDE0538510600A7627&Page=SubmissionDetail - Google Chrome u/EnableWeb/Compliance/SubmissionDetail.aspx?Projid=96C7F8B8E59712A3E053B510600A57C3&ObjectID=96D8BE38E0D424CDE053B510600A7627&Page=SubmissionDetail Muman Subjects Record Number My example protocol for the talk that I'm giving right now 26289 DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (24010) (NO EXTERNAL SPONSOR) Edit Mode Save Done Change Project Info ? Summaries Attachments (20) Submissions (5) Linkages Communications (6) Approved Docs Home > Submissions > Modification > Submission Modification Submission Number: 26289-0003 Created on: 08-Nov-2019 Status: Under Development Submission Reviews (1) Document/Form Add Type Status Show Route (Route History) IC Checklist Modification of Approved Human Research Modification Completed PDF (Mandatory Form) Codicils Communications (3) Personnel (1) Departments (1) Centers / Programs Locations Attachments (1) Status History (5)

Assignments

When ready, click "Submit" and get to the approval route

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If adding Temple (Hospital or University) personnel, add them to the approval route by clicking "Add New Person to Review Path"

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Click "Add" and repeat until all <u>new</u> personnel are added

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At any time, click "Show Route" to see who has Acknowledged and been notified

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The date under "Notified" only reflects when a person was notified

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All documents for the study can be viewed in the general "Attachments" tab

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Reportable New Information	23074-0005	N/A	N/A	N/A	Under Development	N/A	N/A	N/A	Log	Delete		

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