

University of California, San Francisco  
Helen Diller Family Comprehensive Cancer Center

**Policy for Obtaining Informed Consent of Potential Participants for  
Oncology Research**

Process and workflows for obtaining and documenting informed consent

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**Purpose**

This policy defines research personnel who may obtain consent [i.e., Key Study Personnel (KSP)] and describes the steps required by the KSP for obtaining informed consent from potential study participants in a clinical research study at the Helen Diller Family Comprehensive Cancer Center (HDFCCC).

**Scope**

This policy applies to all clinical research studies, including Investigator-Initiated, Industry-Sponsored, and National Cancer Institute’s (NCI) National Clinical Trials Network (NCTN) trials.

## Definitions

- **Certified Bilingual/Multilingual Clinicians and Staff:** UCSF faculty or staff who are certified by the Interpreting and Translation Services Department to discuss medical or clinical information directly with participants and their family/guardians without the assistance of a Professional Medical Interpreter and: a) are proficient in speaking and understanding both spoken English and at least one other spoken or signed language, including any necessary specialized vocabulary, terminology and phraseology, and b) are able to effectively, accurately, and impartially communicate directly with Individuals in their preferred languages. Certified Bilingual/Multilingual Clinicians and Staff are not permitted to act in the capacity of an interpreter for third parties, only to conduct their normal job duties in their certified language(s).
- **Informed Consent Form (ICF):** a document outlining possible study procedures, risks, benefits and alternatives, along with the participant's rights. The ICF serves as a way of documenting the participant's understanding and is only part of the informed consent process.
- **Key Study Personnel (KSP):** As per the Human Research Protection Program (HRPP), UCSF Key Study Personnel (KSP) are defined as all individuals who contribute in a substantive way to the scientific development or execution of the study at or on behalf of UCSF or affiliated institutions. KSP for therapeutic trials are defined as the Principal Investigator, the Co-Investigator, or Sub-Investigators (i.e., MDs and Advanced Practice Providers, including NPs and PAs) employed by the research program that are listed as "Key Study Personnel" in 1) the UCSF *IRB protocol application* and 2) on the protocol-specific [Delegation of Authority \(DOA\) log](#), or equivalent, with the role of obtaining consent.
  - Fellows: Fellows may be listed as KSP and assigned the responsibility on the DOA log for consenting study participants in both therapeutic and non-therapeutic studies. Fellows should be listed on the FDA 1572 as co-investigators and are required to complete the DSMC Investigator training prior to consenting any participants.
  - For therapeutic trials in the HDFCCC, the Clinical Research Coordinator (CRC), Registered Nurse (RN), and other study staff are **not** considered Key Study Personnel for obtaining consent and re-consent.
  - CRCs, RNs and other study staff may be listed as KSP and obtain informed consent for non-therapeutic minimal risk trials (including collection of blood and urine samples, germ-line tissue banking trials, imaging studies without an investigational product, etc.).
    - The Clinical Research Manager (CRM) submits a request for CRCs/RNs/other study staff to have consenting privileges for the non-therapeutic minimal risk trial to the Associate Director of Clinical Research Programs and the DSMC Director (or designee). This request includes the protocol and ICF for the non-therapeutic trial. After this one-time approval is granted for the trial, any CRC, RN, or other study staff who needs consenting privileges would be trained by the DSMC Education and Training Manager (ETM) or approved trainer on the consent process. Additionally, the trained CRCs, RNs, or other study staff will be listed as Research Support Staff and their responsibilities for consenting will be outlined in the UCSF IRB Application.

- *Participant:* Persons enrolled in clinical research. Studies may enroll people with a specific disorder or people without health problems to provide baseline information on overall health. The term “participant” covers all people enrolled in studies regardless of their health status. For the purpose of this policy, participant may also refer to the guardian of a minor child. Quick reference guides for consenting pediatric participants can be found in Appendix 1.

## Background

Informed consent is a term for the communication process used by a clinical investigator to facilitate an individual’s educated choice about beginning or continuing participation in a clinical research study. Informed consent is an ongoing exchange of information between the study participant and the research team before the start of eligibility screening and throughout the duration of the clinical trial. As part of the informed consent process, a discussion of the study’s procedures, interventions, time investment, risks, benefits, purpose, costs, other treatment options, and the voluntary nature of participation must occur with the participant and, if required, a legally authorized representative.

The written contents of the informed consent form (ICF) are governed by Federal Regulations, and by institutional policies and guidance. The ICF and any required revisions to the original consent must be approved by the UCSF IRB or the IRB of record. The approved versions serve as a reference for monitoring and auditing the conduct of participant informed consent throughout the clinical trial.

An ICF must be signed by the participant, the person obtaining informed consent, and witness (if applicable) **BEFORE** any study specific procedures can be conducted in the clinical trial.

## Procedures

### 1.0 Responsibilities of the Key Study Personnel:

- 1.1 Participant Selection: Determine that a participant may be a candidate for a specific clinical research study.
- 1.2 Review and have the participant sign the California Experimental Subject’s Bill of Rights document.
- 1.3 Review the ICF and conduct the informed consent discussion:
  - 1.3.1 Discuss with the study participant the prospect of clinical trial participation, including: the purpose of the clinical trial, a general description of the study (including information about the investigational product), risks, possible benefits, expected outcomes of this study, alternatives to participation and the right to refuse to participate.
  - 1.3.2 Answer all questions to the participant’s satisfaction. Arrange for a follow-up discussion if unanswered questions remain.
- 1.4 Sign the HIPAA Authorization Form:
  - 1.4.1 After the ICF discussion, the investigator will ensure that the participant reviews and signs the HIPAA Authorization Form.

- 1.4.2 The participant must personally sign and date the HIPAA Authorization Form.
  - 1.4.3 The participant must initial all relevant options in section C and G of this document. If the participant does not consent to any of the options in section C and G, then the CRC should write a note at the top of the form indicating that all options were reviewed, and the participant decided to decline initialing these sections. The CRC should inform the PI if the participant does not consent to any option in section C or G so the PI can determine if eligibility, end point data collection or safety follow-up will be affected.
- 1.5 Sign the Informed Consent Form (ICF):
- 1.5.1 The participant will sign the consent to acknowledge that the study and its procedures have been presented in a manner they understand and that they wish to participate in the clinical research study.
  - 1.5.2 Then, the Investigator will sign as the person obtaining consent.
  - 1.5.3 If the participant cannot travel back to the clinic to sign the consent prior to starting screening procedures, then the participant may sign the consent while on the phone (or telehealth/video visit) with the Investigator, after the Investigator has answered any questions. The study team should follow the process below (remote consenting) to obtain a signed copy of all documents.
- 1.6 Document the Verbal Consent Process: Document the consent process in the study participant's medical chart in the format recommended in Appendix 2 of this policy.
- 1.7 Distribute copies of the signed California Experimental Subject's Bill of Rights, HIPAA Authorization Form and ICF.
- 1.7.1 Make one copy of all signed consent documents.
  - 1.7.2 Give the participant a signed copy of all consent documents to take home.
  - 1.7.3 Record the study participant's UCSF medical record number on the copies of the signed ICF, signed California Experimental Subject's Bill of Rights, and signed HIPAA authorization.
  - 1.7.4 File the original signed ICF, signed California Experimental Subject's Bill of Rights, and signed HIPAA authorization in the participant's research source document binder as determined by the unit.
  - 1.7.5 Upload a copy of the consent documents into APeX.
  - 1.7.6 Register participant into OnCore CTMS, along with ICF signing date and version date of ICF (and language, if applicable).

## 2.0 Remote Consent

In situations where the person obtaining informed consent and the study participant are unable to connect in person prior to any study procedures (including screening for eligibility), remote consent may be an option. The consent discussion should be conducted via secure UCSF

Zoom video visit so that the identity of the potential participant can be confirmed (see details below). UCSF Zoom is [HIPAA compliant](#).

- 2.1 The person obtaining consent should remind the potential participant that the informed consent discussion should occur in a private location to help ensure privacy and confidentiality. The study team should also advise participants against the use of public computers when signing the ICF, California Experimental Subject's Bill of Rights, and HIPAA forms electronically.
- 2.2 PDF versions of the ICF, California Experimental Subject's Bill of Rights, and HIPAA forms should be sent to the participant via email ahead of the scheduled consent visit so that the participant may review prior to the call/video visit.
- 2.3 The person conducting the consent process should confirm the identity of participant through government issued ID where possible (e.g., ask the potential study participant to hold up their ID up to screen to verify their identity). The person conducting the consent process should document how the potential participant's identity was verified in their consent documentation (Appendix 2). If the participant does not have government issued ID (or the consent discussion is done via phone instead of video), the use of study personnel generated security questions can also be considered e.g. ask the participant to confirm their date of birth. Note: Minimal risk studies do not need to have identity verified prior to obtaining informed consent.
  - 2.3.1 If UCSF Zoom video visit details i.e. date, time and hyperlink to join the consent visit are shared via MyChart, it is not necessary to require government issued ID to verify identity. Anyone with MyChart access has had their identity confirmed when MyChart access was [provided](#). Use of MyChart to confirm identity should be documented in the consent note (Appendix 2).
- 2.4 The consent process should follow the same process as described in Section 1.0.
- 2.5 At the end of the conversation, the person obtaining consent should confirm the best way to send digital copy of all documents for signature:
  - 2.5.1 FDA regulated studies: when using electronic signatures, the participant, the person conducting the consent process and the witness (where applicable) should sign all documents using a 21 CFR Part 11 compliant system (note: an FDA compliant version of DocuSign was made available to UCSF Investigators as of April 14, 2021). Alternatively, the participant can print all documents and follow the process for a wet-ink signature as described in Section 1.0. Instructions for using the FDA compliant version of DocuSign are available on the UCSF Information Technologies website: <https://it.ucsf.edu/how-to/signing-21-cfr-part-11-compliant-document-docusign>
  - 2.5.2 For all other studies, the best practice is to send the link to sign the documents using MyChart since MyChart requires the user to use a

secure username and password to access the system. If MyChart is not available, the participant should confirm the correct email address to use. If email is used, the ICF should be sent to the participant using secure email.

- 2.6 If the participant does not sign during a meeting with the investigator, once the participant signs all documents, best practice is for the person conducting the consent process to arrange for another video visit or telephone call to confirm that 1) the participant did in fact sign using their e-signature and 2) that the participant had no further questions. Once the follow-up discussion has occurred, the person conducting the consent discussion may sign the ICF.
- 2.7 Copies should be provided to the participant and filed in the research chart and medical record as detailed above. If a 21 CFR Part 11 compliant system is used for signature, copies of the signature certification should be downloaded and stored with the ICF.
- 2.8 If the consent discussion occurred in person, but the participant is unable to return to the clinic to wet ink sign the documents prior to the start of the study, Sections 2.4-2.6 may be followed above.

### 3.0 Re-consent for risk and ICF modifications

- 3.1 High Risk Adverse Events: For participant notification of new high-risk adverse events, the study team should follow the process as outlined in the [HDFCCC Policy for Verbal Notification of High-Risk Adverse Events](#).
- 3.2 ICF Modifications: If the ICF has been significantly modified and requires re-consent per the IRB, participants must be re-consented at the study participant's next scheduled visit. It is a reportable violation to the IRB for study participants to not be re-consented by their next visit for the trial. The procedures outlined in Section 1.0 should be followed for any re-consent discussions. Participants are not required to re-sign the HIPAA authorization and the Experimental Subject's Bill of Rights Document for the re-consent process.
- 3.3 For study participants in the survival follow-up phase of the trial, re-consent is not necessary unless mandated by the sponsor (for delayed risks) or the IRB.
- 3.4 Re-consenting participants on "renewed" ICFs that are updated from the annual Continuing Renewal process where only the IRB stamp has been updated is not required.
- 3.5 Reconsenting will not be required for minor changes to the ICFs that do not involve participant safety (i.e., pagination corrections, grammatical errors, etc.). Changes that do not affect study participants would not require re-consent (i.e., a study participant may have completed the part of the trial with the specific changes or was not enrolled in the arm of this trial that included these changes).

#### 4.0 Consenting Non-English Speaking Participants

Certified bilingual staff and clinicians can consent participants, but they cannot interpret for another clinician or staff member who does not speak the participant's language and is consenting the participant. The UCSF IRB has published guidelines for consenting non-English speaking participants. Appendix 3 summarizes the process to follow and the signatures to obtain.

UCSF faculty or staff may act as translators for the consent discussions if they are certified by the [UCSF Interpreting and Translation Services](#). Further details on how faculty or staff can be certified by UCSF Interpreting and Translation Services can be found in Appendix 4

## **Policy Exemptions**

None

## **References**

45 CFR 46

21 CFR 50

Federal HIPAA Privacy Rule (45 CFR 164)

UCSF HRPP website: [irb.ucsf.edu](http://irb.ucsf.edu)

[FDA Guidance Document: Use of Electronic Informed Consent \(December 2016\):  
https://www.fda.gov/media/116850/download](https://www.fda.gov/media/116850/download)

## **Appendices**

Appendix 1 – Pediatric Consenting Requirements

Appendix 2 - Document consent process in clinic chart


Appendix 3 - UCSF IRB Informed Consent for Non-English Speaking Participants

Appendix 4 – Process for Requesting Bilingual/Multilingual Certification



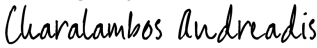
## Policy Approval

This policy document was approved by the following personnel on the following dates:

DocuSigned by:  
  
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Kate Shumate  
Chief of Staff  
Helen Diller Family Comprehensive Cancer Center

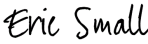
9/4/2023

Date

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## Appendix 1 – Pediatric Consenting Requirements

### REQUIRED DOCUMENTS

- California's Experimental Subject's Bill of Rights
- HIPAA Form
- Informed Consent Form (additional Assent or Youth Information Sheet, which depends on the IRB and child's age)

For pediatric participants ages 17 years or younger, the Experimental Subject's Bill of Rights (BOR) and HIPAA form will be signed by the participant's parent or legal guardian. Pediatric participants ages 18 and older will sign their own BOR and HIPAA forms.

### CENTRAL IRB (CIRB)

For studies under the CIRB, there is an ICF and starting, September 2019, an additional Youth Information Sheet (YIS) or an assent form.

- For newer studies, CIRB provides Youth Information Sheets for ages 7-13 and 14-17.
- For older studies, the HDFCCC Central Regulatory Team will create an assent for ages 7-13. Participants ages 14-17 will sign the participant line on the ICF to document assent.

Age	0-6 years old	7-13 years old	14-17 years old	18 years old
<b>Informed Consent</b>	- Parent (also initials*) - Person Obtaining Consent	- Parent (also initials*) - Person Obtaining Consent	- Participant ( <i>if there is no YIS</i> ) - Parent (also initials*) - Person Obtaining Consent	- Participant (also initials*) - Person Obtaining Consent
<b>Youth Information Sheet</b> ( <i>newer studies</i> )		- Person Obtaining Consent	- Person Obtaining Consent	
<b>Assent</b> ( <i>older studies</i> )		- Person Obtaining Consent ( <i>if there is no YIS</i> )		

\*Initials are for the optional procedure sections on the ICF

### UCSF IRB

For studies under the UCSF IRB, there are three types of consent forms available. The type of consent form or combination of consent forms that you will use is dependent on the participant's age. Please utilize the correct document and obtain the necessary signature(s) for each document.

Type of Consent	0-6 years old	7-12 years old	13-17 years old	18 years old
<b>Minor/ Parent ICF</b>	- Parent (also initials*) - Person Obtaining Consent	- Parent (also initials*) - Person Obtaining Consent		

<b>Separate Assent</b>		- Person Obtaining Consent		
<b>Adult/Adolescent ICF</b>			- Participant - Parent (also initials*) - Person Obtaining Consent	- Participant (also initials*) - Person Obtaining Consent

\*initials are for the optional procedure sections on the ICF

## Appendix 2 - Document consent process in clinic chart

*Suggested standardized consent process documentation which can be printed on UCSF clinic progress note.*

### **CLINICAL TRIAL NUMBER: (insert number)**

Informed consent was discussed for participation in the above referenced study with **(insert study participant's name)** who has voluntarily agreed to participate by signing the consent form document on **(insert date, mm/dd/yyyy)**. **<<If remote consent was used>>** Identification was confirmed by **(insert method to confirm identification)**.

The following points were discussed and must be yes:

- ☐ **Yes** ☐ **No** The UCSF Experimental Subject's Bill of Rights and HIPAA documents have been reviewed with the study participant/parent prior to signing the consent form. The California Experimental Subject's Bill of Rights document MUST be presented first and signed by the study participant/parent prior to signing the HIPAA document and the ICF.
- ☐ **Yes** ☐ **No** A signed copy of the ICF, HIPAA, and Bill of Rights documents have been given to the participant/guardian.
- ☐ **Yes** ☐ **No** Alternative treatment to the participant's disease in lieu of clinical trial participation has been discussed.
- ☐ **Yes** ☐ **No** Possible risks and possible side effects of participation in this clinical trial have been discussed.
- ☐ **Yes** ☐ **No** The participant/guardian has been given the opportunity to ask questions.
- ☐ **Yes** ☐ **No** The participant/guardian has acknowledged that his/her questions were satisfactorily answered.
- ☐ **Yes** ☐ **No** ☐ **N/A** The requirement for the use of birth control while participating in this clinical trial was discussed.
- ☐ **Yes** ☐ **N/A** A copy of the prohibited medication list has been provided to the participant/guardian. This list has been reviewed with the participant. The participant has been instructed to provide this list to any health care providers that may prescribe medication for the participant outside of this clinical trial.

Comments:

PRINT THE NAME OF PERSON OBTAINING CONSENT: \_\_\_\_\_

PI/Sub-Investigator's signature

Date signed

### Appendix 3 - UCSF IRB Informed Consent for Non-English Speaking Participants

**Background:** Non-English speaking participants are not allowed to sign the English version of the Experimental Subject's BOR, HIPAA and ICF. The person obtaining consent **must use** a translated BOR and HIPAA when consenting non-English speaking participants.

As per the UCSF IRB, if consenting:

- More than two non-English speaking participants who are fluent in the same language, it is required for investigators to consent using the preferred method. Therefore, a **translated ICF must be made available**.
- Only 1-2 non-English speaking participants who are fluent in the same language, then investigators may consent using the short form method.

**Please always obtain and document the interpreter's full name and license number each time a consenting/re-consenting process takes place.**

<b>Preferred Method</b> (Use this method when a translated ICF is available in the participant's native language)		
	<b>Participant</b>	<b>Person obtaining consent</b>
Translated BOR w/signature	x	
Translated HIPAA	x	
Translated ICF	x	x
Optional procedure initials	x	

<b>Short Form Method</b> (Use this method when using an English ICF)			
	<b>Participant</b>	<b>Person obtaining consent</b>	<b>Witness*</b>
Translated BOR w/signature	x		x
Translated HIPAA	x		
English ICF		x	x
Optional procedure initials		x	x

*\* The witness is signing to document that an oral presentation in a language the participant can understand took place. **For the BOR and the ICF**, the witness can be the interpreter or another adult (other than the person obtaining consent/family member) who witnesses the involvement of an interpreter. Ideally the witness should be impartial to the study, but may be the CRC or other study staff member if no one else is available. The witness may use the English version of the Experimental Subject's BOR as a reference document to ensure that the participant and the witness signs the translated version of this document correctly.*

#### **Appendix 4 – Process for Requesting Bilingual/Multilingual Certification**

1. Email [Bilingual@ucsf.edu](mailto:Bilingual@ucsf.edu) to request certification and indicate if you are a clinician (MD, NP, PA, Pharm D) or staff (all others from RN – Social Work, etc.).
2. UCSF Interpreting and Translation Services will send the appropriate Qualtrics Survey link via email.
3. Once the survey is complete, information is entered into the database for candidates who qualify for certification.
4. If available for the candidate's language(s), telephone language assessments are assigned.
5. The candidate receives an email from ALTA Language Services with instructions and an access code for the appropriate language assessment.
6. Upon completion of the language assessment, results are reported out to the candidate.
7. RETESTS are only allowed under the following circumstances:
  - a. Technical difficulty lead to an incomplete exam that cannot be scored (credit issued to UCSF).
  - b. An emergency interruption lead to an incomplete exam – PLEASE NOTIFY [BILINGUAL@UCSF.EDU](mailto:BILINGUAL@UCSF.EDU) IMMEDIATELY SO A CREDIT CAN BE REQUESTED BEFORE THE EXAM IS SCORED.
  - c. A marginal passing score is obtained on the clinician exam (75%-79%).
  - d. The candidate failed the test and has proof of 6-12 months of enhanced language learning or coursework.

Note: UCSF Interpreting and Translation Services will accept the ALTA test from another institution. If a UCSF faculty or staff were certified at one of the UCSF sister "Health" organizations (UCD, UCLA, UCI, UCSD), UCSF Interpreting and Translation Services would look at those on a case-by-case basis and confer with the manager of Interpreting Services at that institution to determine which test was used. If you have one of these certifications, provide the details in the initial request.

## Clinical Research Policy Revision Summary of Changes

**Policy Title:** Policy for Obtaining Informed Consent of Potential Participants for Oncology Research

**Version Date:** 08/30/2023

**Version Number:** Revision 10 (replaces version 9 dated June 6, 2022)

Section(s)	Summary of Change	Rationale
Scope	Replaced “Cooperative Group” with NCTN	Clarity and specificity
Definitions	Added Advanced Practice Providers to Key Study Personnel (KSP) and detailed requirements for Fellows on KSP	Make KSP inclusive of Physician’s Assistants, remove reference to another policy
Section 1.5.3	Added telehealth/video visit to remote consent visit options	Align with options in Section 2
Section 2	Re-numbered subsections	Additional subsection added (2.2)
Section 2.2	Added instructions to send documents in advance of consent discussion via email	Correction; MyChart does not allow attachments by all users
Section 2.3	Added options for identifying participant without a government issued ID or via phone	Provide identification method for all remote visit types
Appendix 1	Revised age ranges for CIRB consents	Correction to align with NCI CIRB SOPs
Appendix 3	Added witness impartiality recommendation and suggestion that English speakers use an English document as a guide when signing as a witness during short form consenting	To align with August 2023 FDA Informed Consent Guidance and UCSF IRB Short Form guidance

**Certificate Of Completion**

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Signatures: 3

Envelope Originator:

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Initials: 0

Andrea Skafel

AutoNav: Enabled

1855 Folsom St

Envelopeld Stamping: Disabled

Suite 601

Time Zone: (UTC-08:00) Pacific Time (US &amp; Canada)

San Francisco, CA 94103

andrea.skafel@ucsf.edu

IP Address: 128.218.42.177

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Location: DocuSign

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andrea.skafel@ucsf.edu

**Signer Events****Signature****Timestamp**

Eric Small

eric.small@ucsf.edu

Professor

University of California, San Francisco

Security Level: Email, Account Authentication (Optional)

DocuSigned by:



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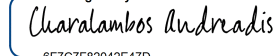
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University of California, San Francisco

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Katherine Shumate

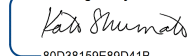
kate.shumate@ucsf.edu

Chief of Staff, Director of Administration

University of California, San Francisco

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Signature Adoption: Uploaded Signature Image

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**In Person Signer Events****Signature****Timestamp****Editor Delivery Events****Status****Timestamp****Agent Delivery Events****Status****Timestamp****Intermediary Delivery Events****Status****Timestamp****Certified Delivery Events****Status****Timestamp****Carbon Copy Events****Status****Timestamp**



Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
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Certified Delivered	Security Checked	9/4/2023 3:16:59 PM
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Payment Events	Status	Timestamps