**University of California, San Francisco**

**Helen Diller Family Comprehensive Cancer Center**

**[Policy Title – Arial 12pt bold]**

[Brief, but Broad Descriptor of Procedures Covered by Policy – Arial 11pt]

**Table of Contents (Arial 11pt bold)**

[Indicator of the page numbers for each section of the policy]

[Text – Arial 11 pt]

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# Purpose (Arial 11pt bold)

[Descriptor of why the policy is in place]

[Text – Arial 11 pt]

Scope **(Arial 11pt bold)**

[Descriptor of who or what function the policy applies to]

[Text – Arial 11 pt]

**Definitions (Arial 11 pt bold)**

[List of all words or phrases, and their associated definitions, included in the policy that may be ambiguous or uncommon in the daily work functions for all roles listed in the scope of the policy. Indicate ‘None’ if not applicable]

[*Word – Arial 11 pt italics*] [Definition – Arial 11 pt]

Background **(Arial 11 pt bold)**

[Descriptor of any background information that may help the reader understand what was done in the past or any regulations/guidance applicable to the topic covered by the policy (e.g., CCSG Guidelines)]

[Text – Arial 11 pt]

Procedures **(Arial 11 pt bold)**

[General descriptor of overall function]

[Text – Arial 11 pt]

## [Section/Item Header] (Arial 11 pt underline)

[Detailed content on specific topic]

[Text – Arial 11 pt]

## [Section/Item Header] (Arial 11 pt underline)

[Detailed content on specific topic]

[Text – Arial 11 pt]

## [Section/Item Header] (Arial 11 pt underline)

[Detailed content on specific topic]

[Text – Arial 11 pt]

Policy Exemptions **(Arial 11 pt bold)**

[General Descriptor of all alternate procedures. Indicate ‘None’ if not applicable]

[Text – Arial 11 pt]

References **(Arial 11 pt bold)**

[List all references – including hyperlinks if available – applicable to the content policy. Special consideration should be given to reference all applicable FDA, OHRP, CCSG and UCSF policies and regulations. Indicate ‘None’ if not applicable]

[Text – Arial 11 pt]

Appendices **(Arial 11 pt bold)**

[List all Appendices. Appendices should be numbered in order starting with ‘1’]

[Text – Arial 11 pt]

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Policy Approval **(Arial 11 pt bold)**

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<<Insert name and degrees>> Date

Deputy Director

Helen Diller Family Comprehensive Cancer Center

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<<Insert name and degrees>> Date

Director, Administration and Planning

Helen Diller Family Comprehensive Cancer Center

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[Name], Degrees Date

[Title]

Policy contact:

XXXX, title

Contact information

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Appendix 1 – Name **(Arial 11 pt bold)**

[Appendices should be numbered in order starting with ‘1’]

[Text – Arial 11 pt]

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**Clinical Research Policy Revision**

# Summary of Changes

Summary of changes must include high-level edits to the policy, the rational for change, and indicate the section of the policy where the edit can be found (see table below). High-level edits include additions or deletions of tasks and workflows; new references or regulations that are applicable to the policy; new forms or appendices; and any other relevant information that would change the reader’s ability to adhere to the policy. Administrative edits do not need to be included in the summary of changes but must be identified in the track-changes version.

A full track changes version of the policy (detailing all changes from one version to another) must be prepared by the Responsible Office and submitted to the Policy Coordinator. The Policy Coordinator will keep the track changes version in a shared file, and available for review if required.

|  |  |  |  |
| --- | --- | --- | --- |
| **Policy Title**: | |  | |
| **Version Date**: | |  | |
| **Version Number**: | |  | |
| **Section(s)** | **Summary of Change** | | **Rationale** | |
|  |  | |  | |
|  |  | |  | |

**<<REMOVE STYLE NOTES AND NOMENCLATURE FROM FINALIZED POLICIES>>**

Included as reference only

**Style Notes:**

* Dates: all dates are to be written in the MM/DD/YYYY format
* Footer updates are completed by the Author. During the review cycle, the draft version number should increase by ‘1’ and the date updated every time the Author makes updates and circulates for review and edits. Once finalized, the draft line should be removed and the phrase “Final Version” inserted with the version date. The Effective date should be within 30 days of the Final Version date. If the policy has been revised, ‘Revision #’ will replace the “Final Version” phrase. The revision # should increase by ‘1’ for each new version. The draft version line should be added back in while draft revisions are under review.

# Policy Nomenclature

The following words and phrases should be used in all HDFCCC clinical research polices and guidelines in order to standardize language and remove ambiguity or confusion.

|  |  |  |
| --- | --- | --- |
|  | Also Known As | Definition |
| Investigator Initiated Trial (IIT) | Investigator Sponsored Trial (IST); Investigator Sponsored Study (ISS); Institutional study | All clinical research studies where UCSF is considered the sponsor (i.e., owns the study data). |
| Participant | Patient, Subject | Women, men and children enrolled in clinical research. Studies often enroll people with a specific disorder, but some also accept 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. The HDFCCC use of “participant” matches the nomenclature used by the National Institutes of Health. |