UCSF Helen Diller Family Comprehensive Cancer Center

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

## Policy on Clinical Research Policies

Development, release, review and revision procedures for HDFCCC Clinical Research polices

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### Purpose

To establish policy management controls in the development, authoring, review, approval, distribution, storage and maintenance of new, revised and retired Helen Diller Family Comprehensive Cancer Center (HDFCCC) Clinical Research Policies.

### Scope

This policy applies to all staff and faculty developing and writing HDFCCC policies for the conduct of clinical research.

## Definitions

*Appendices* – Supplementary information which may be helpful to comply with the policy. Appendices may include, but are not limited to, procedure specific details, supplementary data or tables, reference materials.

*Author* – HDFCCC staff or faculty subject matter expert, who is assigned responsibility for development, ongoing documentation and maintenance of the policy. The policy author is assigned by Responsible Office.

*Guideline* – Written detailed instructions to capture and outline clinical research best practices and recommended workflows related to study activation, study coordination, study maintenance and study close-out.

*Policy* – A written statement of HDFCCC principles intended to define the parameters within which clinical research must be conducted at the HDFCCC. Polices are documented in a controlled manner.

*Policy Coordinator* – The assigned HDFCCC staff member who is responsible for ensuring compliance to the Policy on Clinical Research Policies. The Policy Coordinator is listed after the signatures at the end of this policy.

*Responsible Office* – The organizational unit within the HDFCCC Clinical Research infrastructure responsible for the workflows described by the policy. The HDFCCC organizational units consist of the: Clinical Research Network Office (CRNO), Clinical Research Support Office (CRSO), Data and Safety Monitoring Committee (DSMC) and Protocol Review and Monitoring System (PRMS). The Policy Coordinator will assign the Responsible Office. The Responsible Office contact information is stated after the signatory of each policy. Anyone can contact the Responsible Office to ask questions or clarifications about the policy. The Responsible Office is obligated to keep the policy up to date.

*Subject matter expert* – The HDFCCC staff or faculty who has expertise in the process being described in the policy.

## Background

Any HDFCCC clinical research staff or faculty may identify the need for new, revised or discontinuation of existing policies or guidelines. The HDFCCC staff or faculty identifying the need will contact the Policy Coordinator, who will then assign a Responsible Office to author the new policy. If a policy already exists, the Responsible Office will revise the existing policy as appropriate.

HDFCCC policies do not negate the laws and regulations governing clinical research. If there is a discrepancy, the law or regulation [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP)] must be followed. HDFCCC policies also do not negate UCSF-wide policies [e.g., Institutional Review Board (IRB)] unless specifically noted and stakeholders of the conflicting policies are in agreement.

The verbs “will”, “must” or “shall” denote policy requirements. The verb “should” denotes policy elements that are strongly recommended, but not required.

All clinical research policies will be signed by the following HDFCCC Leadership roles:

- Deputy Director, Helen Diller Family Comprehensive Cancer Center
- Director, Administration and Planning, Helen Diller Family Comprehensive Cancer Center
- Faculty Lead, Responsible Office
- Additional signatories may be added on an ad hoc, policy-dependent, basis

**Procedures**

1.0 New Clinical Research Policies

The Author will use the HDFCCC template (Policy Template and Style Guide form) and will follow the indicated format and style guide to draft the clinical research policy. Once a final draft is complete, the Author will forward the draft to the following reviewers: 1) other subject matter experts; 2) other applicable offices/departments at UCSF who may have insight into the process described; and 3) all staff and faculty leaders for all responsible offices.

Upon receipt of comments, the Author will make the appropriate changes and issue the revised draft to the reviewers as a means of communication of the changes made. The review and comment process described above will be repeated until the Author is satisfied with the final draft.

Once the final draft is complete, the Author will forward the final draft to all signatories for final review and comments. The Author will incorporate all feedback received and finalize the policy. Once finalized, the author will update the footer with a final date, identify an effective date (no later than 30 days after the date the policy is finalized) and send the policy for signature.

Any forms associated with the policy should be dated contemporaneously and reference the associated policy title in the footer. The fully executed policy and associated forms (if applicable) will be posted on the HDFCCC website. The Author will notify the Policy Coordinator and all applicable HDFCCC clinical research staff and faculty of the new policy. The policy release communication should indicate the effective date, a high-level summary of the policy and any training that is required.

The Policy Coordinator will update the master list of all clinical research policies with the new policy.

2.0 Clinical Research Policy Amendments

When the need for a policy amendment is identified, the Author will ensure the policy is on the current HDFCCC clinical research policy template. The Author will make the appropriate updates and send the draft for review as per the review process noted in section 1.0. The summary of changes will be documented at the end of the policy.

Once finalized, the Author will release as per the process noted in section 1.0. All associated forms should be reviewed and updated as appropriate.

All previous versions of the policy, and applicable forms, will be removed from the HDFCCC website. The Policy Coordinator will update the master list of all clinical research policies.

## 3.0 Retired Clinical Research Policies

All HDFCCC clinical research polices remain in effect, no matter when written or last updated, as long as they are posted on the official HDFCCC website.

Any clinical research policy that is no longer relevant, or superseded by a UCSF-wide policy, can be retired. Once identified for possible retirement, the Policy Coordinator should share the current version and the rationale for retirement with all signatories and leadership in the Responsible Offices. If all parties agree, the Policy Coordinator will remove the retired policy from the HDFCCC website, place a "Retired" watermark on it, add the retired date to the footer, and file in the Archives.

The Policy Coordinator will notify the appropriate staff and faculty that the policy is retired and will indicate the effective date, the rationale for retiring, and the alternative policy (if applicable). The Policy Coordinator will update the master list of all clinical research policies with the retired policy.

All retired clinical research policies are available for audit or inspection by contacting the Policy Coordinator.

## 4.0 HDFCCC Website

The HDFCCC website is the primary source of all HDFCCC clinical research policies. The HDFCCC website will list all clinical research policies and their current version date. The clinical research policy will have a hyperlink to the fully executed final clinical research policy. Any policy not available on the HDFCCC website should be considered retired.

## 5.0 Review of Clinical Research Polices

All clinical research policies will be reviewed every 3 years (based on effective date). The Policy Coordinator will review effective dates quarterly to determine if policies are coming up for review and notify the Responsible Office. The review process should start at least 3 months before the due date (i.e. 3 years after the effective date).

If, after review of the policy, changes are required, the Author will follow the review and approval steps detailed in section 1.0.

If no changes are required to the policy, then the Responsible Office will update the version date in the footer, note that no changes are required in the summary of changes, and send to all signatories. The version number will not be modified. The fully executed version will be updated on the HDFCCC website and the previous version will be removed and archived.

The Policy Coordinator will update the master list of all clinical research policies with this revised policy version (if applicable) and version date.

## Policy Exemptions

HDFCCC Guidelines are managed by the Data and Safety Monitoring Committee Office of Education and Training. For more information, please contact DSMC Education and Training Manager.

Note: there was no policy in effect for archiving and retiring previous clinical research policies prior to the effective date of the Final Version of this policy. Previous versions of any HDFCCC clinical research policy prior to the effective date may not be available for review during an audit or inspection. Contact the Policy Coordinator for a list of available archived or retired policies.

## References

None

## Appendices

None

**Policy Approval**

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

DocuSigned by:
Eric Small
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10/6/2021

Eric Small, MD
Deputy Director
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Date

DocuSigned by:
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10/7/2021

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