



ACTC Policy on Maintaining Confidentiality

1.0 Overview

This policy guides the maintenance of confidentiality in the conduct of the Alzheimer's Clinical Trials Consortium (ACTC) infrastructure and project work, across all participating institutions. It is critical that confidential information is adequately protected during each of the stages of project development and conduct. Confidential information may include details regarding investigational product (IP), study design, safety findings, study progress information, study data and results. Confidential information may include processes and procedures, such as those used to randomize participants or to monitor participant safety. In the conduct of ACTC infrastructure work, confidential information includes the results from Steering Committee Voting, any non-anonymous Survey results, as well as personal information about ACTC members' financial relationships.

The purpose of this policy is to facilitate effective collaboration, while maintaining the necessary confidentiality of proprietary information for collaborators and partnering pharmaceutical companies.

ACTC members will treat information provided in ACTC Meetings, communications, and processes as confidential unless and until the information is made public (for example a scientific meeting or publication).

2.0 Policy

Agreement

This Policy will be distributed annually to ACTC Members, and members will be asked to sign agreement to follow this policy. In addition, prior to attending an in-person meeting, ACTC members will sign a participation agreement to maintain confidentiality.

"I agree to hold in confidence materials I have access to, whether presented or disclosed, orally, electronically, visually or in writing, as part of my participation in the Alzheimer's Clinical Trials Consortium (ACTC). I agree not to distribute, use or disclose this information outside of ACTC settings beyond its intended purpose."

Labeling

It is recommended that confidential documents be labeled as such, however, all materials should be considered confidential unless made public.

Presentation

ACTC Meetings are closed and by invitation only. When signing in for ACTC Meetings, attendees will confirm agreement to maintain confidentiality of presented information. When feasible, webinars will include password entry.

All materials presented at meetings should be assumed to be confidential. Presenters may elect to label materials as confidential.

No video recordings will be taken during presentations. Photos that include speakers and slides will be reviewed prior to sharing to confirm no confidential information is included.

Distribution

When appropriate, confidential materials will be redacted, removing sensitive information prior to being shared electronically. When necessary to distribute confidential materials by email or download link, it is recommended that the individual responsible for distribution utilize a password sent in a separate message and specify in the email text which material is confidential (i.e. name of document).

Archival

Confidential information will be archived in a secure location at the ACTC Coordinating Center and will be accessible to a minimum number of users.

3.0 Reference Documents

4.0 Definitions

ACTC: Alzheimer's Clinical Trial Consortium

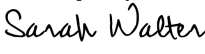
ACTC Consortium Member: Persons doing the work of ACTC Committees or Units, project leaders, investigator, DSMB member.

ACTC Infrastructure Work: Tasks completed in the set up and running of the consortium, including committees, task forces, and working groups.

ACTC Project work: work in development or implementation of an ACTC study (developed by ACTC consortium and funded through the ACTC RO1 mechanism) or a study affiliated with ACTC (utilizing one or more aspects of ACTC infrastructure).

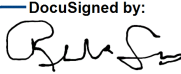

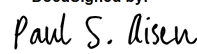
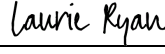
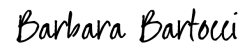
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Author:

Name	ACTC Role	Signature	Date
Sarah Walter	Program Administrator	DocuSigned by:  <small>776C14F8A4EA499...</small>	April 25, 2019 14:07:28 PDT

As a publicly-funded consortium, all ACTC Policies are public documents. Current versions are maintained centrally by the ACTC Program Administrator. Copies of this controlled document are not considered controlled.

Reviewed and Approved by:

Name	ACTC Role	Signature	Date
Reisa Sperling, MD	ACTC Co-PI	DocuSigned by:  <small>C3BC3CA148AB4F6...</small>	April 25, 2019 14:19:47 PDT
Ron Petersen, MD, PhD	ACTC Co-PI	DocuSigned by:  <small>ECFA43AD8EAF4B7...</small>	April 26, 2019 11:21:34 PDT
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Barbara Bartocci	ACTC Quality Assurance Lead (Administration Unit)	DocuSigned by:  <small>1453C18E35A9407...</small>	April 26, 2019 11:27:10 PDT

Revision History:

Number	Version Date	Revision Summary
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