ACTC Policy on Data, Image, and Biospecimen Sharing

1.0 Overview

This policy defines the guidelines for responsibly sharing data, images and biospecimens from any project conducted or managed by the Alzheimer's Clinical Trials Consortium (ACTC) and applies to all personnel responsible for the conduct of the project. The primary goal of this policy is to make available project research data, images and biospecimens from ACTC clinical trials to the scientific community in a timely manner, while safeguarding the safety and privacy of trial participants and protecting confidential and proprietary data.

Each ACTC project will have a plan for data, image and biospecimen sharing that will align with this policy. Biospecimens include tissue collected postmortem, when applicable for a given project. The plan for each project will follow the Collaboration for Alzheimer's Prevention (CAP) principles and the requirements stated in the National Institutes on Aging (NIA) ACTC Request for Applications (RFA), as well as NIH data sharing policy.

Data, images and biospecimens will be shared at two time-points for each project:

1. Pre-randomization data, images and biospecimens will be shared within twelve (12) months of the final participant randomization.
2. Project data, images and biospecimens will be shared with the scientific community after the earlier of either regulatory approval of the tested treatment, at time of publication of top line results, or nine (9) months after the completion or early termination of the trial.

Consent forms for ACTC projects will include allowances for broad data, image and biospecimen sharing as described in this policy. Contracts and agreements to collaborate with any investigator, commercial or non-commercial entity/entities must be in accordance with this policy.

Project budgets will include adequate resources to support the effort required by the ACTC Units and participating sites for the sharing of data, image, and biospecimens.

As stated in the CAP Publication, the first priority for biospecimen use are to satisfy the goals/endpoints of the project, and ACTC investigators will ensure appropriate retention of biospecimens in sufficient quantities for analyses during ongoing trials. Specimens will also be banked for confirmatory testing after trial completion and to advance ACTC Biomarker Unit aims and sponsor/collaborator aims. Residual biospecimens will be reserved for sharing under independent oversight by the Biospecimen Allocation Review Committee (BARC).

ACTC will track all data, image and biospecimen requests and projects and report to NIA on a regular basis.

2.0 Policy

At the start of each project, plans will be developed for data, images and biospecimen sharing. Approvers of the sharing plan(s) must at minimum include ACTC Leadership and the Project PIs, a representative of the regulatory sponsor (if applicable) and any appropriate Unit Directors.

Sharing plans will include at a minimum:

1. Which data and images are to be shared or not shared, with timepoints

2. Procedures for de-identifying data, images, and biospecimens (where needed)
3. Delineation of tiers of data and images, so that access can be restricted based on the inclusion of potential identifiers in data to be shared
4. Quantities of biospecimens to be allocated for study and ACTC aims and for sharing
5. Study documents to be provided with data, images and biospecimens
6. Requirements for requesters to provide an annual update on their use of project data, or to submit manuscripts for review
7. Data Use Agreement (DUA) and Biospecimen Sharing Agreement (BSA) terms

Data, image and biospecimen requestors must acknowledge the ACTC investigators, ACTC Units, and the NIA as the project sponsor with relevant grant numbers on all publications (manuscripts, abstracts), presentations and press releases that result from the use of the data, the images and/or biospecimens.

3.0 Reference Documents

- ACTC Policy for Affiliated Studies
- ACTC Policy on Maintaining Confidentiality
- ACTC Policy on Publications
- Biospecimen Allocation Resource Committee (BARC) Charter
- 45 CFR 155.260 – Privacy and security of personally identifiable information
  45 CFR 164.501 – DHHS Definitions
  45 CFR 164.508 – Uses and disclosures for which an authorization is required
  45 CFR 164.512(I) – Uses and disclosures for which an authorization or opportunity to agree or object is not required
- ACTC Request for Project Applications PAR-18-513: https://grants.nih.gov/grants/guide/pa-files/par-18-513.html
- Guidance Regarding Methods for De- identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (November 12, 2012) - http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf
- Collaboration for Alzheimer's Prevention (CAP) Guideline Publication: Weninger S, Carrillo MC, Dunn B, Aisen PS, Bateman RJ, Kotz JD, Langbaum JB, Mills SL, Reiman EM, Sperling R, Santacruz AM, Tariot PN, Welsh-Bohmer KA. Collaboration for Alzheimer's Prevention: Principles to guide data and sample sharing in preclinical Alzheimer's disease trials. *Alzheimers Dement*. 2016 May;12(5):631-2. doi: 10.1016/j.jalz.2016.04.001. PMID: 27157073; PMCID: PMC5111162.
- Garrett, Elizabeth, and Todd R Dickey. "HIPAA Privacy Rule RES-301: Uses and Disclosures of Protected Health Information for Research Purposes." *University of Southern California POLICY*, University of Southern California, 15 July 2014, policy.usc.edu/files/2014/02/RES-301-Uses-and-Disclosures-of-Protected-Health-Information-for-Research-Purposes.pdf.
- "Data Use Agreement." *Data Use Agreement*, USC Office of Compliance, Mar. 2015, policy.usc.edu/files/2014/07/Data-Use-Agreement.doc.
- NIH Data Sharing Policy and Implementation Guidance: https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#rest

4.0 Definitions

- **ACTC**
  Alzheimer's Clinical Trials Consortium
- **ACTC Project**
  Any study conducted by ACTC, including all clinical trials
- **Biospecimen**
  A sample of material, such as urine, blood products, tissue, cells, DNA, RNA collected from participants as part of clinical trial procedures
- **BARC**
  Biospecimen Allocation Resource Committee
- **Research Data**
  Recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law

(e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

- **De-identification**
  Removal of personally identifying information in order to protect personal privacy. Under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, data is considered de-identified when the 18 types identifiers are removed.
- **DUA**
  Data Use Agreement
- **BSA**
  Biospecimen Sharing Agreement

Document ID	Version Number	Effective Date	Review Date
ACTC-POL-009	v1.1	25Aug2022	25Aug2024

Author:

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Sarah Walter	Program Administrator	DocuSigned by: Sarah Walter 776C14F8A4EA499...	July 6, 2022 | 11:55:58 PDT

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Revision History:

Number	Version Date	Revision Summary
v1.0	20200408	Original
v1.1	20220705	No changes