# Adult Changes in Thought (ACT) Research Program

# Data Request and Manuscript Proposal Form

**Instructions:**

Please first review the [ACT Proposals & Publications (P&P) Committee Policies and Procedures](https://actagingresearch.org/download_file/6fd2dc9e-d337-4301-9d72-86d1b1fc6eb0/9).

Then complete this form to:

1) request data for a new manuscript proposal or other scholarly work, or

2) obtain data for another purpose (e.g., harmonization efforts, feasibility studies or preparatory research that cannot be accomplished with the [ACT Data Query Tool](https://actagingresearch.org/resources/data-query-tool)), or

3) request to use previously obtained data for a new manuscript or other scholarly work

Send completed form to kpwa.actproposals@kp.org. Incomplete forms will be returned to the proposal leader for revision.

Requests are considered by the ACT P&P Committee at monthly meetings following a [schedule](https://actagingresearch.org/collaboration/p-p_committee).

If approved, the requested data may be used **only** for the purposes described in this form. Additional or modified uses either require a new or updated proposal form.

Please **do not** use this form if you:

* have a final draft manuscript or abstract resulting from a previously approved proposal that is now ready for P&P Committee review. Instead please complete either the [Manuscript](https://actagingresearch.org/download_file/view/5e8cba59-43ce-4391-b51e-7c1e6091e015/322)or[Abstract](https://actagingresearch.org/download_file/view/71ac7470-1714-410d-8cd6-b96174b60364/322) Submission Checklist. Then send the completed checklist and final draft manuscript or abstract to kpwa.actproposals@kp.org.
* are proposing a new study to be supported by a grant other than the ACT U19. Instead, complete and submit an [Ancillary Study Application](https://actagingresearch.org/download_file/view/23721ec6-297a-4615-90f5-4af3754a3638/322)**.**

# Section One: Project Title and Information about Collaborators

**1.1 Project title and lead collaborator**

|  |  |
| --- | --- |
| Date proposal submitted to ACT: |   |
| Project title:  |  |
| Short title (5 words or fewer): |  |
| Project leader name: |  |
| Project leader affiliation / organization: |  |
| Project leader address: |  |
| Project leader e-mail address: |  |
| Project leader phone number: |  |
| Is project leader a student? [ ]  Yes [ ]  No  | If **yes**, provide mentor’s name, affiliation, and email address: |
| Is project leader an ACT researcher\*? [ ]  Yes [ ]  No  | If **no**, provide the name of the ACT researcher with whom you have consulted for this proposal (required): |

\* An ACT researcher is defined as someone who receives funding from the ACT U19 grant or one of its subcontracts. The ACT website includes [a list of ACT researchers](https://actagingresearch.org/about/meet-our-researchers). If you are not an ACT researcher or already working with one on this proposal, ACT requires you to reach out to one for consultation on your proposal **prior to submission**.

**Please list all collaborators (add additional rows if necessary)**

|  |  |  |
| --- | --- | --- |
| **Name** |  **Affiliation**  | **E-mail Address** |
|  |  |  |
|  |  |  |
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|  |  |  |

**1.2 Lead Collaborator Attestations**

*Please check the box and enter your initials on the line below to complete the attestations.*

As the lead researcher of this proposal, I attest that:

[ ]  I have consulted with an ACT researcher in the preparation of this proposal. **Initials: \_\_\_\_\_\_\_\_\_\_\_\_**

[ ]  All listed collaborators have had adequate opportunity to review this proposal and endorse its submission for review by the ACT Proposals & Publications Committee. **Initials: \_\_\_\_\_\_\_\_\_\_\_\_**

[ ]  I have reviewed the ACT [Collaborative Research Attestation and Data Use Agreement](https://actagingresearch.org/download_file/604cc38f-ddf0-4649-a608-c7e6ec2ee191/9) which are required to be signed and executed to conduct this research. **Initials: \_\_\_\_\_\_\_\_\_\_\_\_**

[ ]  If I am a student, my mentor is listed as a collaborator and has reviewed and endorsed this proposal. **Initials: \_\_\_\_\_\_\_\_\_\_\_\_**

# Section Two: General information regarding the request

**2.1 What is the purpose of this request?** (Check all that apply):

|  |  |
| --- | --- |
| [ ]  | Use data to support a new manuscript Please list at least 3 Key Words for this manuscript:  |
| [ ]  | Use data to support a new scholarly workPlease briefly describe the type of scholarly work planned (e.g., conference workshop, lecture, etc.) and list at least 3 Key Words for this scholarly work:  |
| [ ]  | Use data to assess feasibility of, or prepare for a study  |
| [ ]  | Other, please describe:  |

**2.2 Are there any deadlines associated with this request?**

[ ]  Yes -> Please specify date and type of deadline: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  No

**2.3 How did you hear about the ACT study and determine that its data would be a good fit for your project?**

[ ] Previous work with ACT

[ ]  Alzheimer’s Disease Genetics Consortium (ADGC)

[ ] Introduction by ACT researchers (conference talk, publication, personal contact, etc.)

[ ] ACT Study website

[ ]  Federal repository (dbGaP, NIAGADs, etc.)

[ ]  Allen Institute website

[ ] Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2.4 If needed, do you currently have funding to support ACT study staff work on this project?**

This includes funding for programming, assistance with analyses, and/or preparation of lab samples. Funding has no bearing on whether your proposal is approved.

|  |  |
| --- | --- |
| [ ]  | **Yes**, I currently have sources of funding to pay for ACT work (please state all sources):Source: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Start & end dates (month/yr - month/yr) ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| [ ]  | **No**, I do not currently have any sources of funding. |
| [ ]  | **Other** (e.g., planned grant application): |

**2.5 Is this request associated with one or more of ACT’s ongoing U19 Projects or Cores, affiliated grants, or a prior approved proposal?**

 [ ] [ ]  Yes à Please complete item 2.6

[ ]  No à Please skip to item 2.7

**2.6 Please indicate which ACT U19 Project, Core, ACT-affiliated project, or prior approved proposal with which this proposal is associated.**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | ACT U19 Project 1: Physical activity, sedentary behavior, and sleep | [ ]  | ACT U19Admin Core  |
| [ ]  | ACT U19Project 2: Cognitively defined subgroups | [ ]  | ACT U19Clinical Core |
| [ ]  | ACT U19Project 3: Translational pharmacoepidemiology | [ ]  | ACT U19Data & Analysis Core |
| [ ]  | ACT – EYE | [ ]  | ACT U19Life Course Core |
| [ ]  | ACT - AIR (Imaging Records) | [ ]  | ACT U19Neuropathology Core |
| [ ]  | Alzheimer’s Disease Genetics Consortium Special Analysis Group (SAG) | [ ]  | ACT U19Neuroimaging Core |
| [ ]  | Other grant, please specify: | [ ]  | Previously approved proposal, please specify assigned number and title: |

**2.7 IRB approval and waiver of consent are required if this use is not covered by the ACT consent form and an already approved IRB application.**To the best of your knowledge, do you believe that the proposed work would be covered by:

**[ ]** Current ACT IRB Approval, please specify application #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[ ]**  Other IRB Approval, please complete box below:

|  |  |
| --- | --- |
| IRB application #:  | IRB Application Title:  |
| Approval Date: | Name of Reviewing IRB: |

# Section Three: Description of research study

**3.1 Please describe your proposed manuscript, or other request below.**

**3.1.1 Abstract (30 lines of text)**

**3.1.2 Specific Aims, Research Questions or Hypotheses (or Objectives if a feasibility study/preparatory research) (~250 words)**

**3.1.3 Descriptions of the following (skip the remainder of Section 3 for a feasibility study/preparatory research):**

|  |  |
| --- | --- |
| Inclusion/exclusion criteria |  |
| Sample size (anticipated) |  |
| Exposure(s) of interest |  |
| Outcome(s) of interest |  |
| Covariate(s) |  |
| Brief planned statistical approach (100-200 words) |

**3.1.4 Main results mock tables**

**3.1.5** **References (3-5 key references)**

**Note: If you have a previously approved grant proposal associated with this scholarly work, you may attach it for reference, but please also summarize the relevant information in this form.**

# Section Four: Data Specifics

**Please use the available ACT Study** [**data documentation resources**](https://actagingresearch.org/resources/act-data-repository) **on the ACT Study website to complete this section to the best of your ability. Once the proposal is approved, an ACT representative will work with you to finalize the specifications for your dataset.**

**4.1 Which categories of data will be associated with this request?** Check all that apply*.*

(External researchers: Please work with your internal ACT collaborator to identify needed data.)

|  |  |
| --- | --- |
| [ ]  | **ACT research study visit** **data**  |
| [ ]  | **Life Course** **data**: (select all that apply) [ ]  Life Course survey data [ ]  geospatially-based data  |
| [ ]  | **Electronic health record & utilization data** |
| [ ]  | **Medical record abstraction data** (currently only available on autopsy population) |
| [ ]  | **Neuropathology data**  |
| [ ]  | **Neuroimaging data:** [ ]  [ ]  Scored/derived data [ ]  Raw MRI scan\* |
| [ ]  | **Activity monitoring device (accelerometry) data**: (select all that apply) [ ]  ActivPAL [ ]  ActiGraph [ ]  Actiwatch (sleep)  |
| [ ]  | **Genetic data**\*: (select all that apply) [ ]  APOE [ ]  Genome wide SNP data [ ]  Other genetic data: Please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  | **Biospecimens\*\***: (select all that apply) **[ ]** Blood or blood product [ ]  [ ]  DNA [ ]  [ ]  Plasma [ ]  [ ]  Neuropathology tissue samples. Please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Note:** To request tissue samples to link with ACT data, you must **also** complete and submit the [UW Neuropathology Core Resource Request Form](https://docs.google.com/forms/d/1ht1VDvhYjqDgOT11t8otpO0w6xTIZX-PV7dGq6OcEBo/viewform?edit_requested=true) |
| [ ]  | **ACT curated dataset** at ADGC available for approved SAG proposals |
| [ ]  | **Other** **repository data** (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

\*Requires IRB review at recipient institution.

\*\*Requires IRB review at recipient institution and a material transfer agreement.

**4.2 What type of data set are you requesting?**Please select only one category below.

|  |  |
| --- | --- |
| [ ]  | **Aggregate data** (grouped data: no individual-level data included) |
| [ ]  | **De-identified individual level data**: Data set contains no Protected Health Information (PHI), i.e., no dates, zip codes, or specific ages >89 |
| [ ]  | **Limited dataset**\***:** De-identified individual level data with the following PHI (specify below): [ ]  Dates [ ]  Specific age >89 years [ ]  Zip codes (*generally not released without adequate justification and confidentiality protections)* |
| [ ]  | **No additional data are needed.** This request is for a manuscript or scholarly work using data received for a previously approved data request, project, or core, and does not require a new data set.**Previous Proposal Number: \_\_\_\_\_\_\_**The dataset being used for this purpose is: [ ]  Aggregate [ ]  De-identified [ ]  Limited**If no additional data are needed and there are no changes to the remainder of items in Section Four, please skip items 4.3-4.8.**  |
| **Please check if either of the following are true:**  |
| [ ]  | We propose to link the above indicated dataset to data obtained from a private source (such as an affiliated ACT grant or previously approved proposal). \*Please be prepared to share a list of any participant/study IDs you have already obtained once the proposal is approved.  |
| [ ]  | We propose to link the above indicated dataset to data obtained from a public source (such as eMERGE, dbGAP, ADGC, NCRAD, Allen Institute Brain Atlas, etc.) \*Please be prepared to share a list of any participant/study IDs you have already obtained once the proposal is approved.  |

**\*** A “Limited Dataset” as defined under the Health Insurance Portability and Accountability Act (HIPAA) may contain the listed types of PHI. If you are requesting a limited dataset, a Data Use Agreement is required and additional time may be required to meet the data request.

**4.3 Please indicate what data structure is needed** using information about [the ACT Cohort](https://actagingresearch.org/resources/act-cohort)

[ ]  Participant level (each record, or row, represents all data for one participant)

[ ]  Visit level (each record, or row, represents all data from a single visit for one participant)

[ ]  Unsure

**4.4 Which visits should the dataset include:**

[ ]   Baseline

[ ]   Most recent biennial follow-up visit

[ ]   All biennial visits

[ ]   Subset of biennial visits: please describe:

[ ]   Cognitive referral visit(s)

[ ]   Annual visit data

[ ]   Other structure for visits or data, please describe:

**4.5 What group of participants should be included:**

[ ]   All participants from all cohorts

[ ]   Subset of participants (please describe):

**4.6 Please list all requested data variables available from the standard ACT data freeze (e.g., variables from participant study visits, standard neuropathology derived variables, etc.) in the table below.** Please refer to information about the [ACT Data Repository](https://actagingresearch.org/resources/act-data-repository) on the ACT Study website to create the list, adding additional rows if needed or attaching an Excel file.

|  |
| --- |
| **Variable Name**  |
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**4.7 Please list any requested data variables that do not arise from standard ACT freeze datasets using the table below.** Variables here would require special curation or derivation beyond standardly available variables from sources such as ICD codes from the Electronic Health Records or the ACT chart abstraction project.

|  |  |
| --- | --- |
| **Variable Description** | **Variable Source** |
|  |  |
|  |  |
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**4.8 Data security status of the proposal lead collaborator:** Please select one of the following:

|  |  |
| --- | --- |
|  [ ]   | ACT researcher within KP |
| [ ]  | ACT researcher external to KP, funded by ACT U19 (Data Use Agreement not required if proposal is related to U19) |
| [ ]  | ACT researcher external to KP, not funded by ACT U19 (Data Use Agreement may be required/existing Data Use Agreement may need to be amended.) |
| [ ]  | Non - ACT researcher within KP |
| [ ]  | Non – ACT researcher external to KP (Data Use Agreement may be required/existing Data Use Agreement may need to be amended.) |

**4.8.1 Please explain how you will store and protect ACT data from unauthorized access:**

**4.8.2 Data security for other collaborators who will have access to the dataset:** Select all that apply.

|  |  |
| --- | --- |
| [ ]  | No other collaborators will have access to the dataset.  |
| [ ]  | My collaborator is a KP researcher, and the dataset will remain behind the KP firewall.Collaborator name(s):  |
| [ ]  | My collaborator is an ACT researcher external to KP, funded by the ACT U19. (Data Use Agreement not required)Collaborator name(s): |
| [ ]  | My collaborator is an ACT researcher external to KP, not funded by the ACT U19 and/or does not have an existing DUA with ACT for the requested data. (Data Use Agreement may be required.)Collaborator name(s):Please explain how this collaborator will store and protect ACT data from unauthorized access: |
| [ ]  | My collaborator is an ACT researcher external to KP and has an existing DUA that may need to be amended. Collaborator name(s):Please explain how this collaborator will store and protect ACT data from unauthorized access: |

*Thank you for your data request. We will be in touch once the ACT review process is complete. If approved, you will be provided a Collaborative Research Attestation to sign and notified whether a Data Use Agreement is required.*