# Adult Changes in Thought (ACT) Research Program

# Ancillary Study Application

**Instructions:**

Researchers should use this application to propose an ancillary study to be supported by a grant that will:

* conduct a new analysis of existing ACT data,
* curate new data sources, such as new measures from medical records, that have not been previously used in the ACT cohort, or
* collect new data from ACT participants

Please review the [Ancillary Studies Policy](https://actagingresearch.org/download_file/view/2bbf696e-90ee-4eaa-b429-0d60cc32e742/308) before completing this application.

Complete **Part I** of this application and submit for concept review by the ACT Admin Core.

Researchers will be notified of proposal concept approval and then should complete **Part II** of this application in advance of a presentation to and full proposal review by the Ancillary Study Review Committee (ASRC).

Note: Please answer all applicable items directly in the form itself rather than referring to an attachment, unless explicitly requested. Incomplete forms will be returned to the researcher for revision.

Submit completed forms to kpwa.actproposals@kp.org. If you are external to ACT, please also copy your ACT collaborator on your submission email.

## Part I: Proposal Concept

# Section One: Project Title and Contact Information

**1.1 Project type, title, leader and collaborators**

What type of Ancillary Study are you proposing? (Refer to the [Ancillary Studies Policy](https://actagingresearch.org/download_file/view/2bbf696e-90ee-4eaa-b429-0d60cc32e742/308) for definitions)

[ ]  Type 1 (Secondary analysis of existing ACT data)

[ ]  Type 2 (Use of biospecimens, raw scan data, or new EHR data fields)

[ ]  Type 3 (Collection of new data from ACT participants)

|  |  |
| --- | --- |
| 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**, please provide mentor’s name, affiliation, and email address: |
| Is project leader an ACT researcher\*? [ ]  Yes [ ]  No  | If **no**, please provide the name of the ACT researcher with whom you have consulted for this proposal (required): |
| If **Type 2 or 3** indicated above and the project lead and/or ACT collaborator are not located at KPWHRI, please provide the name and email of your KPWHRI PI (site PI) below: |

\* 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 boxes 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: \_\_\_\_\_\_\_\_\_**

[ ]  If a Type 2 or 3 Ancillary Study, I have identified a KPWHRI site PI who is available and willing to serve if the grant is funded. **Initials: \_\_\_\_\_\_\_\_\_\_**

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

[ ]  I have reviewed the [ACT Collaborative Research Attestation & Data Use Agreement](https://actagingresearch.org/download_file/604cc38f-ddf0-4649-a608-c7e6ec2ee191/9) (if external to KPWHRI) 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: \_\_\_\_\_\_\_\_\_\_\_\_**

**1.3 Is this request associated with one or more of ACT’s U19 Projects or Cores, affiliated grants, or prior approved proposals?**

[ ] [ ]  Yes, please specify which one(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  No

**1.4 For external researchers only: How did you hear about the ACT study and determine that its cohort would be a good fit for your study?**

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

# Section Two: Information about grant opportunity and key dates

**2.1 For what funding opportunity will this proposed ancillary study be designed?** Please provide a link to the grant announcement:

**2.2 Targeted grant submission date:** (month/day/year)

**2.3 Proposed start and end dates of the study**: (month/year)

# Section Three: Ancillary Study Abstract and Specific Aims

**3.1 Please provide a lay summary of the ancillary study in the form of an abstract (30 lines maximum).**

**3.2 Specific aims (1 page maximum)**

# Section Four: Implementation Items

**4.1 General description of ACT data needed either existing or currently being collected** (e.g., participant demographics, cognitive assessment data, etc.) and frequency with which you will need updated data pulls. Use available [data documentation](https://actagingresearch.org/resources/act-data-repository) for the ACT Data Repository. Please explain whether your study will require new curation of ACT data such as abstraction of previously unused data from participants’ records.

**4.2 Description of New Participant Data Collection Procedures and Participant Burden (Type 3 only)** If your study will collect new data from ACT participants, please address the items below.

**4.2.1 Types of data to be collected (survey, procedure, etc.) and estimated participant time required.** Please state which specific tests you intend to administer, the rationale for each, and considerations for reducing the burden on our older participants, especially if the data collection will be done at the same time as other examinations.

**4.2.2 Description of how and when data will be collected, including:**

* When will the data be collected? (i.e., at a scheduled ACT visit or separate visit - specify desired timing of separate visit in relation to scheduled ACT visits).
* Who will collect the data? (i.e., staff employed by ACT vs. staff employed by new study)
* Must data be collected at a clinic, or can they be collected at a home or telephone visit?

**4.2.3 Please provide a justification as to why the new data collection is needed**. Note that the frequency of data collection over time should be carefully considered if repeated measures are being proposed, and a strong scientific rationale for the time intervals between measures should be provided.

**4.3 Linkages to Other Data Sources** If your study proposes to link ACT Study data to other data sources, please describe how the linkage will be conducted including what ACT Study variables are needed for the linkage, what other data sources will be involved in the linkage, who will perform the linkage, and where the linkage will take place.

**4.4 Considerations related to integrating data into the ACT Repository and/or other means of data sharing**

**4.4.1** If your project will generate a data resource that can be integrated into the ACT data repository in the future, please describe your plan for data integration. As this may require a collaboration with KP programmers and budgeting for resources, it is advised that you reach out to an ACT researcher and or a representative from the Data & Analysis Core to learn more about specifications related to the dataset formats and requirements for a data dictionary.

**4.4.2** In addition, if your generated data resource will be shared via a mechanism other than through the ACT repository, please describe in detail how you propose this data sharing process to occur. [Note that as of January 2023 the NIH requires a more extensive data sharing plan that is likely to require additional resources.]

**End of Part I**

*Please submit the completed Part I of this application form to* *kpwa.actproposals@kp.org**. We will be in touch following the ACT Admin Core concept review.*

## Part II: Full Proposal

# Section Five: Research Strategy

**5.1 Describe the research strategy for the proposed ancillary study, focusing on the methodological approach (4-6 pages maximum).**

# Section Six: Data needed for proposed study

**6.1 Which existing ACT data/specimen categories do you anticipate using for your proposed grant?** Check all that apply including data needed for sample selection, recruitment, and data analysis activities. (External researchers: Please work with your ACT collaborator to identify the categories you will need.)

|  |  |
| --- | --- |
| [ ]  | **ACT study visit** **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.

**6.2 Do you need any preliminary ACT data in order to write your grant proposal?**

[ ]  Yes à please complete items 6.2.1 – 6.2.5 to the best of your ability, using available [ACT Study data documentation](https://actagingresearch.org/resources).

[ ]  No à please skip to Section Seven

**6.2.1 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

**6.2.2 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:

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

[ ]   All participants from all cohorts

[ ]   Subset of participants (please describe):

**6.2.4 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.

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| --- |
| **Variable Name**  |
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**6.2.5 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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# Section Seven: Data Security and IRB

**7.1 Who will be legally responsible for the data?**

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| --- | --- |
| Legally responsible individual name: |  |
| Institution: |  |
| Email address: |  |
| Telephone number: |  |

**7.2 Please list all individuals who will have access to the data (add additional rows if necessary)**

|  |  |  |
| --- | --- | --- |
| Name & Institution | Role on project | Email address |
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**7.3 Please describe the data storage method and location (local hard drive, network server, cloud).** Include a description of data security measures in place.

**7.4 Lead Collaborator Attestations**

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

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

[ ]  Data will be encrypted **Initials: \_\_\_\_\_\_\_\_\_**

[ ]  Data will be segregated from other institutional data **Initials: \_\_\_\_\_\_\_\_\_\_**

[ ]  Multi-factor authentication will be required for users outside the institutional firewall **Initials: \_\_\_\_\_\_\_\_**

[ ]  Access will be restricted to authorized users **Initials: \_\_\_\_\_\_\_\_\_**

[ ]  Data will be used only for approved purpose **Initials: \_\_\_\_\_\_\_\_\_**

**7.5 IRB Plan**

Please outline your plans for obtaining IRB approval once grant has been approved, including the name of the reviewing IRB.

# Section Eight: Responsibilities of collaborators and preliminary plans for budget

**8.1 Please briefly describe the distribution of labor between ACT researchers and staff, and the proposal leader and their collaborators and staff.** Please include the location(s) where the key activities of the proposed project will take place and how associated efforts will be allocated among ancillary study team members.

**8.2 Please provide staffing FTE estimates to the best of your current knowledge**. These estimates allow ACT to assess if adequate resources and staffing will be available to support the proposed grant. Listed estimates do **not** need to be final, and ACT understands they may change as grant development progresses.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Personnel Expenses** | **Role** | **FTE Y1** | **FTE Y2** | **FTE Y3** | **FTE Y4** | **FTE Y5** |
| ACT Researchers |  |  |  |  |  |  |
| Data processing/storage at KP |  |  |  |  |  |  |
| ACT data collection staff  |  |  |  |  |  |  |
| ACT project management staff |  |  |  |  |  |  |
| ACT programmers |  |  |  |  |  |  |
| ACT biostatistical support  |  |  |  |  |  |  |
| Other staff |  |  |  |  |  |  |

**8.3 Additional Budget Notes/Comments**:

Section Nine: Attachments (if applicable/available)

**9.1 Please include drafts of**:

* Informed consent (required if new data will be collected from ACT participants)
* New questionnaires (if applicable)
* Data collection forms for new procedures (if applicable)
* Manuals

**End of Part II**

*Please submit the completed Part II of this application to* *kpwa.actproposals@kp.org**. We will be in touch to schedule a presentation to the ACT Ancillary Study Review Committee (ASRC) as part of the full proposal review.*