Background
This guidance describes the procedures associated with discovering and returning research results/incidental findings to participants.

After considering whether the study includes the possible discovery of relevant research results/incidental findings, it is the responsibility of the Principal Investigator (PI) to include appropriate language in the consent/parental permission/assent form(s) advising subjects/parents whether relevant research results/incidental findings will be returned, what types of findings are expected, to whom and how the findings will be provided, what and when the findings will be provided, etc. and provision for allowing the subject/parent to indicate whether they want to receive such findings.

Definitions
An incidental finding is a finding concerning an individual research participant that has potential medical or behavioral health or reproductive importance and is discovered in the course of research but is beyond the aims of the study.

Research results are broken into three subcategories:
- Baseline finding – A finding that is the result of information collected at the beginning of a subject’s participation in the study such as tests done to address inclusion/exclusion criteria. These findings could include results from routine lab tests, memory tests, IQ tests, etc.
- In-study finding – A finding that is generated during the progress of the research. These findings could include blood pressure and vital sign measurements, lab tests, etc.
- End-of-study finding – A finding that is collected, collated, or interpreted after the study has ended and analysis of all participant data is complete.

To What Type of Research Does this Guidance Apply?
This guidance applies to research which may generate results or incidental findings that may significantly affect the behavior or medical health of the participants or their family. This includes but is not limited to research involving:
- Genetic testing
- Imaging – such as MRI scans, CT scans, PET scans, and X-rays. Specifically, high density images that provide anatomic or physiological data of the type that is used in clinical diagnosis or treatment;
- Cognitive or behavioral testing
- Other procedures for which there is probability that the results, tests, or procedures could identify results or incidental findings, such as EEGs and psychological/psychiatric batteries, or biospecimen testing.
Criteria to Determine Whether Research Results or Incidental Findings Should be Returned

In general, research results/incidental findings that meet all of the criteria listed below should be returned unless the participant states that he/she does not want to know the results or unless the IRB has approved a written request for not returning results or incidental findings.

In general, research results/incidental findings should be offered to study participants if:

- The finding has important behavioral or medical health implications for the participant, and the associated risks are established and substantial.
- The test is analytically valid or in case of imaging, qualified professionals interpret the scan, and the disclosure plan complies with all applicable laws.
- The informed consent used to collect the tissue/specimen/data informed the participants that results may be returned, or the participant opted to receive his or her individual results.

In cases where the consent is silent about return of results, but the researcher later discovers something they feel the subject should be made aware, please consult with the HSPP for further instruction prior to proceeding.

Other considerations include:

- Level of confidence in the findings
- As recommended by the Secretary’s Advisory Committee on Human Research Protections (SACHRP) and the PI:
  - **Findings that should be returned:**
    - The findings are valid and actionable, which include the following:
      - Findings determined to be clinically significant.
      - Findings that reveal a condition that is likely life-threatening or grave that has an available course of action to treat the condition, or make the condition better or more tolerable.
      - Findings that may be useful for reproductive decision making to avoid significant risk, make better or more tolerable to an offspring a condition likely to be life-threatening or grave.
  - **Findings that should consider for being returned:**
    - The findings are not validated but could be actionable:
      - Non-validated results should be followed up with validated testing to help provide certainty but there will not be approved or validated tests available.
  - **Findings should consider not being returned**
    - Findings that are neither validated nor clinically actionable:
      - Findings that are experimental results in basic science studies
Returning the Research Results or Incidental Findings to Participants
Should a researcher discover a research result or incidental finding, they should:

1. Contact the participant directly to tell them about the incidental finding. Have them sign a release of records form to send the relevant scans (on a disk if possible) or data along with a letter explaining the finding to the doctor of their choosing.
2. The participant notification should always indicate that these scans and data are for research purposes and are insufficient for diagnosis. Additional follow-up may be warranted through their primary physician and insurance.
3. Provide a de-identified report to the IRB of the incident to ensure that the finding and, more importantly, the investigator response to it, is documented as a reportable item.
4. Consent forms should state that scans and procedures are for research purposes only and are not meant to provide medical evaluation or diagnosis.

There is no ethical responsibility to provide additional scanning or medical treatment if the scan was obtained for purely research purposes. However, for licensed medical professionals who are conducting research AND clinical care, follow-up with routine medical screening may be necessary and is at the discretion of the clinical provider.

It is not necessary to report incidental findings that are considered part of “normal aging” or normal developmental anomalies. For example, older adult may have some small regions of damage to their white matter (axons in the brain). They also usually have volume loss of the cortex. Then it is a judgement call on the part of the researcher as to whether the finding is severe enough to be considered outside the range of normal.

When a researcher is in doubt about reporting a finding, they should seek guidance from colleagues who regularly works in this area, or they may contact the IRB.

Consent Considerations
The following is suggested consent talking points if research results will be shared with the research participants:

-Your results are not intended to provide medical benefit to you, and the investigators are not trained or licensed to clinically review your results. You are free to do as you wish with the results provided, but we make no promises as to the clinical value of the data. Further follow up with your physician may be needed and will be at your own discretion and cost. The University of Arizona and its employees have no funds set aside for the payment of treatment expenses that may arise from you volunteering in this research study.

-Please do not rely on our data and/or analyses to reveal abnormalities. This data is generated for research purposes only.
Resources

- SACHRP Attachment F – Recommendations for Returning Incidental Findings
- NIH Human Genome Research Institute – Return of Research Results