### IRB Application Process and Timeline

***Before you apply:***

1. The first step in preparing an IRB application is to determine whether an IRB application is warranted. To accomplish this, the investigator should follow the steps of completing a Research Determination form found at: [<https://www.clayton.edu/about/administration/academic-affairs/institutional-review-board/forms-applications>](http://www.clayton.edu/provost/irb/forms%29). In addition, you should consider reviewing the NIH-provided flow chart for *Research Involving Private Information or Biological Specimens*, available online at: <https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf>.

Further information can be found in the *Research Determination* section (page 9) of the IRB Policy and Procedures document.

1. Determine if your study requires an exempt, expedited, or full review. Further information can be found in the *Categories of Review* section(page 13) of the IRB Policy and Procedure document.
For questions, please contact your [College IRB Representative](https://www.clayton.edu/about/administration/academic-affairs/institutional-review-board/committee).
2. Each investigator included in an IRB application, and other key personnel who are responsible for the design and/or conduct of the study (e.g., research assistants), must complete Human Subjects training. If the training is not current (within the last 5 years), then Human Subjects training can be completed for free at <https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html>. Each investigator must complete all five lessons and submit all 5 completion certificates when you submit your IRB application. Applications will not be reviewed until all members of the research team have completed the Human Subjects training and evidence has been documented in the IRB office.

### Initial review materials:

Materials should be submitted with sufficient detail for the IRB to make decisions regarding a) risk; b) potential benefits; c) informed consent; and d) safeguards for human subjects. IRB application and supporting materials must be submitted to irb@clayton.edu.

Materials should include, but are not limited to:

1. IRB Cover Sheet, *required* (summary email is sufficient if addressed to irb@clayton.edu).
2. IRB Application (Exempt, Expedited, or Full Review, as appropriate), *required.*
	1. Applications are available at <https://www.clayton.edu/about/administration/academic-affairs/institutional-review-board/forms-applications>
	2. The first page of the IRB application must be signed by all investigators.
3. Proposed informed consent document, *required.* Consent form templates and examples can be found at <https://www.clayton.edu/about/administration/academic-affairs/institutional-review-board/forms-applications>
4. Survey instrument(s) and/or experimental procedure as applicable, *required*.
5. Recruitment materials for subjects, *required*.
6. Human Subjects training completion certificates for all investigators, *required*.
7. Letter(s) of Approval from cooperating entities (Letter from district or principal if conducting research in schools), *if applicable.*
8. Relevant grant applications, *if applicable*.
9. Investigators brochure (a comprehensive document summarizing the body of information about an investigational product), *if one exists*.
10. If study is supported by the Department of Health & Human Services, a copy of the HHS approved sample, informed consent form, and HHS protocol*, if they exist*.

Please note that research cannot begin until Human Subjects training has been completed and an approval letter by the IRB Chair for the study has been received.

***Review timeline:***

***Exempt:*** An Exempt review application is processed by the IRB Chair or Vice Chair, or by another IRB member designated by the IRB Chair. Once a completed application is received, the PI (Principal Investigator) can expect up to two weeks (10 normal business days during which the university is open and classes are in session) for feedback or a decision from the IRB Chair. If additional information or revisions are requested by the IRB, then the timeline will be extended to allow for reasonable follow-on review once the requested feedback is received by the IRB. CSU advises that investigators plan for at least six (6) weeks from the submission of an Exempt IRB application before they plan to begin executing the study. This timeline will be longer during periods in which classes are not in session, including major holidays, time between semesters. The timeline will also be extended during summer semester.

***Expedited:*** An Expedited review application is processed by the IRB Chair or Vice Chair, or by another IRB member designated by the IRB Chair. Once a completed application is received, the PI can expect up to four weeks (20 normal business days during which the university is open and classes are in session) for feedback or a decision from the IRB Chair. If additional information or revisions are requested by the IRB, then the timeline will be extended to allow for reasonable follow-on review once the requested feedback is received by the IRB. CSU advises that investigators plan for at least six (6) weeks from the submission of an Exempt IRB application before they plan to begin executing the study. This timeline will be longer during periods in which classes are not in session, including major holidays, time between semesters. The timeline will also be extended during summer semester.

***Full:*** A Full review application is prepared by the IRB Chair or Vice Chair, or by another IRB member designated by the IRB Chair, and then reviewed by the full IRB and voted on electronically or during a scheduled session. Once a completed application is received, the PI can expect up to six weeks (30 normal business days during which the university is open and classes are in session) for feedback or a decision from the IRB Chair. If additional information or revisions are requested by the IRB, then the timeline will be extended to allow for reasonable follow-on review once the requested feedback is received by the IRB. CSU advises that investigators plan for at least eight (8) weeks from the submission of the IRB application before they plan to begin executing the study. This timeline will be longer during periods in which classes are not in session, including major holidays, and time between semesters. Full reviews received after April 15 will be prepared for review beginning during Faculty Planning Week in Fall Semester, at which time the review process will begin. Full review applications are not reviewed during Summer Semester, and any received after April 7 do not present enough time for the IRB to conduct due diligence prior to the end of the academic year. In the event that a Full review application is received during the last week of March or first week of April, the PI accepts the risk that a decision may not be reached until Fall Semester if the IRB requires substantial additional information or revisions. PIs are encouraged to plan accordingly, and submit IRB applications well in advance of academic year end.