

Research Review Committee

By-Laws for Agencies in Alabama

The Research Review Committee (RRC) is designed to maintain and promote ethical conduct in behavior analytic research.

The RRC adheres to state and federal regulations regarding conducting research with human subjects. Specifically, the RRC complies with federal regulations regarding committee composition, committee training, and operational procedures (Protection of Human Subjects, 2009).

Members

The RRC membership is comprised of a minimum of five members who have specific functions and diversity (i.e. gender, profession). Additionally, members may add a non-voting consultant if/when is necessary. One of the members is deemed the Chairperson. One member is deemed the ex-officio member. This member will be the CEO of Glenwood, or their designee. In this role, the ex-officio member will have full rights of other voting members but not be required to attend meetings. They may be called upon for input and approval on protocols at the discretion of the Chairperson. Their main role will be to aid the Chairperson in the agency application process and project proposal approval process submitted by outside agencies. Specifically, the Chairperson will send agency applications and project proposal submissions to the ex-officio member along with a recommendation to accept, reject, or request revisions of such submissions. The ex-officio member may agree or disagree with the recommendations made by the chairperson. Processes for applications and submissions that are approved, rejected, or need revising can be found in Section 4 of the bylaws. Below are the other four types of members that compose the RRC. Two members may fulfill the same role. It is recommended that the Chairperson be a scientist or competent expert, as described below. One member is elected at the start of the term (May 1st) as the Vice Chairperson. They may also serve a member function as described below. This person will serve a one-year term in which they receive additional guidance from the Chairperson on accepting and reviewing submissions. Specifically, they will review a minimum of two project submissions along with the chairperson. As Vice Chairperson, they will serve as chair in the unlikely event that the chairperson is unable to do so.

Table 1 Research review committee member, function, U.S. regulation, and recruitment tips

Member	Function	U.S. regulation	Recruitment
Nonscientific	Voices concerns about potential research subjects and provides a broader community perspective	Protection of Human Subjects (2009): "at least one member whose primary concerns are in nonscientific areas"	Human resources representative, local human rights committee representative
Nonaffiliated	Unbiased to organization's financial concerns and represents a community perspective	Protection of Human Subjects (2009): "at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution"	Can be a local scientist (e.g., physician) or retired professional (e.g., schoolteacher, administrator) who will not have a conflict of interest
Scientist	Provides expertise on experimental design for research that aligns with that of the organization	Protection of Human Subjects (2009): "at least one member whose primary concerns are in scientific areas"	Local university training program faculty members, relevant research authors aligned with organization's activity
Competent experts	Supports projects that require additional expertise outside of that represented by the committee	Protection of Human Subjects (2009): "individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB"	Researchers who have recently published in the relevant area

IRB Institutional review board

Note. Reprinted from "Establishing Consumer Protections for Research in Human Service Agencies," by L.A. LeBlanc, M.R. Nosik, and A. Petursdottier, 2018, *Behavior Analysis in Practice*, 11, p. 449. Copyright 2018 by the Association for Behavior Analysis International.

- A. Members are reviewed as needed, at a minimum annually. Members commit to the committee for one year but may extend their tenure for up to three years.
 - a. Current members may nominate individuals for committee positions as they come available by submitting in writing to the chairperson. The committee will be capped at 8 members. Terms start on May 1st of each year.
 - b. The committee members should find the best candidate for each position. A review of qualifications and eligibility for each candidate will be conducted to ensure alignment of RRC bi-laws.
 - c. In the case that the number of nominations equals the number of open positions, the chairperson will contact the nominee and offer the committee position. The chairperson will notify the existing committee in writing of that nominee's decision on acceptance of the position. If the nominee is not willing to serve, the committee needs to find another candidate.
 - d. In the case that the number of nominations exceeds the number of open positions, the chairperson will submit in writing a ballot to the existing committee to vote on persons for the positions. In the case of a tie vote, the CEO of Glenwood will determine the tie.
- B. Members are expected to attend meetings, review materials provided, participate in discussion and committee activities.
- C. Chairperson duties:
 - a. Receives all protocols submitted by principal investigators.
 - b. Follows protocol review policies as outlined below.
 - c. Communicates with the RRC committee members regarding any follow-up to protocols as outlined below.
 - d. Sets up and conducts meetings semi-annually, at a minimum.

Meetings

- A. Meetings are held semi-annually, at a minimum. Meetings may occur more often or less often at the discretion of the Chairperson. Semi-annual meetings will be a guideline.
- B. Meetings may be held in-person at Glenwood, virtually, or in a hybrid manner.
- C. The majority of committee members must be present in-person or virtually for a meeting to commence.
- D. Agenda items and meeting minutes are maintained by the Chairperson.
- E. Due to the nature of the committee, all meetings are confidential. Members and non-voting meeting participants sign a confidentiality agreement that is kept with the official minutes of the meetings. No materials can be taken from the RRC meetings. All information is gathered and disposed of according to policy by the Chairperson.

Oversight

All research projects will be initiated in an orderly and systematic process. It is the policy of the Research Review Committee (RRC) that an organization must submit an application for their agency to become an approved research site. This application will specify a research coordinator that will be responsible for ensuring that all protocols submitted to the RRC follow all guidelines listed below. Specific information related to this application and the role and responsibilities of the research coordinator are listed below. Once an agency is approved by the RRC to submit protocols, each individual research project must be approved by the RRC, including the ex officio committee member prior to implementation. Additionally, all submitting agency policies regarding research with individuals must be adhered to and principal investigators must sign an affidavit signifying that all procedures have been followed (see section 2a below).

Current members may submit proposed amendments to the bi-laws in writing for a vote. Amendments should be submitted directly to Glenwood's Director of Compliance and Performance. The RRC By-Laws (initial and ongoing changes) will be reviewed and approved by Glenwood's Policy and Practices Committee. Such changes will become official only after approved by the CEO of Glenwood.

Policies and Procedures

Agency Application Process

To submit research project proposals for approval by the RRC, an agency must first submit an application to become an approved research site. The application will outline the following:

- A. Designated research coordinator
 - a. The research coordinator will ensure that all principal investigators have taken a training in human rights in relation to research (i.e. CITI, PHRP). They will store all trainees certificates and ensure that certification is renewed in a timely manner as necessary.
 - b. The research coordinator will ensure that all protocol submission packets have all the necessary forms (see 2A) filled out completely and accurately.
 - c. The research coordinator will describe their level of experience conducting research with a particular population.

- B. Location where the research will be conducted
- C. Population characteristics including age and diagnoses.
- D. Type(s) of behavior analytic research that will be conducted (e.g., applied research with specific population, research on service-delivery models, research involving staff training).
- E. Nomination of agency employee willing to serve in the future on the RRC.

In the event that the research coordinator is no longer employed by the agency or the agency wishes to place a new individual in this role, the agency must submit a new application to the RRC specifying the person who will assume the research coordinator role.

The RRC will review the agency application and let the agency know in writing whether or not the application has been accepted. Agencies are allowed to resubmit the application based on the feedback provided.

Project Proposal Process

The RRC will determine whether a proposed project qualifies as either, exempt from review, expedited review, or must undergo full committee review. This determination is based on whether or not the proposed project meets the criteria described in the Common Rule (2018).

1. Description and determination of review type:

Exempt: There are three categories of exemption that apply to all potential participants, and one category that only applies to adults over the age of 18. Protocols submitted for exemption may be reviewed solely by the Chairperson and solely approved or denied by the Chairperson, without input from the RRC. In the event that the principal investigator is also the Chairperson, or a member of the RRC, the protocol will be sent to Vice Chairperson. The vice Chairperson will make the determination whether or not the protocol will be eligible for exemption based on the criteria below.

- A. The categories of exemption are as follows:
 - a. 45 CFR 46.104(d)(1): the study is conducted “in established or commonly accepted educational settings” and involves “normal educational practices” (Protection of Human Subjects, 2009). In other words, if the intervention and data collection would occur identically if the research were not being conducted. Page 4 of Human Subject Regulations Decision Chart: 2018.
 - b. 45 CFR 46.104(d)(4): the study is conducted with archival data that are de-identified. Page 7 of Human Subject Regulations Decision Chart: 2018.
 - c. 45 CFR 46.104(d)(7): the study utilizes identifiable private information for secondary research (archival research) provided that broad consent has previously been obtained for such use. Page 10 of Human Subject Regulations Decision Chart: 2018.
 - d. 45 CFR 46.104(d)(2) *only applies to adult (over 18) subjects*: studies involving the use of “educational tests” (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior (Protection of Human Services, 2009) may be exempt IF data are recorded anonymously or when the data can be linked to individual subjects but there is no risk of harm to the subject if the data were to be disclosed outside of research. For instance, if revealing the data do not pose a risk to the individual’s employability,

criminal or civil liability, damage to financial standing, or reputation. Page 5 of Human Subject Regulations Decision Chart: 2018.

- B. Expedited:** Protocols submitted for expedited review are reviewed by the Chairperson first. If the chair deems the protocol appropriate for expedited review, they may conduct that review alone, or with one or more RRC members as designated by the chair. The RRC chair or designee can approve the protocol or request revisions. However, if the chair or designee determines that the protocol should be denied, it must be referred to the full RRC for review.

A study qualifies for expedited review under the requirements set forth in 45 CFR 46.110 if the following conditions are met according to the Common Rule:

- a. The research presents no more than minimal risk to the participant. Minimal risk is subjective but is generally understood as “that which does not exceed risks ordinarily encountered in daily life or during routine physical or psychological examinations or test” (Protection of Human Subjects, 2009). If the level of risk seems open to interpretation, the protocol goes to full committee review.
 - b. The protocol involves procedures included in the Department of Health and Human Services list of expedited categories. There are 7 categories total, three of which are directly relevant to behavioral research:
 - i. Research on individual or group characteristics of behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
 - ii. Collection of data from voice, video, digital, or image recordings made for research purposes.
 - iii. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- C. Full Review:** A study qualifies for full review if it does not meet criteria for exemption or an expedited review OR the RRC chair prefers input from the full committee.
- a. Committee members may excuse themselves from reviewing specific protocols if a conflict of interest is apparent.
 - b. RRC may solicit additional review from one or more experts who are not members of the RRC if a protocol warrants expertise outside that provided for by the members. These experts can provide opinions but may not vote on the approval of an application.
 - c. RRC will vote whether to approve, deny, or require modifications for protocols going through full review. Written notification will be provided to lead investigator within 10 business days of meeting.
 - i. If approved: research protocol can begin.
 - ii. If modifications are requested, the lead investigator has 30 business days to make all modifications and send back to the RRC.
 - iii. If denied: research protocol may not begin.
- D. Final approval** should specify the risk level of study
- a. If risk level is deemed minimal or less, the approval motion should specify whether future review of modifications or continuing review of that protocol can occur via the expedited route or must be performed by the full RRC.

- b. If risk level is deemed to be more than minimal, review of modifications and continuing review must be performed by RRC.

2. Submission Instructions

To ensure consistency and timeliness of the review process, the following documents should be submitted for each RRC review request. All documents should be submitted on the Glenwood.org website. Any questions regarding submission or submission documents should be directed to the Chairperson.

- A. Original submissions must include the following:
 - a. Project Proposal Submission Form
 - b. Consent documents (including assent documents if participant(s) is a minor)
 - c. Recruitment materials (flyers, emails, etc.)
 - d. Study instruments (Survey, questionnaire, etc.)
 - e. Accredited Human Rights training documentation of the principal investigator and additional investigator(s) or data collector(s).
 - f. Signed attestation that the project has undergone any internal review deemed necessary by the submitting author's organization.
 - g. Signed attestation that the by-laws have been reviewed prior to submission.
- B. Revision Submissions:
 - a. Memorandum addressing RRC reviewer's requested clarifications or revisions
 - b. Revised documents (as listed above) with all requested revisions highlighted
 - c. Copy of all items listed above without highlighted changes
 - d. Additional material that were altered since original submission
- C Renewal Applications:
 - a. Original application
 - b. Initial approval letter
 - c. Renewal application form
 - d. If applicable, additional material that were altered since original submission

3. Informed Consent Process

Participants in research studies, as well as their parents/guardians (as appropriate), will be given the opportunity to make an informed consent/assent. An informed consent provided to the individual served and / or parent / guardian includes the following information:

- A. The rationale for the proposed project
- B. The benefits to be expected
- C. Any potential discomforts/risks
- D. The procedures to be followed
- E. The right to refuse or withdraw from the research project
- F. Privacy
- G. Confidentiality
- H. The name, signature, and title of the staff person providing the information
- I. Date the information was provided.

To ensure that all of this information is included, researchers are encouraged to use the informed consent/assent templates provided by the RRC.

4. Approval timeline and criteria:

In order to approve a research study, the following criteria must be met for both the initial and continuing review. These criteria must also serve as the framework for the RRC's evaluation of research and decision-making procedures (Protection of Human Subjects, 2009). As stated in LeBlanc, Nosik, and Petursdottir (2018), the criteria are as follows:

- A. Participant risks are minimized by using procedures consistent with sound research design and if appropriate using treatment approaches already being implemented based on best practice.
- B. Risks to participants are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result.
- C. Selection of participants is unbiased.
- D. Informed consent will be obtained from each participant or his or her legally authorized representative and it will be documented properly.
- E. Appropriate safeguards are included to protect participants from coercion or undue influence (e.g., overly generous incentives, dual relationships).
- F. When the research involves vulnerable populations (e.g., children, individuals with disabilities, students), the research also meets those requirements.

The chairperson will send a decision letter on behalf of the RRC to the principal investigator.

For continued review of a protocol (i.e. for research projects extending beyond one year), the RRC will assume that the previously approved protocol met all aforementioned criteria and will evaluate new information at that time (USDHHRP, 2016c). Below are the four primary considerations during continued review of a protocol, as stated by LeBlanc, Nosik, and Petursdottir (2018):

- A. Risk assessment and monitoring (e.g., any new information that would alter the RRC's previous conclusion that risks to participants are minimized).
- B. Adequacy of the process for obtaining informed consent (e.g., review a sample of the investigator's informed consent document to ensure that the approved version is being used).
- C. Researcher issues (e.g., complaints, changes in employment status).
- D. Research progress (e.g., participant enrollments and withdrawals).

5. Protocol changes

In the event that an approved protocol, informed consent procedures, recruitment materials, or any other materials or documents relating to a study need to be changed, altered, or eliminated, they must be reviewed by the RRC and approved before the changes are implemented. All proposed changes should be submitted to the Chairperson so that they can determine whether the change is minor enough to be handled through an expedited process (i.e. the chair reviews and approves), or requires approval by the full RRC committee. The following are examples of changes that warrant notification to the Chairperson:

- A. Researchers wish to introduce an additional intervention that may involve more than minimal risk to the participant not otherwise specified or included in the protocol.

- B. Researchers wish to include additional participants that are in a protected class not otherwise specified or included in the protocol.
- C. Researchers wish to perform additional analyses that may involve more than minimal risk to the participant and not otherwise specified or included in the protocol.
- D. Researchers wish to provide participants with additional written materials as part of an intervention package not otherwise specified or included in the protocol (i.e. additional parent training materials in a study aimed at training parents to implement functional communication strategies with their child).

The aforementioned are examples and not meant to be a comprehensive list of changes that warrant notification to the Chairperson.

Additionally, any unanticipated problems such as the loss of data from an unsecure laptop holding sensitive, identifiable data must be reported to the chair (USDHHOHRP, 2016d).

The chairperson will send a revised decision letter to the principal investigator.

6. Audit and record retention

To ensure compliance with federal, state, local, and agency requirements, the lead investigator for each study will be responsible for ensuring the proper retention of all data pertaining to participants in each study as outlined below.

Anonymity and Protected Health Care Information: To ensure privacy for each participant is maintained, researchers should attempt to minimize using personally identifiable information on data collection forms or other paperwork unless it is necessary to identify and distinguish between participants in a study. Alternative methods of identification, for the purpose of facilitating the study, include the use of the individual's served Glenwood identification number or the individual's served initials. Additionally, anytime a participant's data is shared in a presentation or publication, the lead investigator of the study is responsible for ensuring a pseudonym is used to maintain the confidentiality of the participant and comply with the proper regulations surrounding his or her protected healthcare information. No personally identifiable information may be used when presenting data or studies for conferences or publication.

Maintenance and destruction of data and records related to research studies: The lead investigator for each research study will be responsible for ensuring the following criteria are met:

- A. No records related to a study or protected health care information for participants will be released without the written and voluntary consent of the individual or individual's representative or legal guardian as appropriate prior to the release of information., except in the following circumstances:
 - a. medical or clinical emergency
 - b. court ordered subpoena
 - c. in instances when the primary investigator's organization is being reviewed for purpose of funding, accreditation, reimbursement, or audit by a state or federal agency information may be disclosed provided that the personally identifiable information is necessary to accomplish the purposes of the review. These representatives will sign the Access to Records form.

- B. Individual served information can be used in instructional procedures only when the identity of the individual has been appropriately disguised and written permission is given.
- C. Every individual's case record will be kept securely maintained (as defined in the policy and procedure of Storage and Retrieval of Active Records).
- D. Upon termination of employment with the agency of the primary investigator employees shall continue to respect the confidentiality of any and all individual served information or sensitive agency information.
- E. All hard copies of individual served records will be stored in a locked area at all times.

Retrieval and Destruction of Persons Served Records the following guidelines will be followed in the destruction of clinical records after they are no longer required for storage:

- A. An individual's served records containing personally identifiable information will be kept for a period of ten (10) years after discharge from treatment.
- B. At the end of the ten-year retention period, parent / guardian / individuals served will be notified in writing of the intent to destroy the record. In addition, an advertisement will be placed in newspapers throughout the state notifying the public of the intent to destroy records. The parent / guardian will have 30 days from the date of notification to respond with the option to receive information or have it destroyed by the agency.
- C. If the parent / guardian / individual served does not respond in the 30-day period or cannot be located, the clinical record will be destroyed.
- D. All clinical records will be destroyed, by shredding, under the supervision of the principal investigator.