



# ABP Corporate Policy

## Research and Other Systematic Investigations

### BACKGROUND

To fulfill the mission of the ABP, the ABP Board conducts systematic investigations about its operations (e.g., internal processes and programs). Most pediatricians and pediatric subspecialists interact with the ABP through testing and other Board Certification activities. These activities present valuable opportunities to conduct systematic Investigations, including Research, that may contribute to the efficiency of the Board, the value of ABP programs, or to public knowledge of topics related to the mission of the ABP.

The objective of this policy is to: (1) clarify the distinction – and the ethical implications – of conducting Systematic Investigations for operational versus research purposes, (2) articulate processes for conducting Systematic Investigations at the ABP, including research funded by the ABP Foundation, and (3) protect the rights of candidates and diplomates who seek or want to maintain Board Certification.

### DEFINITIONS USED IN THE POLICY (IN ALPHABETICAL ORDER)

**Generalizable Knowledge.** “Generalizable knowledge” refers to information obtained for the purpose of expanding the knowledge base of a scientific discipline.<sup>1</sup>

**Generalizable Research or “Research”.** “Generalizable Research”, termed “Research” by the Federal Office for Human Research Protections and used hereafter in this policy, means a Systematic Investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge.<sup>2</sup> Thus, a Systematic Investigation designed for the purpose of expanding (i.e., for the purpose of developing or contributing to) the knowledge base of a scientific discipline constitutes Research. Research typically involves formulating and testing a specific hypothesis, with systematic data collection, and interpretation of results relative to the hypothesis.<sup>3</sup> Research may also include more qualitative, mixed methods, or process evaluation studies.

**Operational Investigations.** “Operational Investigations” are investigations of administrative, business process, program development, program implementation, program evaluation (e.g., formative, summative, and process), quality assurance, and quality improvement (QI) activities.<sup>4,5</sup> These investigations are necessary to support ABP’s mission (see above).<sup>6</sup>

**Systematic Investigation.** A “Systematic Investigation” collects or analyzes data to answer a specific questions.<sup>7</sup> Systematic investigations are used both in Research and in Operational Investigations to validate outcomes. Note: Neither the use of nor the publication or other dissemination of the results of a Systematic Investigation, in and of itself, constitutes Research.

### DIFFERENTIATING BETWEEN RESEARCH AND OPERATIONAL INVESTIGATIONS UNDER THE COMMON RULE

While “research” is defined by the federal government as a “Systematic Investigation designed to develop or contribute to generalizable knowledge,” this policy acknowledges that the interests of the ABP include various types of Systematic Investigations that extend beyond the narrow federal definition of research.



## ABP Corporate Policy

### Research and Other Systematic Investigations

If the investigation is designed to contribute to “generalizable knowledge,” then the work constitutes Research under the Common Rule and requires review and approval by ABP’s designated Institutional Review Board (IRB) or the equivalent.

On the other hand, if the investigation is not designed to develop or contribute to “generalizable knowledge,” but instead is designed for routine operational purposes (e.g., quality improvement [QI] projects) that are essential to fulfilling the mission of the ABP, then the investigation does not constitute Research under the Common Rule and does not require review and approval by ABP’s IRB.

Many of the investigations conducted by and for the ABP can be classified as Systematic Investigations as they employ traditional “research” methodologies but they are not designed to contribute to generalizable knowledge, and thus do not constitute “Research” under the federal regulations. Thus,

- A Systematic Investigation designed for the purpose of expanding the knowledge base of a scientific discipline is considered Research.
- A Systematic Investigation that is designed for purposes other than expanding the knowledge base of a scientific discipline does not constitute Research.
- A Systematic Investigation constitutes an Operational Investigation if both of the following criteria are satisfied:
  1. The investigation is designed and implemented for internal purposes necessary to fulfill ABP’s mission and
  2. The investigation is not designed and implemented for the specific purpose of expanding the knowledge base of a scientific discipline.

Examples of ABP Operational Investigations include, but are not limited to the following routine activities:

- The ABP analyzes results of examinations to ensure that they result in fair and accurate pass/fail decisions for candidates and diplomates (e.g., validity, reliability, standard-setting).
- Quality improvement studies designed to evaluate the effectiveness and possible improvement of operations essential to fulfilling ABP’s mission.
- Studies of efficiency, quality, and cost-effectiveness to evaluate and/or improve the ABP certification and maintenance of certification (MOC) processes.
- Surveys with program directors and census workforce surveys with trainees and diplomates designed to support the ABP certification and maintenance of certification (MOC) processes.
- Other investigations designed to support the administrative, business process, program development, program implementation, program evaluation (e.g., formative, summative, process), quality assurance, and quality improvement activities of ABP departments.
- Investigations of the use of information science, computer science, and emerging technology to help in development of new tools and applications for ABP administrative, business, and certification processes.
- ABP customer satisfaction surveys.



# ABP Corporate Policy

## Research and Other Systematic Investigations

*Note: Creation (and dissemination) of ABP's Annual Workforce Data Book is considered an operations activity that reports data collected in the course of fulfilling the ABP's mission.*

### When Operational Investigations Become Research

- An investigation designed as an Operational Investigation remains an Operational Investigation (rather than Research) even if it generates results that are of interest to a scientific audience, are presented at a scientific meeting, or are published in a scientific journal.
- An Operational Investigation becomes Research if the ABP adds elements beyond what is needed to fulfill the operational purpose of the investigation, in order to produce results that can expand the knowledge base of a scientific discipline.

For example, if the ABP requests that “extra” elements (i.e., questions not needed for ABP’s operational purposes) be added to an ABP Operational Investigation in order to make the results applicable outside ABP, then those “extra” questions cannot be considered operational in nature and the investigation using the added questions would be considered Research.

If an external organization requests that “extra” elements (i.e., questions not needed for ABP’s operational purposes) be added to an ABP Operational Investigation in order to meet the needs of the external organization, then those “extra” questions cannot be considered operational in nature, and the investigation using the added questions would be considered Research.

- In contrast, if an ABP department or committee were to request that additional questions be added to an ABP Operational Investigation for a legitimate operational purpose (i.e., for an ABP administrative, business process, program development/implementation/ evaluation, or quality assurance/improvement objective), then the subsequent investigation using the additional questions would still be considered an Operational Investigation, regardless of whether the results were disseminated more broadly.

### Secondary Use of Data from ABP Operational Investigations

It is important to distinguish data collected in an ABP Operational Investigation from subsequent (secondary) use of the collected operational data for Research.

Data collected in an ABP Operational Investigation subsequently may be combined or analyzed in a different way in order to produce information that expands the knowledge base of a scientific discipline. In such cases, only the subsequent investigation using the collected operations data would be considered Research.

- For example, if an ABP department or committee requests the combination of psychometric data (test analysis) from several Operational Investigations in order to expand the psychometric science knowledge base, then the subsequent investigation using the combined data would be considered Research.



## ABP Corporate Policy

### Research and Other Systematic Investigations

- On the other hand, if an ABP department or committee requests that these same data be combined for an operational purpose (i.e., for an ABP administrative, business process, program development/implementation/evaluation, or quality assurance/improvement objective), then the subsequent investigation using the collected data is considered an Operational Investigation. The ABP department or committee using the data must ensure that any required and the current privacy policy permit such use of the data.

#### Investigations Conducted for, or in Partnership with, External Organizations

External organizations frequently request that ABP partner with them in conducting investigations involving areas of mutual interest. The ABP also may initiate partnerships with external organizations to conduct Operational Investigations or Research.

Such investigations are considered if they address information beyond that required for ABP internal operational purposes necessary to fulfill ABP's mission.

- For example, if an external organization requests that ABP analyze data collected in an ABP Operational Investigation for a different purpose as defined by the external organization, and for the external organization's purposes, such an investigation is considered Research. The same is true if the ABP requests similar analyses by the external organization with the sole purpose to generate generalizable knowledge.
- Likewise, if an external organization requests that ABP operations data be combined with the external organization's data for purposes defined by the external organization, the investigation using the combined data will be considered research if it contributes to generalizable knowledge in the given field. The same is true if the ABP conducts similar analyses linking its data with data from an external organization with the purpose to generate generalizable knowledge.

For all projects, Research or otherwise, conducted with the assistance of consultants and/or third-party vendors or individuals, the external organizations must abide by this and all relevant policies indicated in the contract, master services agreement, task order, or its equivalent before starting work.

#### **ETHICAL OVERSIGHT OF SYSTEMATIC INVESTIGATIONS NOT UNDER THE COMMON RULE**

Ethical principles for the conduct of Research were laid out in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*<sup>9</sup> in 1978. Three general principles are widely recognized in society: respect for persons, beneficence (i.e., benefits are proportionate to the risks), and justice (i.e., those who will benefit from the results should be the ones who undertake the risk of participation).

Efforts are underway to address ethical oversight of Systematic Investigations that do not meet or overlap with the federal definition of Research. Such investigations include evaluation (e.g., formative, summative, process), QI, and secondary data analyses. These efforts are in response to the following:



## ABP Corporate Policy Research and Other Systematic Investigations

1. Increasing recognition that Systematic Investigations generate concerns regarding privacy and data safety/monitoring, even if they do not qualify as “Human Subjects Research”. Several national organizations have established standards for such data collection. For example, the Joint Committee, which is accredited by the American National Standards Institute (ANSI). and endorsed by the American Evaluation Association– incorporates “Propriety Standards” into its guidelines, stating, “evaluations should be designed and conducted to protect the human and legal rights and maintain the dignity of participants and stakeholders”.<sup>10</sup>
2. Newer research designs such as process evaluation, implementation science, and other social science-based investigations may be considered by some stakeholders (e.g., participants, communities, funders, regulators), as “Research”, given that the methods used will draw from multiple “research” disciplines;
3. Uncertainty in the scientific community following controversial rulings by the Office for Human Research Protections (OHRP) regarding QI and its overlap with research
4. Many journals request documentation from an IRB or other institutional oversight body stating that such investigations, including QI efforts, have been deemed exempt or do not meet the definition of “Human Subjects Research”;
5. A variety of groups such as the Hastings Center<sup>11</sup>, the Commonwealth Fund<sup>12</sup>, Working Group participants drawn from the Clinical Effectiveness Research Innovation Collaborative of the IOM Roundtable on Value & Science-Driven Health Care<sup>13</sup>, and members of the Society of Thoracic Surgeons<sup>14</sup> have published thought leaders’ discussion papers about the ethics of evaluation, QI, and secondary data analyses.

These factors all point to the need for an efficient, effective process for reviewing these types of investigations in a manner that promotes rigor, transparency, and protection of participants’ rights and privacy but will not impede improvement and innovation.

Because the ABP is committed to standards of excellence, this policy provides a standardized approach for the assessment of Systematic Investigations below.

### TRIAGE PROCESS FOR SYSTEMATIC INVESTIGATIONS AT THE ABP

The ABP has constituted a Systematic Investigations Review Committee (SIRC) to assist with reviewing and triaging Systematic Investigations when questions are raised that cannot be routinely answered based on the definitions provided within this policy. This committee consists of the VP of Research, the VP of Psychometrics and Assessment Services, the Privacy Officer, and the VP of Technology and Informatics. It is staffed by the Research Program Manager. The goal of the SIRC is to provide a rapid review of those Systematic Investigations that are not routine and where it is not clear whether an IRB review is indicated.

As depicted in Figure 1 below, there are two types of studies that do not require review by the SIRC:

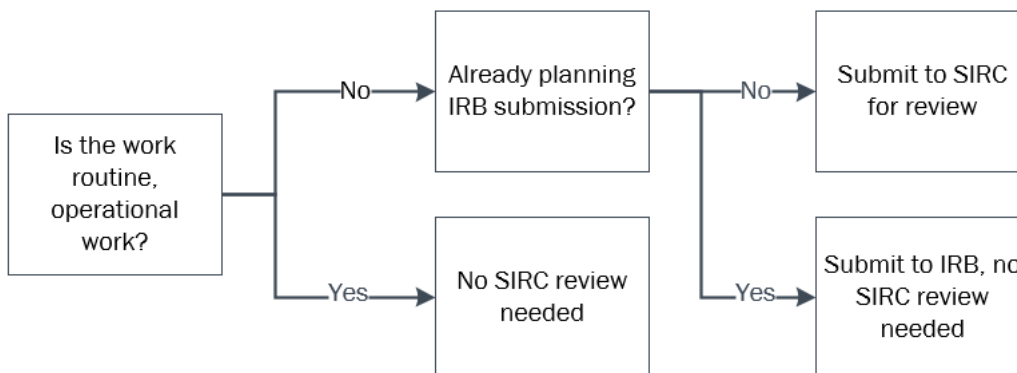
1. Routine operational work and analyses at the ABP; routine work should abide by other ABP policies and data access for Operational Investigations should be limited to the data necessary for the specific area(s) of operation.



## ABP Corporate Policy Research and Other Systematic Investigations

2. Systematic Investigations where the Lead plans to submit to the ABP's IRB of record (e.g., Research, Operational Investigation with planned publication).

Figure 1. When is an SIRC review required?



Other than those two exceptions, the ABP employees and/or external organizations must submit a brief proposal and seek approval from their responsible ABP Senior Management Official(s) or Director(s) and the ABP SIRC. Investigators seeking review may follow the short template in *Appendix A*.

In reviewing and approving proposed investigations, the SIRC must first determine that the investigation does not constitute routine operations or Research and then determine the following (as depicted in Figure 2 below):

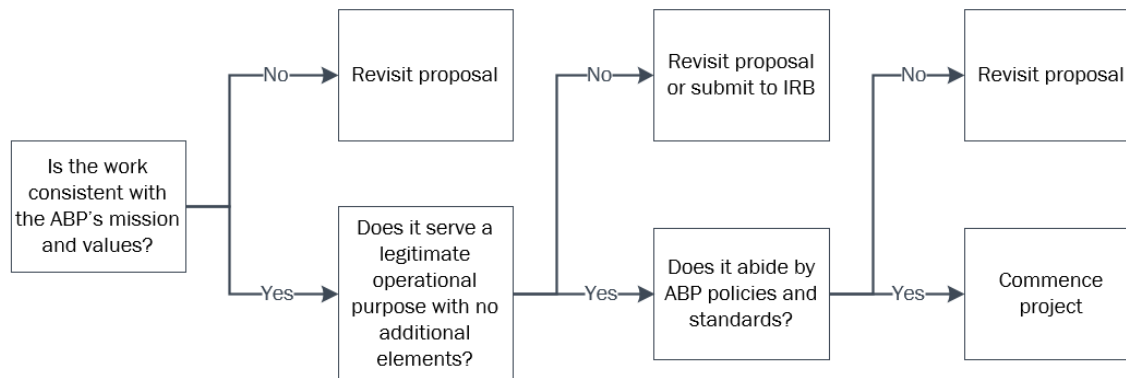
1. That the investigation is consistent with the ABP's mission and organizational values;
2. That the investigation has been designed and will be implemented to fulfill a legitimate operational purpose (i.e., for an ABP administrative, business process, program development/implementation/evaluation, or quality assurance/improvement objective necessary to support ABP's mission); and
  - a. The investigation includes only those elements needed to fulfill the stated operational purpose; and
  - b. The investigation does not include elements beyond those needed to fulfill the stated operational purpose; and
3. That the investigation abides by:
  - a. ABP privacy policy and, in the case of secondary analyses or linkages of existing data, any associated consents permit the proposed use of the data;
  - b. Ethical standards of data collection, safety, and monitoring;
  - c. All other applicable ABP Policies and Guidelines, including but not limited to, the Associated Policies and Guidelines listed below.



# ABP Corporate Policy

## Research and Other Systematic Investigations

Figure 2. How will the SIRC decide?



If a majority of the SIRC raises concerns that the proposed Systematic Investigation may be perceived as constituting human subjects research and the issue cannot be resolved, then the Systemic Investigation must undergo IRB review prior to beginning the investigation.<sup>9</sup>

### Ownership of Data

For additional guidance regarding sharing ABP data with external organizations, please see the “ABP Data Sharing Policy.”

### Privacy and Confidentiality

All ABP information obtained for Systematic Investigations shall establish standards to protect and safeguard the confidentiality of all participants and subjects and govern the use of data obtained from them. Unless the proposed investigations have progressed through the above-mentioned approval processes, access of ABP staff conducting investigations will be limited to only those data necessary for their specific area(s) of operation.

For guidance on maintaining privacy and confidentiality when data are shared with one or more external organizations, see the ABP “Data Sharing Policy” for additional recommendations.

### Reports of Systematic Investigations

Systematic Investigations conducted at the ABP, whether Research or Operational Investigations, are to be shared within and across departments and with the ABP and ABP Foundation Boards of Directors as determined on a case-by-case basis.

For any Investigations funded by the ABP Foundation, the funded principal investigator or project lead must provide a written proposal as well as interim and final progress and financial reports as delineated in the contract, master services agreement, task order, or its equivalent. These may be reviewed by members of the Research Department, the Research Advisory Committee, the ABP Senior Management Team, or other Departments or reviewers (e.g., subject matter experts). If the project is deemed to constitute Research, an IRB determination must be provided to staff associated with the ABP Foundation, prior to commencing the Research.

Final copies of scientific/professional papers, abstracts, and presentations should be submitted



## ABP Corporate Policy Research and Other Systematic Investigations

to [abpfoundation@abpeds.org](mailto:abpfoundation@abpeds.org) for tracking purposes. All papers and scientific/professional abstracts or presentations will be catalogued by the Research Department or other relevant Department and retained by the ABP following guidelines in its retention plan.

Products from Systematic Investigations funded by the ABP Foundation will be shared with the ABP and ABP Foundation Boards of Directors by the president and CEO or his/her designee a report to the directors at meetings.

In the event that a publication or presentation from a Systematic Investigation is deemed to warrant immediate consideration by either the ABP or the ABP Foundation Boards of Directors in terms of its impact for the mission of the ABP, the publication will be shared prospectively with the appropriate board(s) by the president and CEO or his/her designee.

The ABP retains the right to restrict the dissemination of all results that it perceives may breach the confidentiality of the ABP, the ABP Foundation, or any of the trainees or diplomates it serves.

### **Possible Conflict of Interest with Systematic Investigations Conducted by the ABP**

Because work conducted and/or supported by the ABP should align with its mission, the ABP has a vested interest in all the Systematic Investigations that it conducts. In the rare case that the ABP Board of Directors, the ABP Foundation Board of Directors, or the Research Advisory Committee believe a critical area of investigation represents a true conflict of interest, the relevant Department, in conjunction with the ABP senior leadership, will propose a solution to the ABP and/or ABP Foundation Boards of Directors. Recommendations may include that the investigation be reviewed and/or conducted by an external entity. In addition, any presentation or paper should state the ABP's role in the project in the section required by the scientific conference proceedings or journal (e.g., disclosures, methods, conflict of interest, acknowledgement, and disclaimer).

If an external entity is concerned about possible conflict of interest with respect to Research conducted by a foundation-funded project, the entity may provide a written request for review by an external party to the current chair of the ABP Foundation Board of Directors.





# ABP Corporate Policy

## Research and Other Systematic Investigations

### References

1. VHA Handbook 1058.05 §4.a.
2. 45 CFR 46.102(d). [As revised/effective 2017/2018: 45 CFR 46.102(l)]
3. VHA Handbook 1058.05 §4.d.
4. Health Resources and Services Administration: Quality Improvement (HRSA). <https://www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/qualityimprovement.pdf>
5. Office for Human Research Protections (OHRP): Quality Improvement Activities (Frequently Asked Questions). <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>
6. ABP: Mission Statement. <https://www.abp.org/content/mission-statement>
7. VHA Handbook 1058.05 §4.e
8. Veterans Health Administration (VHA) Handbook 1058.05 (2011): VHA Operations Activities That May Constitute Research. <https://www.va.gov/ORO/oropubs.asp>
9. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1978). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. [Bethesda, Md.]: The Commission.
10. Yarbrough DB, Shulha LM, Hopson RK, & Caruthers FA. (2011). *The program evaluation standards: A guide for evaluators and evaluation users* (3rd ed.). Thousand Oaks, CA: Sage.
11. Baily MA, "Quality Improvement Methods in Health Care," in *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, ed. Mary Crowley (Garrison, NY: The Hastings Center, 2008), 147-152.
12. Taylor HA, Pronovost PJ, Faden RR, Kass NE, Sugarman J. The Ethical Review of Health Care Quality Improvement Initiatives: Findings from the Field. [http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2010/Aug/1436\\_Taylor\\_ethical\\_review\\_hlt\\_care\\_qual\\_improve\\_ib\\_v4.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2010/Aug/1436_Taylor_ethical_review_hlt_care_qual_improve_ib_v4.pdf)
13. Selker H, Grossman C, Adams A, Goldmann D, Dezii C, Meyer G, Roger V, Savitz L, Platt R. The Common Rule and Continuous Improvement in Health Care: A Learning Health System Perspective. <http://www.nationalacademies.org/hmd/Activities/Quality/~media/Files/Activity%20Files/Quality/VSRT/Discussion%20Papers/CommonRule.pdf>
14. Dokholyan RS, Muhlbaier LH, Falletta JM, Jacobs JP, Shahian D, Haan CK, Peterson ED. Regulatory and ethical considerations for linking clinical and administrative databases. *Am Heart J.* 2009 Jun;157(6):971-82. doi: 10.1016/j.ahj.2009.03.023.
15. ABP: Research Activities Policy (November 1, 2016), page 4.

Policy Adopted Date: 03/18

Last Non-Contextual Revised: 09/19

Last Revision Approved by the Board of Directors/Executive Committee: 03/18



# ABP Corporate Policy

## Research and Other Systematic Investigations

### Appendix A

#### The American Board of Pediatrics – Systematic Investigation Review Form

Project Title/Name \_\_\_\_\_  
Department(s) \_\_\_\_\_  
Name(s) \_\_\_\_\_  
Date of Work Beginning \_\_\_\_\_  
Date of Submission for review \_\_\_\_\_

#### 1. Briefly describe the project.

*In just a few sentences, please describe the project and its operational or research significance to your department/work.*

*Also, please mention if you will be using existing data, generating new data, using surveys, focus groups, or otherwise contacting people to complete this project.*

#### 2. Does this work involve the combination of data sets? If yes, please describe the data sets.

Yes, combining only internal data  Yes, combining internal and external data  No

*Data Set 1: who owns it; publicly available, contain PII or private information, etc.?  
Data Set 2:  
Etc.*

#### 3. Do you intend to publish or otherwise publicly disseminate information on this project? If yes, please describe your intentions.

Yes  No

*Please list what mechanisms you plan to publish on this work.*

#### 4. Does this project include any interactions with human participants (e.g., focus groups, interviews)? If yes, describe your intentions and how you are addressing the three core principles of the Belmont report (i.e., respect for persons, beneficence, justice) and the three primary applications (i.e., informed consent, assessment of risks and benefits, participant selection).

Yes  No

*Please describe how you are addressing the three core principles of the Belmont report and the three primary applications.*



## ABP Corporate Policy

### Research and Other Systematic Investigations

5. Please describe why you think this Systematic Investigation qualifies as an Operational Investigation as defined by the ABP Policy titled “Research Activities and other Systematic Investigations Policy (formerly Research Activities Policy).”

*Specify:*