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A Novel Protocol for Streamlined IRB Review of PBRN Card Studies

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Abstract

Purpose—The “card study,” in which clinicians record brief information about patient visits during usual clinical care, has long been a rapid method for conducting descriptive studies in practice-based research networks (PBRNs). Since an increasingly stringent regulatory environment has made conducting card studies difficult, we developed a streamlined method for obtaining card study Institutional Review Board (IRB) approval.

Methods—We developed a protocol for a *study of the card study method*, allowing new card study proposals of specific research questions to be submitted as *addenda* to the approved Card Study Protocol.

Results—Seven card studies were proposed and approved under the Card Study Protocol during the first year post implementation, contrasted with one card study proposed in the previous year. New card study ideas submitted as addenda to an approved protocol appeared to increase IRB comfort with the card study as a minimal risk method while reducing the hurdles to developing new study ideas.

Conclusions—A Card Study Protocol allowing new study questions to be submitted as addenda decreases time between idea generation and IRB approval. Shortened turn-around times may be useful for translating ideas into action while reducing regulatory burden.

Keywords

practice-based research network; practice-based research; card study; weekly return; HIPAA; primary care research; institutional review board

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Introduction

The majority of research conducted in the United States is basic science investigation carried out in academic medical centers.¹ Discoveries from this research can take years or decades to translate into clinical practice² and are often not directly applicable to clinical practice, since research conducted in highly controlled settings differs greatly from community medical offices, the setting where most medical care is delivered to most patients.^{3, 4}

In response to concerns about the relevance and slow translation into practice of most research, two threads of solutions have emerged. One thread is the practice-based research network (PBRN), in which clinicians on the front lines of health care band together to generate relevant new knowledge.⁵⁻¹² Another more recent development is the NIH Clinical and Translational Science Award (CTSA),¹³⁻¹⁵ which aims to transform the way research is conducted and translated into practice and community applications.^{10, 13-15} Many CTSA involve collaboration with PBRNs.¹⁶

The Card Study and the Research Regulatory Environment

A staple PBRN study method developed by the Ambulatory Sentinel Practice Network (ASPN) more than two decades ago is the weekly return card,^{17,18} or “card study.”¹⁹ In card studies a question about clinical practice is refined by the network into a short series of observational data elements that can be quickly recorded on a pocket-sized data collection card during the course of routine practice.¹⁹ Card studies are used by many PBRNs for rapid turnaround pilot studies and have made important contributions of new knowledge to the published literature.¹⁹⁻²⁴ Example study cards are included in the online appendix and in Figure 1.

Institutional Review Boards (IRBs) must review research protocols to ensure that the research is ethical and protects the rights and welfare of human subject participants.²⁵ However, IRB review can be a difficult process for practice-based researchers, as these researchers struggle to learn and apply unfamiliar rules regarding research.¹⁶ A rapid cycle between raising and answering PBRN questions facilitates ongoing clinician engagement. The wide variation in how IRBs review research,²⁶ including observational research studies,²⁷ creates confusion and can create a bottleneck in the PBRN research process.^{28,29}

The card study has traditionally been a low risk method that often received expedited IRB review. However, the research regulatory environment has become more stringent³⁰ since the card study method was first developed, increasing barriers to conducting PBRN card studies. Additional privacy regulations imposed by the Health Insurance Portability and Accountability Act (HIPAA)³¹ along with increased regulatory scrutiny cause IRBs to raise their threshold of concern, even for minimal risk observational studies, such as card studies.³²⁻³⁷ This challenge causes researchers and clinicians to modify study ideas, or forgo certain study designs altogether when IRB submission is viewed as “not worth the effort.”³⁷

Streamlining the process of clinical and translational research while protecting participants is a major focus of CTSA, and many have dedicated shared resources to research regulation. In Cleveland, the Clinical & Translational Science Collaborative worked to

engage the experience of both our PBRN and Regulatory Shared Resources to develop, implement and evaluate a novel approach to streamline the process of IRB approval for card studies. This paper describes that process, and includes an appendix that can be adapted by other PBRNs, CTSA's and IRBs seeking to meet the joint aims of protecting research participants, developing PBRNs, and speeding the translation of clinical research questions into investigation and dissemination.

Methods

Development of a Single, Streamlined IRB Protocol for Card Studies

Given this clinical and regulatory environment, the PBRN Shared Resource began to investigate facilitation of efficient turnaround of card studies. In brainstorming with the CTSA Head of Regulatory Knowledge, a *study of the card study method* was suggested as a possible method for allowing easy review of specific card studies asking new study questions.

The Card Study Protocol

A parent study *of the card study method*, the Card Study Protocol, was developed by the PBRN Shared Resource. The objective of the Card Study Protocol is to understand the uptake of different card studies. The Card Study Protocol outlines a set of requirements for low risk card studies, such as collection of de-identified data, and describes a standard set of procedures including recruitment methods, data collection, data management, and privacy procedures. Specific *new card studies are then added as addenda to the parent protocol*, so long as the individual card studies fit the standard criteria.

The Card Study Protocol modifies the traditional process of conducting card studies through generating and submitting a protocol and IRB submission that must undergo new protocol review for each individual card study. The Card Study Protocol combines multiple de-identified and/or limited dataset (minimal risk) card studies into one continuous protocol, under one principal investigator. As new card studies are proposed, the Card Study Protocol is amended to include additional research questions and the clinician or researcher who proposes the new card study idea is added as a co-investigator to the parent protocol.

Results

Combing all minimal risk card studies into one study *of the card study method* facilitated IRB review, resulting in increased efficiency as the IRB does not have to revisit the issue of what a card study is each time an additional question is submitted. In addition, review of amendments is a more efficient process focused almost exclusively on “changes” compared with new protocol reviews requiring review of all aspects of a proposed study, including methods previously approved under separate IRB applications. The complete Card Study Protocol is included in the online appendix for those who wish to use this as a model for their own IRB applications.

The Card Study Protocol was submitted for IRB review in March of 2009 and approved in June of 2009, a quicker process than usual, attributed to meetings with the IRB regarding the

proposed Card Study Protocol prior to submission. Seven card studies were proposed and approved as part of the protocol during the first year of use, compared to the previous year where one card study was proposed but not submitted to the IRB or implemented. The most recent card study addendum received approval in seven calendar days, compared with similar risk studies not tied to the Card Study Protocol having previously taken nearly one year to receive approval.

In addition, we are finding that the threshold for proposing ideas is reduced for PBRN members as well as academic health center investigators because of a sense that new ideas have a chance to get into the field quickly, while enthusiasm from initial idea generation is fresh. Similarly, IRB staff and members report that seeing new study ideas as addenda to a protocol that has already been reviewed and judged to be minimal risk makes it easier to understand the context and minimal risk nature of new card studies. This familiarity with the method increases the likelihood of identifying and determining the particular risks and benefits of the new question, data, and study sample.

While card studies under the Card Study Protocol are limited to low risk studies involving de-identified data, a wide range of study types are still possible. Card studies approved under the Card Study Protocol have included exploring patient visits, such as developmental surveillance in well-child health visits, the frequency of patients presenting information gathered online before visits, patients mentioning direct to consumer advertising in visits, and patients raising dental concerns during medical visits. A survey study of clinicians has also been included, stretching the notion of cards to include large, two-sided data collection forms.

Discussion

Engaging clinicians, patients, and questions from real world practice are vital to efforts to increase the relevance and utility of clinical research. Card studies are a tried and true method for accomplishing this, with continued relevance to complement or be applied to electronic data collection.^{19,38} We have found the Card Study Protocol described here to be feasible and useful in educating IRBs and PBRNs about each other, while facilitating safe and timely clinical research.

This Card Study Protocol is not appropriate for greater than minimal risk studies that may use extensions of the card study method.¹⁹ Such studies should undergo individual review. Our evaluation of this protocol is informal and based on a single IRB and handful of local PBRNs over a short period. However, we believe that this early experience and the face value of the idea of studying the card study method through a single protocol where additional minimal risk study questions are introduced through addenda justify sharing this idea with the PBRN and research regulatory communities so that additional experience can be gained and immediate benefits we observed can be realized by others. Further research should examine the longer-term effects of the Card Study Protocol on the relationships between PBRN investigators, IRB staff and relevant IRB members, as well as on protocol review time, participant safety, and the generation of new knowledge relevant to clinical practice. This work embodies a goal of the CTSA, to reduce regulatory burden for

investigators in order to promote the conduct and growth of clinical/translational research.^{13–15, 39}

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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| Evolution of Reason for Visit | ID _____ |
| Patient Characteristics Sex: F M Age: _____ Race: _____ | |
| English Primary: Y N Insurance: Private Public Both None | |
| Was another person in room: Y N If yes, relationship: _____ | |
| I felt time pressure: Not at all [1 2 3] A lot Visit duration: _____ min | |
| I know this patient: Not at all [1 2 3] A lot | |
| Number chronic conditions: _____ Number Current Medications: _____ | |
| Primary diagnosis: _____ Total problems addressed: _____ | |
| Secondary diagnoses: _____ | |
| <i>Continued on back</i> → | |
| Reason for visit provided to office staff: _____ | |
| Reason for visit provided to you at beginning of visit: _____ | |
| What do you think was the patient's main reason for visit today: _____ | |
| Was this brought up: <input type="checkbox"/> Early <input type="checkbox"/> Mid-Visit <input type="checkbox"/> Late | |
| As the physician, what was your main concern for the visit today: _____ | |
| Concordance: <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Absent | |
| Additional comments: _____ | |

Figure 1.
Identification of developmental delays card study data collection card.