### 45 CFR 46 Subpart D—Additional Safeguards for Children

| **ALL** | • Adequate provisions for child's assent & parental permission  
• Appropriate documentation |
|---|---|
| **Minimal Risk**  
(§46.404) | • No greater than minimal risk to children is presented  
• Permission of **one** parent is sufficient |
| **Greater than minimal risk; direct benefit to subject**  
(§46.405) | • Risk is justified by anticipated benefit  
• Benefit to risk relationship is at least as favorable as that of alternatives  
• Permission of **one** parent is sufficient |
| **Greater than minimal risk; likely to yield generalizable knowledge**  
(§46.406) | • Minor increase over minimal risk  
• Likely to yield knowledge of vital importance for the understanding or amelioration of the disorder or condition  
• Procedures reasonably commensurate with those inherent in actual or expected medical, dental, psychological, social, or educational situations  
• **Both** parents must give permission* |
| **Not otherwise approvable but presents opportunity to understand, prevent, or alleviate a serious problem**  
(§46.407) | • Reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children  
• Approval granted by HHS Secretary (or FDA Commissioner, if applicable)  
• **Both** parents must give permission* |

*unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
IRB Primer: Incidental and Secondary Findings

In December 2013, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) released its report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*. The report outlines the types of findings that can arise from various tests and procedures in a variety of contexts, and makes 17 recommendations for the ethical and professional management of such findings.

This primer was designed to help institutional review boards (IRBs) understand and implement the Bioethics Commission’s recommendations regarding how to manage incidental and secondary findings ethically in the research setting. IRB members can use it to improve their understanding of the Bioethics Commission’s recommendations and consider how to ensure the ethical management of incidental and secondary findings that could arise in the protocols they review. Please see *Anticipate and Communicate* for further reading on the Bioethics Commission’s analysis and recommendations (Executive Summary, pp. 2-20 and Chapter 5, pp. 75-93).

The final page of this primer provides a list of recommended considerations for IRBs and their members as they review researchers’ procedures for ethically managing incidental and secondary findings. This primer and the list of considerations are not derived from regulations. Rather, the primer reflects the Bioethics Commission’s recommendations regarding the ethical management of incidental and secondary findings. IRBs can use this primer to aid in their ethical decision making.

IRBs should consider how they will evaluate researchers’ plans and polices for the management of incidental and secondary findings. There are many ways that IRBs can ensure that research teams have procedures in place, including clear informed consent materials that convey the plan for incidental findings management; an appropriate plan for the incorporation of outside expertise if necessary to evaluate or return incidental findings; thoughtful consideration of whether, when, and how to incorporate participant preferences; and, if researchers decide to return certain incidental findings, a clear policy outlining what follow-up assistance will be provided. IRBs can find further guidance regarding these elements below.

**FREQUENTLY ASKED QUESTIONS**

1. **What are incidental and secondary findings?**
   
   Incidental findings traditionally are defined as results that are outside the original purpose for which a test or procedure was conducted. These are distinct from *primary findings*, which are the results that are actively sought as the primary target of a test or procedure.
Incidental findings can be either “anticipatable” or “unanticipatable.” An anticipatable incidental finding is one that is known to be associated with a test or procedure. Anticipatable incidental findings need not be common or even likely to occur—their defining characteristic is that the possibility of finding them is known.

Unanticipatable incidental findings include findings that could not have been anticipated given the current state of scientific knowledge. Researchers cannot plan for these types of findings specifically. However, they can consider in advance what they might do if a particular kind of unexpected finding arises, for example, one that could be actionable or lifesaving.

A secondary finding, by contrast, is not the primary target of the test or procedure; rather, it is an additional result actively sought by the practitioner. Secondary findings might be sought deliberately when doing so is recommended by an expert body or by a consensus of practitioners. The following table provides examples of each type of finding.

### Bioethics Commission Classification of Individualized Results of Medical Tests

<table>
<thead>
<tr>
<th>TYPE OF RESULT DISCOVERED</th>
<th>DESCRIPTION</th>
<th>EXAMPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Finding</td>
<td>Practitioner aims to discover A, and result is relevant to A</td>
<td>In a child with unknown vaccine history, a test done to determine a child’s immunity status before the chickenpox vaccine is administered</td>
</tr>
<tr>
<td>Incidental Finding: Anticipatable</td>
<td>Practitioner aims to discover A, but learns B, a result known to be associated with the test or procedure at the time it takes place</td>
<td>Discovering misattributed paternity when assessing a living kidney donor and potential recipient who believe they are biologically related</td>
</tr>
<tr>
<td>Incidental Finding: Unanticipatable</td>
<td>Practitioner aims to discover A, but learns C, a result not known to be associated with the test or procedure at the time it takes place</td>
<td>When a DTC genetic testing company identifies a health risk based on a newly discovered genetic association not knowable at the time a previous sample was submitted</td>
</tr>
<tr>
<td>Secondary Finding</td>
<td>Practitioner aims to discover A, and also actively seeks D per expert recommendation</td>
<td>ACMG recommends that laboratories conducting large-scale genetic sequencing for any purpose should actively look for variants underlying 24 phenotypic traits</td>
</tr>
</tbody>
</table>


2. **What are some of the tests or procedures that could give rise to incidental and secondary findings?**

A variety of tests and procedures can give rise to incidental and secondary findings. Examples include:

• **Large-Scale Genetic Sequencing**: Genetic sequencing is the analysis and ordering of the billions of base pairs—the As, Ts, Cs, and Gs—that make up the human genome. Large-scale genetic sequencing techniques include whole genome sequencing, whole exome sequencing, and other next-generation genomic analyses. Because of the large number of base pairs sequenced and potentially analyzed, large-scale genetic sequencing has the potential to yield large numbers of incidental and secondary findings. While some variants discovered during large-scale genetic sequencing reveal clinically relevant information, much of the data produced are of unknown or uncertain medical value. In addition, incidental and secondary findings that arise in genetic sequencing also can have implications for biologically-linked family members.

• **Testing of Biological Specimens**: Analysis of biological specimens such as blood, urine, or bodily tissues can be a source of incidental or secondary findings. Incidental and secondary findings arising from blood and tissue testing could definitively indicate a health issue of concern, or could require a series of additional diagnostic tests to determine the health implications, if any, of the result. For example, a researcher might order a metabolic panel to assess kidney function, but the laboratory results might reveal an incidental finding of liver dysfunction.

• **Imaging**: Medical imaging includes magnetic resonance imaging (MRI), computed tomography (CT) scans, X-rays, neuroimaging, and ultrasounds, among others. The images produced provide visualization of an entire field of study and can give rise to incidental and secondary findings in areas outside the area of diagnostic interest. For example, scans of the abdomen and pelvis can include images of the kidneys, liver, adrenal glands, and pancreas, only one of which might be the organ of interest to researchers.

3. **Why should researchers inform research participants about the possibility of incidental and secondary findings?**

Researchers should communicate the fundamental aspects of their research—including the possibility of discovering incidental or secondary findings and the plan for their disclosure or management—so that participants can make fully informed decisions about whether to enroll. IRBs should review informed consent materials to ensure that researchers have included information about incidental and secondary findings and the plan for management of these findings.

Researchers can ascertain at the outset what participants prefer to know—and not know—about incidental or secondary findings. For example, a participant might prefer to know about only those findings that are clinically significant, actionable, and lifesaving. Acting in accordance with participants’ expressed preferences about whether to receive incidental and secondary findings, to the extent possible, helps researchers to respect participants’ autonomy. If practical
or logistical constraints prevent a researcher from searching for, interpreting, or disclosing incidental findings, the researcher can propose a plan that incidental and secondary findings will not be returned. Disclosing a plan for managing incidental findings, and allowing for nonparticipation if a prospective participant chooses, appropriately respects an individual’s ability to make autonomous and informed decisions about whether to participate in research.

4. What are some of the arguments in favor of returning—or not returning—incidental and/or secondary findings?

Researchers and IRBs should carefully consider both the potential benefits and risks of disclosure of incidental and secondary findings. Disclosing certain incidental findings might lead participants to obtain lifesaving medical interventions, or help participants make informed medical decisions. However, disclosure also could lead to needless further testing, additional incidental findings, costs, and anxiety and distress, potentially with no corresponding medical benefit. Researchers should evaluate whether the prospective benefits of an action outweigh the risks.

Researchers also should consider carefully whether to allocate time and resources to seeking secondary findings, or to interpreting, assessing, and disclosing incidental findings, especially when these decisions might benefit individuals in the research study but stall broader societal benefits of the research activity. Researchers do not have an ethical duty to seek secondary findings. However, researchers must determine how their incidental findings management policy will affect participants as individuals, and how it will affect their ability to create generalizable knowledge. The following table of ethical principles and their application to incidental and secondary findings can help researchers reconcile these considerations.
### Ethical Principles in the Research Context

<table>
<thead>
<tr>
<th>Principle</th>
<th>Definition</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for Persons</td>
<td>This principle recognizes the fundamental human capacity for rational self-determination.</td>
<td>Researchers must communicate the fundamental aspects of their research—including the possibility of discovering incidental or secondary findings and the plan for their disclosure or management—so that participants can make informed decisions about whether to enroll.</td>
</tr>
<tr>
<td>Beneficence</td>
<td>This principle calls on professionals to take action to ensure the wellbeing of others. Its corollary, non-maleficence, requires not imposing harm on others.</td>
<td>This principle supports returning findings when disclosure might help forestall or prevent harm. By contrast, disclosing an incidental finding for which no preventive or positive action can be taken has the potential to cause anxiety and distress with no corresponding medical benefit.</td>
</tr>
<tr>
<td>Justice and Fairness</td>
<td>This principle requires fair and equitable distribution of the potential benefits and burdens across society.</td>
<td>The principle of justice and fairness calls upon researchers to take into account how policies for returning incidental and secondary findings could benefit or burden some participants or, alternatively, could burden the research enterprise and the ability to create generalizable knowledge.</td>
</tr>
<tr>
<td>Intellectual Freedom and Responsibility</td>
<td>This principle protects sustained and dedicated creative intellectual exploration that furthers scientific progress, while requiring that researchers take responsibility for their actions.</td>
<td>This principle supports affording wide latitude to researchers in pursuing their scientific goals and engaging in intellectual exploration for the good of society, while also expecting that researchers uphold and respect the trust placed in them by participants. Ethical conduct of research with human participants includes acknowledgment and planning for incidental and secondary findings.</td>
</tr>
</tbody>
</table>

5. **What constitutes an ethically appropriate plan for the management of incidental and secondary findings?**

Researchers have an ethical duty to plan for incidental findings—whether common or rare—to the extent possible. However, researchers do not have an ethical duty to look for secondary findings. Researchers should develop a plan based on evidence about the analytic and clinical validity of potential findings and their clinical or reproductive significance, and careful consideration of the benefits, risks, and costs of disclosure, including the risk that seeking or analyzing incidental and secondary findings might distract from the central goal of research. For certain kinds of research, disclosure of incidental findings is difficult, if not impossible. For example, often, the data stored in biobanks are de-identified, and researchers cannot readily link the data to particular individuals, which makes the return of incidental findings infeasible or impractical. In such cases, researchers can develop a plan of nondisclosure, which should be thoughtfully deliberated and evaluated by an IRB. IRBs should review researchers’ plans for managing incidental findings, and ensure that all relevant issues are considered thoughtfully. IRBs can consider the following elements in determining what guidance to offer investigators.

Informed Consent

Researchers should develop a plan for managing the types of findings that might arise, and clearly communicate the plan to participants during the informed consent process—even if the plan is not to disclose any incidental or secondary findings. This allows individuals to choose not to participate in research if they are uncomfortable with a researcher’s management plan. When reviewing consent materials, IRBs should evaluate whether the following elements have been considered and included.

- Secondary findings that will be actively sought and returned to participants should be conveyed in the informed consent process, and there should be a specific plan for their return.

- A plan for anticipatable incidental findings (e.g., that researchers will or will not return some or all potential findings) also should be conveyed in the informed consent process, and, to the extent that the findings will be returned, a plan should be described.

- For findings that are unanticipatable, researchers should plan for the types of findings that might arise and plan for return if applicable (e.g., that researchers will return unanticipatable lifesaving findings, but will not return unanticipatable findings of unknown significance).

Expertise

Some incidental findings could fall outside of researchers’ expertise. IRBs should verify that researchers are sufficiently familiar with anticipatable incidental findings associated with the tests or procedures used in their research to formulate and communicate a plan for how these findings will be managed. If researchers need additional expertise to manage incidental and secondary findings, an IRB could suggest they add this expertise by, for example:

- adding members to the research team who have sufficient expertise to manage the range of anticipatable incidental findings;

- relying on research ethics consultants or IRBs if there is uncertainty as to the advisability of disclosing a particular finding to a participant; and/or

- seeking qualified clinical or diagnostic experts for consultation when researchers are uncertain whether a finding has clinical or reproductive significance.

IRBs should consider whether they have the resources or expertise to assist researchers when considering difficult cases. In addition, IRBs should provide guidance to inform how researchers might develop and communicate the plan for disclosing and managing findings that are outside the researchers’ area of expertise. For example, researchers might wish to disclose genetic
incidental findings in the presence of a genetic counselor to assist participants in understanding the finding’s significance.

**Participant Preferences**

If researchers plan to inform participants of certain types of incidental or secondary findings, they should decide in advance how to respect the wishes of participants who choose to opt out of receiving these findings. IRBs should review researchers’ plan for communicating findings, which should be communicated as part of the informed consent process.

- If researchers have ethical objections to allowing participants to opt out of receiving clinically significant, actionable, and lifesaving findings, they need not enroll such individuals in their research study. Delineating such exclusion criteria for study enrollment will minimize this type of ethically challenging situation once the research protocol is underway.

- If researchers do not object to allowing participants to opt out of receiving incidental findings—and participants are well informed regarding what opting out could mean for their health and wellbeing—researchers may enroll such participants in the research.

- If a researcher discovers a potentially lifesaving unanticipatable incidental finding for a participant who has opted out of receiving incidental findings generally, the investigator should seek advice from an IRB about whether and how to disclose it. IRBs should be prepared to answer researchers’ questions about whether to disclose a lifesaving incidental finding to a participant who has opted out.

**Researcher Responsibilities**

Researchers’ plans for managing incidental findings also should include a description of the research team’s responsibilities following disclosure of such a finding. In some cases, researchers might provide:

- basic educational information about the nature of the finding;

- advice regarding how to seek care from a clinician or specialist;

- guidance about obtaining health insurance to secure treatment; and/or

- a referral to a clinical specialist, if one is required.
Considerations for Ethical Management of Incidental and Secondary Findings

Identifying Incidental and Secondary Findings:
- Researchers should identify any secondary findings they plan to seek actively during their research.
- Researchers should identify any anticipatable incidental findings that might arise during their research.
- Researchers should identify the general types of unanticipatable incidental findings that might arise during their research (e.g., lifesaving, clinically actionable, of unknown significance).

Recognizing and Analyzing Incidental and Secondary Findings:
- Researchers should have a plan for recognizing, analyzing, and handling incidental and secondary findings.
- If anticipatable incidental or secondary findings might require additional expertise to recognize or analyze, researchers should consider adding such expertise to the team (e.g., consulting a professional with the necessary expertise or otherwise having one available for consultation).

Informed Consent for Incidental and Secondary Findings:
- Researchers should inform potential participants of the following:
  - Secondary findings they intend to seek and return.
  - Anticipatable incidental findings that might arise during the research and the plan for returning results.
  - General types of unanticipatable incidental findings that might arise during the research and the plan for management of such findings.
- Researchers should describe the kinds of findings that might be disclosed, the process for disclosing them, and whether and how participants might opt out of receiving certain findings.
- Researchers should indicate in the informed consent process any exclusion criteria for individuals who wish to opt out of receiving clinically significant, actionable, and lifesaving findings.

Returning Incidental and Secondary Findings:
- Researchers should have a designated plan for returning incidental and secondary findings to participants. The plan might include the option for participants to opt out of receiving incidental or secondary findings, or might be to return no findings to participants.
- Researchers should respect the wishes of participants who choose to opt out of receiving incidental or secondary findings, but in the event a researcher discovers a potentially lifesaving unanticipatable incidental finding for a participant who has opted out of receiving incidental findings, the investigator should seek advice from an IRB about whether and how to disclose it.
FDA grapples with oversight of fecal transplants

WASHINGTON (AP) — Imagine a low-cost treatment for a life-threatening infection that could cure up to 90 percent of patients with minimal side effects, often in a few days.

It may sound like a miracle drug, but this cutting-edge treatment is profoundly simple — though somewhat icky: take the stool of healthy patients to cure those with hard-to-treat intestinal infections. A small but growing number of physicians have begun using these so-called fecal transplants to treat Clostridium difficile, commonly referred to as C-diff, a bacterial infection that causes nausea, cramping and diarrhea. The germ afflicts a half-million Americans annually and kills about 15,000 of them.

But fecal transplants pose a challenge for the Food and Drug Administration, which has decided to regulate the treatment as an experimental drug. Stool transplants don’t fit neatly into the agency’s standard framework. And while regulators have shown flexibility in their approach, some critics say the mere presence of government oversight is discouraging many doctors from offering transplants. That’s led some patients to seek out questionable “do-it-yourself” websites, forums and videos.

Most researchers agree that the FDA’s concerns are warranted. Patients can contract HIV, hepatitis and other viruses and parasites from fecal matter that is not properly screened. Additionally, there are no long-term studies on potential side effects of stool transplantation.

FDA officials declined to be interviewed for this story, but said in a written response that the fecal transplantation "shows promise in treating C. difficile infection that has not been responsive to other therapies."

Indeed, with many patients no longer responding to potent antibiotics, fecal transplants have emerged as an effective therapy against drug-resistant strains of the C-diff superbug. The procedure works because the healthy bacteria found in donors’ faces can help fight off foreign infections.

"We’re dealing with something that is pretty close to miraculous," says Dr. Lawrence Brandt of New York’s Montefiore Medical Center, who has performed over 200 fecal transplants.

Most products reviewed by the FDA spend years in testing before they are submitted to the agency, usually by large drug or medical device developers. Fecal transplants have followed a different path.

In recent years, a handful of doctors have published small case studies on their use of stool to treat C-diff, with many reporting cure rates of about 90 percent. In January 2013, the New England Journal of Medicine published the first rigorous, head-to-head study showing that fecal transplants were superior to antibiotics for patients with recurring C-diff.

The FDA announced last May that it would regulate stool transplants as an experimental drug, meaning doctors could only perform transplants under an FDA-approved research application. The so-called investigational new drug application must include detailed information on the drug to be tested, the study design and safeguards to protect patients. Assembling a single application can take months or years, even for large drugmakers.

Doctors pushed back, saying the requirement would force them to turn away desperate patients.

"FDA and some others are concerned about the long-term
effects," Brandt said. "But my point was these people are getting ready to die now. They are not going to survive long enough to develop the diseases you're afraid they're going to get."

A few weeks later, the FDA revised its position, saying it would not enforce the requirement for doctors treating patients with drug-resistant C-diff — provided donors are properly screened and patients are informed that fecal transplants are still experimental.

But regulating stool samples as a drug presents other challenges. While it's easy to limit access to experimental drugs, everyone has access to stool. And with detailed instructions available on websites like thepowerofpoop.com, there's nothing to stop patients from trying the procedure at home — especially if they can't find a doctor to perform it.

"Some of these patients are very desperate and they're not going to take no for an answer," says Dr. Michael Edmond of Virginia Commonwealth University, who has performed fecal transplants for patients who travel from as far away as Ohio.

Catherine Duff of Carmel, Indiana, says she had no choice but to help herself. In April 2012, she was suffering through her seventh C-diff. infection, going to the bathroom 20 to 30 times a day and making multiple trips to the hospital due to dehydration.

"My quality of life had gotten to the point where I was beginning to think that it might be better to die," says Duff, 58.

Duff asked three different physicians if she could try a fecal transplant, but none were willing to perform the procedure. Her gastroenterologist did offer to test her husband's stool to make sure it wasn't contaminated.

Using instructions found online, Duff and her husband created a solution from his stool sample, mixing it with saline in a blender and administering it via an enema bottle. Four hours later, Duff said she felt good enough to get up and go for a walk.

Today, Duff runs a nonprofit group, the Fecal Transplant Foundation, which aims to raise awareness of the procedure and help patients. Duff says she gets up to 15 emails a day from patients looking for a doctor or a donor. Some even ask if they can use a stool sample from their infants or pets.

Duff says the unresolved status of FDA's oversight discourages more doctors from offering the treatment. "There are so many doctors who are suspicious that the FDA could change their mind at any given moment and decide to not exercise discretion," Duff says.

According to a list maintained by the foundation, only about 100 physicians offer fecal transplants in the U.S. There is no one method for performing the procedure. Some doctors liquefy the stool and drip it into the patient's colon via colonoscopy. Others use a tube that runs from the nose down into the stomach.

With so few providers available, proponents of stool transplantation have come up with innovative solutions. One big hurdle is the high cost of screening a stool sample, which can run up to $1,500 per sample. Insurance typically doesn't cover testing the stool sample because donors are usually healthy without signs of sickness.

Since October 2013, a Boston-based "stool bank" has managed to bring costs down to about $250 per treatment by screening samples in bulk. To date, OpenBiome has shipped over 300 stool samples in ready-to-use frozen preparations to 30 hospitals.

But in March, the FDA released an updated proposal for regulating fecal transplants, saying doctors should only use stool from a donor who is "known" to either the patient or their physician. Some doctors and patients worried the proposal, if finalized, would shutter OpenBiome and a handful of other stool banks, which use anonymous donors and ship to providers hundreds of miles away.

But OpenBiome founder, Mark Smith, says his group continues operating after having several productive discussions with the FDA. Smith says regulators have encouraged him to set up a formal study in which hospitals that work with OpenBiome will contribute data on the safety and effectiveness of fecal transplants.

"They understand the importance of making treatment available for patients today, while making sure there is adequate oversight of the risks," Smith says. "We're actually totally on the same page."
Even the Editor of Facebook's Mood Study Thought It Was Creepy

"It's ethically okay from the regulations perspective, but ethics are kind of social decisions."

ADRIENNE LAFRANCHE | JUN 28 2014, 2:46 PM ET

Updated, Sunday, 6/29, 9:54 p.m. Eastern.

Catching a glimpse of the puppet masters who play with the data trails we leave online is always disorienting. And yet there's something new-level creepy about a recent study that shows Facebook manipulated what users saw when they logged into the site as a way to study how it would affect their moods.

But why? Psychologists do all kinds of mood research and behavior studies. What made this study, which quickly stirred outrage, feel so wrong?

Even Susan Fiske, the professor of psychology at Princeton University who edited the study for Proceedings of the National Academy of Sciences of America, had doubts when the research first crossed her desk.

"I was concerned," she told me in a phone interview, "until I queried the authors and they said their local institutional review board had approved it—and apparently on the grounds that Facebook apparently manipulates people's News Feeds all the time... I understand why people have concerns. I think their beef is with Facebook, really, not the research."

"Who knows what other research they're doing."

Institutional review boards, or IRBs, are the entities that review researchers' conduct in experiments that involve humans.

[Update, Sunday, 9:54 p.m.: But there seems to be a question of whether Facebook actually went through an IRB. In a Facebook post on Sunday, study author Adam Kramer referenced "internal http://www.theatlantic.com/technology/archive/2014/06/even-the-editor-of-faces...
review practices." A Forbes report, citing an unnamed source, said that Facebook only used an internal review. When I asked Fiske to clarify, she told me the researchers' "revision letter said they had Cornell IRB approval as a 'pre-existing dataset' presumably from FB, who seems to have reviewed it as well in some unspecified way... Under IRB regulations, pre-existing dataset would have been approved previously and someone is just analyzing data already collected, often by someone else."

The mention of a "pre-existing dataset" here matters because, as Fiske explained in a follow-up email, "presumably the data already existed when they applied to Cornell IRB." (She also notes: "I am not second-guessing the decision.")

Universities and other institutions that get federal funding are required to have IRBs, which often rely on standards like the Common Rule—one of the main ethical guideposts that says research subjects must give their consent before they're included in an experiment. "People are supposed to be, under most circumstances, told that they're going to be participants in research and then agree to it and have the option not to agree to it without penalty," Fiske said.

I emailed the study's authors on Saturday afternoon to request interviews. Author Jamie Guillory responded but declined to talk, citing Facebook's request to handle reporters' questions directly. Early Sunday morning, a Facebook spokesman emailed me with this statement: "We carefully consider what research we do and have a strong internal review process. There is no unnecessary collection of people’s data in connection with these research initiatives and all data is stored securely."

Later on Sunday, study author Adam Kramer published a response on his Facebook page, saying he and his fellow researchers didn’t clearly explain the reasons for the study and that they "care about the emotional impact of Facebook."

Having written and designed this experiment myself, I can tell you that our goal was never to upset anyone. I can understand why some people have concerns about it, and my coauthors and I are very sorry for the way the paper described the research and any anxiety it caused. In hindsight, the research benefits of the paper may not have justified all of this anxiety.

("Hope it’s sufficient!" Kramer told me in an email about the Facebook post. "I have had about 200 media and personal requests in the last day so I don’t have time to carefully respond to everything.")

But Facebook, as a private company, doesn’t have to agree to the same ethical standards as federal agencies and universities, Fiske said.

"A lot of the regulation of research ethics hinges on government supported research, and of course Facebook’s research is not government supported, so they're not obligated by any laws or regulations to abide by the standards," she said. "But I have to say that many universities and research institutions and even for-profit companies use the Common Rule as a guideline anyway. It’s voluntary. You could imagine if you were a drug company, you’d want to be able to say you’d done the research ethically because the backlash would be just huge otherwise."

The backlash, in this case, seems tied directly to the sense that Facebook manipulated people—used them as guinea pigs—without their knowledge, and in a setting where that kind of manipulation feels intimate. There’s also a contextual question. People may understand by now that their News Feed...
appears differently based on what they click—this is how targeted advertising works—but the idea that Facebook is altering what you see to find out if it can make you feel happy or sad seems in some ways cruel.

Mood researchers have been toying with human emotion since long before the Internet age, but it's hard to think of a comparable experiment offline. It might be different, Fiske suggests, if a person were to find a dime in a public phone booth, then later learn that a researcher had left the money there to see what might happen to it.

"But if you find money on the street and it makes you feel cheerful, the idea that someone placed it there, it's not as personal," she said. "I think part of what's disturbing for some people about this particular research is you think of your News Feed as something personal. I had not seen before, personally, something in which the researchers had the cooperation of Facebook to manipulate people... Who knows what other research they're doing."

Fiske still isn't sure whether the research, which she calls "inventive and useful," crossed a line. "I don't think the originality of the research should be lost," she said. "So, I think it's an open ethical question. It's ethically okay from the regulations perspective, but ethics are kind of social decisions. There's not an absolute answer. And so the level of outrage that appears to be happening suggests that maybe it shouldn't have been done...I'm still thinking about it and I'm a little creeped out, too."