23

Changing Identities in Disclosure of Research Findings

Emily Postan

23.1 INTRODUCTION

This chapter offers a perspective on the long-running ethical debate about the nature and extent of responsibilities to return individually relevant research findings from health research to participants. It highlights the ways in which shifts in the research landscape are changing the roles of researchers and participants, the relationships between them, and what this might entail for the responsibilities owed towards those who contribute to research by taking part in it. It argues that a greater focus on the informational interests of participants is warranted and that, as a corollary to this, the potential value of findings beyond their clinical utility deserves greater attention. It proposes participants' interests in using research findings in developing their own identities as a central example of this wider value and argues that these could provide grounds for disclosure.

23.2 FEATURES OF EXISTING DISCLOSURE GUIDANCE

This chapter is concerned with the questions of whether, why, when and how individually relevant findings, which arise in the course of health research, should be offered or fed-back to the research participant to whom they directly pertain.[1] Unless otherwise specified, what will be said here applies to findings generated through observational and hands-on studies, as well as those using previously collected tissues and data.

Any discussion of ethical and legal responsibilities for disclosure of research findings must negotiate a number of category distinctions relating to the nature of the findings and the practices within which they are generated. However, as will become clear below, several lines of demarcation that have traditionally structured the debate are shifting. A distinction has historically been drawn between the intended (pertinent, or primary) findings from a study and those termed 'incidental' (ancillary, secondary, or unsolicited). 'Incidental findings' are commonly defined as individually relevant observations generated through research, but lying outwith the aims of the study.[2] Traditionally, feedback of incidental findings has been presented

[1] This chapter will not discuss responsibilities actively to pursue findings, or disclosures to family members in genetic research, nor is it concerned with feedback of aggregate findings. For discussion of researchers' experiences of encountering and disclosing incidental findings in neuroscience research see Pickersgill, Chapter 31 in this volume.

[2] S. M. Wolf et al., 'Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations', (2008) *The Journal of Law, Medicine & Ethics*, 36(2), 219–248.

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as more problematic than that of 'intended findings' (those the study set out to investigate). However, the cogency of this distinction is increasingly questioned, to the extent that many academic discussions and guidance documents have largely abandoned it.[3] There are several reasons for this, including difficulties in drawing a bright line between the categories in many kinds of studies, especially those that are open-ended rather than hypothesis-driven.[4] The relevance of researchers' intentions to the ethics of disclosure is also questioned.[5] For these reasons, this chapter will address the ethical issues raised by the return of individually relevant research results, irrespective of whether they were intended.

The foundational question of *whether* findings should be fed-back – or feedback offered as an option – is informed by the question of *why* they should. This may be approached by examining the extent of researchers' legal and ethical responsibilities to participants – as shaped by their professional identities and legal obligations – the strength of participants' legitimate interests in receiving feedback, or researchers' responsibilities towards the research endeavour. The last of these includes consideration of how disclosure efforts might impact on wider public interests in the use of research resources and generation of valuable generalisable scientific knowledge, and public trust in research. These considerations then provide parameters for addressing questions of *which* kinds of findings may be fed-back and under what circumstances. For example, which benefits to participants would justify the resources required for feedback? Finally, there are questions of *how*, including how researchers should plan and manage the pathway from anticipating the generation of such findings to decisions and practices around disclosure.

In the past two decades, a wealth of academic commentaries and consensus statements have been published, alongside guidance by research funding bodies and professional organisations, making recommendations about approaches to disclosure of research findings.[6] Some are prescriptive, specifying the characteristics of findings that ought to be disclosed, while others provide process-focused guidance on the key considerations for ethically, legally and practically robust disclosure policies. It is not possible here to give a comprehensive overview of all the permutations of responses to the four questions above. However, some prominent and common themes can be extracted.

Most strikingly, in contrast to the early days of this debate, it is rare now to encounter the bald question of *whether* research findings should ever be returned. Rather the key concerns are what should be offered and how.[7] The resource implications of identifying, validating and communicating findings are still acknowledged, but these are seen as feeding into an overall risk/benefit analysis rather than automatically implying non-disclosure. In parallel with this shift, there is less scepticism about researchers' general disclosure responsibilities. In the UK, researchers are not subject to a specific legal duty to return findings.[8] Nevertheless, there does appear to be a growing

[3] L. Eckstein et al., 'A Framework for Analyzing the Ethics of Disclosing Genetic Research Findings', (2014) *The Journal of Law, Medicine & Ethics*, 42(2), 190–207.

[4] B. E. Berkman et al., 'The Unintended Implications of Blurring the Line between Research and Clinical Care in a Genomic Age', (2014) *Personalized Medicine*,11(3), 285–295.

[5] E. Parens et al., 'Incidental Findings in the Era of Whole Genome Sequencing?', (2013) *Hastings Center Report*, 43(4), 16–19.

[6] For example, in addition to sources cited elsewhere in this chapter, see R. R. Fabsitz et al., 'Ethical and Practical Guidelines for Reporting Genetic Research Results to Study Participants', (2010) *Circulation: Cardiovascular Genetics*, 3(6),574–580; G. P. Jarvik et al., 'Return of Genomic Results to Research Participants: The Floor, the Ceiling, and the Choices in Between', (2014) *The American Journal of Human Genetics*, 94(6), 818–826.

[7] C. Weiner, 'Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts', (2014) *American Journal of Epidemiology*, 180(6), 562–564.

[8] Medical Research Council and Wellcome Trust, 'Framework on the Feedback of Health-Related Findings in Research', (Medical Research Council and Wellcome Trust, 2014).

consensus that researchers do have *ethical* responsibilities to offer findings – albeit limited and conditional ones.[9] The justifications offered for these responsibilities vary widely, however, and indeed are not always made explicit. This chapter will propose grounds for such responsibilities.

When it comes to determining what kinds of findings should be offered, three jointly necessary criteria are evident across much published guidance. These are captured pithily by Lisa Eckstein et al. as 'volition, validity and value'.[10] Requirements for analytic and clinical *validity* entail that the finding reliably measures and reports what it purports to. *Value* refers to usefulness or benefit to the (potential) recipient. In most guidance this is construed narrowly in terms of the information's clinical utility – construed as actionability and sometimes further circumscribed by the seriousness of the condition indicated.[11] Utility for reproductive decision-making is sometimes included.[12] Although some commentators suggest that 'value' could extend to the non-clinical, subjectively determined 'personal utility' of findings, it is generally judged that this alone would be insufficient to justify disclosure costs.[13] The third necessary condition is that the participant should have agreed *voluntarily* to receive the finding, having been advised at the time of consenting to participate about the kinds of findings that could arise and having had the opportunity to assent to or decline feedback.[14]

Accompanying this greater emphasis on the 'which' and 'how' questions is an increasing focus upon the need for researchers to establish clear policies for disclosing findings, that are explained in informed consent procedures, and an accompanying strategy for anticipating, identifying, validating, interpreting, recording, flagging-up and feeding-back findings in ways that maximise benefits and minimise harms.[15] Broad agreement among scholars and professional bodies that – in the absence of strong countervailing reasons – there is an ethical responsibility to disclose clinically actionable findings is not, however, necessarily reflected in practice, where studies may still lack disclosure policies, or have policies of non-disclosure.[16]

Below I shall advance the claim that, despite a greater emphasis upon, and normalisation of, feedback of findings, there are still gaps, which mean that feedback policies may not be as widely instituted or appropriately directed as they should be. Chief among these gaps are, first, a continued focus on researchers' inherent responsibilities considered separately from participants' interests in receiving findings and, second, a narrow conception of when these interests are engaged. These gaps become particularly apparent when we attend to the ways in which the roles of researchers and participants and relationships between them have shifted in a changing health research landscape. In the following sections, I will first highlight the nature of these changes, before proposing what these mean for participants' experiences, expectations and informational interests and, thus, for ethically robust feedback policies and practices.

23.3 THE CHANGING HEALTH RESEARCH LANDSCAPE

The landscape of health research is changing. Here I identify three facets of these changes and consider how these could – and indeed should – have an effect on the practical and ethical basis of policies and practices relating to the return of research findings.

[9] Berkman et al., 'The Unintended Implications'.
[10] Eckstein et al., 'A Framework for Analyzing'.
[11] Wolf et al., 'Managing Incidental Findings'.
[12] Ibid.
[13] Eckstein et al., 'A Framework for Analyzing'.
[14] Medical Research Council and Wellcome Trust, 'Framework on the Feedback'.
[15] Ibid.
[16] Berkman et al., 'The Unintended Implications'.

The first of these developments is a move towards 'learning healthcare' systems and translational science, in which the transitions between research and care are fluid and cyclical, and the lines between patient and participant are often blurred.[17] The second is greater technical capacities, and appetite, for data-driven research, including secondary research uses of data and tissues – sourced from patient records, prior studies, or biobanks – and linkage between different datasets. This is exemplified by the growth in large-scale and high-profile of genomic studies such as the UK's '*100,000 Genomes*' project.[18] The third development is increasing research uses of technologies and methodologies, such as functional neuroimaging, genome-wide association studies, and machine-learning, which lend themselves to open-ended, exploratory inquiries rather than hypothesis-driven ones.[19] I wish to suggest that these three developments have a bearing on disclosure responsibilities in three key respects: erosion of the distinction between research and care; generation of findings with unpredictable or ambiguous validity and value; and a decreasing proximity between researchers and participants. I will consider each of these in turn.

Much of the debate about disclosure of findings has, until recently, been premised on there being a clear distinction between research and care, and what this entails in terms of divergent professional priorities and responsibilities, and the experiences and expectations of patient and participants. Whereas it has been assumed that clinicians' professional duty of care requires disclosure of – at least – clinically actionable findings, researchers are often seen as being subject to a contrary duty to refrain from feedback if this would encourage 'therapeutic misconceptions', or divert focus and resources from the research endeavour.[20] However, as health research increasingly shades into 'learning healthcare', these distinctions become increasingly untenable.[21] It is harder to insist that responsibilities to protect information subjects' interests do not extend to those engaged in research, or that participants' expectations of receiving findings are misconceived. Furthermore, if professional norms shift towards more frequent disclosure, so the possibility that healthcare professionals may be found negligent for failing to disclose becomes greater.[22] These changes may well herald more open feedback policies in a wider range of studies. However, if these policies are premised solely on the duty of care owed in healthcare contexts to participants-as-patients, then the risk is that any expansion will fail to respond adequately to the very reasons why findings should be offered at all – to protect participants' core interests.

Another consequence of the shifting research landscape, and the growth of data-driven research in particular, lies in the nature of findings generated. For example, many results from genomic analysis or neuroimaging studies are probabilistic rather than strongly predictive, and produce information of varying quality and utility.[23] And open-ended and exploratory studies

[17] S. M. Wolf et al., 'Mapping the Ethics of Translational Genomics: Situating Return of Results and Navigating the Research-Clinical Divide', (2015) *Journal of Law, Medicine & Ethics*, 43(3), 486–501.

[18] G. Laurie and N. Sethi, 'Towards Principles–Based Approaches to Governance of Health–Related Research Using Personal Data', (2013) *European Journal of Risk Regulation*, 4(1), 43–57. Genomics England, 'The 100,000 Genomes Project', (Genomics England), www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/.

[19] Eckstein et al., 'A Framework for Analyzing'.

[20] A. L. Bredenoord et al., 'Disclosure of Individual Genetic Data to Research Participants: The Debate Reconsidered', (2011) *Trends in Genetics*, 27(2), 41–47.

[21] Wolf et al., 'Mapping the Ethics'.

[22] In the UK, the expected standard of duty of care is assessed to what reasonable members of the profession would do as well as what recipients want to know (see C. Johnston and J. Kaye, 'Does the UK Biobank Have a Legal Obligation to Feedback Individual Findings to Participants?', (2004) *Medical Law Review*, 12(3), 239–267.

[23] D. I. Shalowitz et al., 'Disclosing Individual Results of Clinical Research: Implications of Respect for Participants', (2005) *JAMA*, 294(6), 737–740.

pose challenges precisely because what they might find – and thus their significance to participants – are unpredictable and, especially in new fields of research, may be less readily validated. These characteristics are of ethical significance because they present obstacles to meeting the requirements (noted above) for securing validity, value and ascertaining what participants wish to receive. And where validity and value are uncertain, robust analysis of the relative risks and benefits of disclosure is not possible. Given these challenges, it is apparent that meeting participants' informational interests will require more than just instituting clear disclosure policies. Instead, more flexible and discursive disclosure practices may be needed to manage unanticipated or ambiguous findings.

Increasingly, health research is conducted using data or tissues that were collected for earlier studies, or sourced from biobanks or patient records.[24] In these contexts, in contrast to the closer relationships entailed by translational studies, researchers may be geographically, temporally and personally far-removed from the participants. This poses a different set of challenges when determining responsibilities for disclosing research findings. First, it may be harder to argue that researchers working with pre-existing data collections hold a duty of care to participants, especially one analogous to that of a healthcare professional. Second, there is the question of *who* is responsible for disclosure: is it those who originally collected materials, manage this resource or generate the findings? Third, if consent is only sought when the data or tissues are originally collected, it is implausible that a one-off procedure could address in detail all future research uses, let alone the characteristics, of all future findings.[25] And finally, in these circumstances, disclosure may be more resource-intensive where, for example, much time has elapsed or datasets have been anonymised. These observations underscore the problems of thinking of 'health research' as a homogenous category in which the respective roles and expectations of researchers and participants are uniform and easily characterised, and ethical responsibilities attach rigidly to professional identities.

Finally, it is also instructive to attend to shifts in wider cultural and legal norms surrounding our relationships to information about ourselves and the increasing emphasis on informational autonomy, particularly with respect to accessing and controlling information about our health or genetic relationships. There is increased legal protection of informational interests beyond clinical actionability, including the interest in developing one's identity, and in reproductive decision-making.[26] For example, European human rights law has recognised the right to access to one's health records and the right to know one's genetic origins as aspects of the Article 8 right to respect for private life.[27] And in the UK, the legal standard for information provision by healthcare professionals has shifted from one determined by professional judgement, to that which a reasonable patient would wish to know.[28]

When taken together, the factors considered in this section provide persuasive grounds for looking beyond professional identities, clinical utility and one-off consent and information transactions when seeking to achieve ethically defensible feedback of research findings. In the

[24] Laurie and Sethi, 'Towards Principles–Based Approaches'.

[25] G. Laurie and E. Postan, 'Rhetoric or Reality: What Is the Legal Status of the Consent Form in Health-Related Research?', (2013) *Medical Law Revue*, 21(3), 371–414.

[26] *Odièvre v. France* (App. no. 42326/98) [2003] 38 EHRR 871; *ABC v. St George's Healthcare NHS Trust & Others* [2017] EWCA Civ 336.

[27] J. Marshall, *Personal Freedom through Human Rights Law?: Autonomy, Identity and Integrity Under the European Convention on Human Rights* (Leiden: Brill, 2008).

[28] A. M. Farrell and M. Brazier, 'Not So New Directions in the Law of Consent? Examining *Montgomery v Lanarkshire Health Board*', (2016) *Journal of Medical Ethics*, 42(2), 85–88.

next section, I will present an argument for grounding ethical policies and practices upon the research participants' informational interests.

23.4 RE-FOCUSING ON PARTICIPANTS' INTERESTS

What emerges from the picture above is that the respective identities and expectations of researchers and participants are changing, and with them the relationships and interdependencies between them. Some of these changes render research relationships more intimate, akin to clinical care, while other makes them more remote. And the roles that each party fulfils, or are expected to fulfil, may be ambiguous. This lack of clarity presents obstacles to relying on prior distinctions and definitions and raises questions about the continued legitimacy of some existing guiding principles.[29] Specifically, it disrupts the foundations upon which disclosure of individually relevant results might be premised. In this landscape, it is no longer possible or appropriate – if indeed it ever was – simply to infer what ethical feedback practice would entail from whether not an actor is categorised as 'a researcher'. This is due not only to ambiguity about the scope of this role and associated responsibilities. It also looks increasingly unjustifiable to give only secondary attention to the nature and specificity of participants' interests: to treat these as if they are a homogenous group of narrowly health-related priorities that may be honoured, provided doing so does not get in the way of the goal of generating generalisable scientific knowledge. There is a need to revisit the nature and balance of private and public interests at stake. My proposal here is that participants' informational interests, and researchers' particular capacities to protect these interests, should comprise the heart of ethical feedback practices.

There are several reasons why it seems appropriate – particularly now – to place participants' interests at the centre of decision-making about disclosure. First, participants' roles in research are no less in flux than researchers'. While it may be true that the inherent value of any findings to participants – whether they might wish to receive them and whether the information would be beneficial or detrimental to their health, well-being, or wider interests – may not be dramatically altered by emerging research practices, their motivations, experiences and expectations of taking part may well be different. In the landscape sketched above, it is increasingly appropriate to think of participants less as passive subjects of investigation, but rather as partners in the research relationship.[30] This is a partnership grounded in the contributions that participants make to a study and in the risks and vulnerabilities incurred when they agree to take part. The role of participant-as-partner is underscored by the rise of the idea that there is an ethical 'duty to participate'.[31] This idea has escaped the confines of academic argument. Implications of such a duty are evident in in public discourse concerning biobanks and projects such as *100,000 Genomes*. For example, referring to that project, the (then) Chief Medical Officer for England has said that to achieve 'the genomic dream', we should 'agree to use of data for our own benefit and others'.[32] A further compelling reason for placing the interests of participants at the centre of

[29] G. Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-Between?', (2016) *Medical Law Review*, 25 (1), 47–72.

[30] J. Kaye et al., 'From Patients to Partners: Participant-Centric Initiatives in Biomedical Research', (2012) *Nature Reviews Genetics*, 13(5), 371.

[31] J. Harris, 'Scientific Research Is a Moral Duty', (2005) *Journal of Medical Ethics*, 31(4), 242–248.

[32] S. C. Davies, 'Chief Medical Officer Annual Report 2016: Generation Genome', (Department of Health and Social Care, 2017), p. 4.

return policies is that doing so is essential to building confidence and demonstrating trustworthiness in research.[33] Without this trust there would be no participants and no research.

In light of each of these considerations, it is difficult to justify the informational benefits of research accruing solely to the project aims and the production of generalisable knowledge, without participants' own core informational interests inviting corresponding respect. That is, respect that reflects the nature of the joint research endeavour and the particular kinds of exposure and vulnerabilities participants incur.

If demonstrating respect was simply a matter of reciprocal recognition of participants' contributions to knowledge production, then it could perhaps be achieved by means other than feedback. However, research findings occupy a particular position in the vulnerabilities, dependencies and responsibilities of the researcher relationship. Franklin Miller and others argue that researchers have responsibilities to disclose findings that arise from a particular *pro tanto* ethical responsibility to help others and protect their interests within certain kinds of professional relationships.[34] These authors hold that this responsibility arises because, in their professional roles, researchers have both privileged access to private aspects of participants' lives, and particular opportunities and skills for generating information of potential significance and value to participants to which they would not otherwise have access.[35] I would add to this that being denied the opportunity to obtain otherwise inaccessible information about oneself not only fails to protect participants from avoidable harms, it also fails to respect and benefit them in ways that recognise the benefits they bring to the project and the vulnerabilities they may incur, and trust they invest, when doing so.

None of what I have said seeks to suggest that research findings should be offered without restriction, or at any cost. The criteria of 'validity, value and volition' continue to provide vital filters in ensuring that information meets recipients' interests at all. However, providing these three conditions are met, investment of research resources in identifying, validating, offering and communicating individually relevant findings, may be ethically justified, even required, when receiving them could meet non-trivial informational interests. One question that this leaves unanswered, of course, is what counts as an interest of this kind.

23.5 A WIDER CONCEPTION OF VALUE: RESEARCH FINDINGS AS NARRATIVE TOOLS

If responsibilities for feedback are premised on the value of particular information to participants, it seems arbitrary to confine this value solely to clinical actionability, unless health-related interests are invariably more critical than all others. It is not at all obvious that this is so. This section provides a rationale for recognising at least one kind of value beyond clinical utility.[36]

It is suggested here that where research findings support a participant's abilities to develop and inhabit their own sense of who they are, significant interests in receiving these findings will be engaged. The kinds of findings that could perform this kind of function might include, for example, those that provide diagnoses that explain longstanding symptoms – even where there is no effective intervention – susceptibility estimates that instigate patient activism, or indications

[33] Wolf et al., 'Mapping the Ethics'.

[34] F. G. Miller et al., 'Incidental Findings in Human Subjects Research: What Do Investigators Owe Research Participants?', (2008) *The Journal of Law, Medicine & Ethics*, 36(2), 271–279.

[35] Ibid.

[36] In Chapter 39 of this volume, Shawn Harmon presents a parallel argument that medical device regulations are similarly premised on a narrow conception of harm that fails to account for identity impacts.

of carrier status or genetic relatedness that allow someone to (re)assess of understand their relationships and connections to others.

The claim to value posited here goes beyond appeals to 'personal utility', as commonly characterised in terms of curiosity, or some unspecified, subjective value. It is unsurprising that, thus construed, personal utility is rarely judged to engage sufficiently significant interests to warrant the effort and resources of disclosing findings.[37] However, the claim here – which I have more fully discussed elsewhere[38] – is that information about the states, dispositions and functions of our bodies and minds, and our relationships to others (and others' bodies) – such as that conveyed by health research findings – is of value to us when, and to the extent that, it provides constitutive and interpretive tools that help us to develop our own narratives about who we are – narratives that *constitute* our identities.[39] Specifically, this value lies not in contributing to just *any* identity-narrative, but one that makes sense when confronted by our embodied and relational experiences and supports us in navigating and interpreting these experiences.[40] These experiences include those of research participation itself. A coherent, 'inhabitable' self-narrative is of ethical significance, because such a narrative is not just something we passively and inevitably acquire. Rather, it is something we develop and maintain, which provides the practical foundations for our self-understanding, interpretive perspective and values, and thus our autonomous agency, projects and relationships.[41] If we do indeed have a significant interest in developing and maintaining such a narrative, and some findings generated in health research can support us in doing so, then my claim is that these findings may be at least as valuable to us as those that are clinically actionable. As such, our critical interests in receiving them should be recognised in feedback policies and practices.

In response to concern that this proposal constitutes an unprecedented incursion of identity-related interests into the (public) values informing governance of health research, it is noted that the very act of participating in research is already intimately connected to participants' conceptions of who they are and what they value, as illustrated by choices to participate motivated by family histories of illness,[42] or objections to tissues or data being used for commercial research.[43] Participation already impacts upon the self-understandings of those who choose to contribute. Indeed, it may often be seen as contributing to the narratives that comprise their identities. Seen in this light, it is not only appropriate, but vital, that the identity-constituting nature of research participation is reflected in the responsibilities that researchers – and the wider research endeavour – owe to participants.

23.6 REVISITING ETHICAL RESPONSIBILITIES FOR FEEDING BACK FINDINGS

What would refocusing ethical feedback for research findings to encompass the kinds of identity-related interests described above mean for the responsibilities of researchers and others? I submit

[37] Eckstein et al., 'A Framework for Analyzing'.
[38] E. Postan, 'Defining Ourselves: Personal Bioinformation as a Tool of Narrative Self-Conception', (2016) *Journal of Bioethical Inquiry*, 13(1), 133–151.
[39] M. Schechtman, *The Constitution of Selves* (New York: Cornell University Press, 1996).
[40] Postan, 'Defining Ourselves'.
[41] C. Mackenzie, 'Introduction: Practical Identity and Narrative Agency' in K. Atikins and C. Mackenzie (eds), *Practical Identity and Narrative Agency* (Abingdon: Routledge, 2013), pp. 1–28.
[42] L. d'Agincourt-Canning, 'Genetic Testing for Hereditary Breast and Ovarian Cancer: Responsibility and Choice', (2006) *Qualitative Health Research*, 16(1), 97–118.
[43] P. Carter et al., 'The Social Licence for Research: Why *care.data* Ran into Trouble', (2015) *Journal of Medical Ethics*, 41(5), 404–409.

that it entails responsibilities both to look beyond clinical utility to anticipate when findings could contribute to participants' self-narratives and to act as an interpretive partner in discharging responsibilities for offering and communicating findings.

It must be granted that the question of when identity-related interests are engaged by particular findings is a more idiosyncratic matter than clinical utility. This serves to underscore the requirement that any disclosure of findings is voluntary. And while this widening of the conception of 'value' is in concert with increasing emphasis on individually determined informational value in healthcare – as noted above – it is not a defence of unfettered informational autonomy, requiring the disclosure of whatever participants might wish to see. In order for research findings to serve the wider interests described above, they must still constitute meaningful and reliable biomedical information. There is no value without validity.[44]

These two factors signal that the ethical responsibilities of researchers will not be discharged simply by disclosing findings. There is a critical interpretive role to be fulfilled at several junctures, if participants' interests are to be protected. These include: anticipating which findings could impact on participants' health, self-conceptions or capacities to navigate their lives; equipping participants to understand at the outset whether findings of these kinds might arise; and, if participants choose to receive these findings, ensuring that these are communicated in a manner that is likely to minimise distress, and enhance understanding of the capacities and limitations of the information in providing reliable explanations, knowledge or predictions about their health and their embodied states and relationships. This places the researcher in the role of 'interpretive partner', supporting participants to make sense of the findings they receive and to accommodate – or disregard – them in conducting their lives and developing their identities.

This role of interpretive partner represents a significant extension of responsibilities from an earlier era in which a requirement to report even clinically significant findings was questioned. The question then arises as to who will be best placed to fulfil this role. As noted above, dilemmas about *who* should disclose arise most often in relation to secondary research uses of data.[45] These debates err, however, when they treat this as a question focused on professional and institutional duties abstracted from participants' interests. When we attend to these interests, the answer that presents itself is that feedback should be provided by whoever is best placed to recognise and explain the potential significance of the findings to participants. And it may in some cases be that those best placed to do this are not researchers at all, but professionals performing a role analogous to genetic counsellors.

Even though the triple threshold conditions for disclosure – validity, value and volition – still apply, any widening of the definition of value implies a larger category of findings to be validated, offered and communicated. This will have resource implications. And – as with any approach to determining which findings should be fed-back and how – the benefits of doing so must still be weighed against any resultant jeopardy to the socially valuable ends of research. However, if we are not simply paying lip-service to, but taking seriously, the ideas that participants are partners in, not merely passive objects of, research, then protecting their interests – particularly those incurred through participation – is not supererogatory, but an intrinsic part of recognising their contribution to biomedical science, their vulnerability, trust and experiences of contributing. Limiting these interests to receipt of clinically actionable findings is arbitrary and

[44] E. M. Bunnik et al., 'Personal Utility in Genomic Testing: Is There Such a Thing?', (2014) *Journal of Medical Ethics*, 41(4), 322–326.

[45] S. M. Wolf et al., 'Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets', (2012) *Genetics in Medicine*, 14(4), 361–384.

out of step with wider ethico-legal developments in the health sphere. Just because these findings arise in the context of health research is not on its own sufficient reason for interpreting 'value' solely in clinical terms.

23.7 CONCLUSION

In this chapter, I have argued that there are two shortcomings in current ethical debates and guidance regarding policies and practices for feeding back individually relevant findings from health research. These are, first, a focus on the responsibilities of actors for disclosure that remains insufficiently grounded in the essential questions of when and how disclosure would meet core interests of participants; and, second, a narrow interpretation of these interests in terms of clinical actionability. Specifically, I have argued that participants have critical interests in accessing research findings where these offer valuable tools of narrative self-constitution. These shortcomings have been particularly brought to light by changes in the nature of health research, and addressing them becomes ever more important as the role participants evolves from one of an object of research, to active members of shared endeavours. I have proposed that in this new health research landscape, there are not only strong grounds for widening feedback to include potentially identity-significant findings, but also to recognise the valuable role of researchers and others as interpretive partners in the relational processes of anticipating, offering and disclosing findings.