

Neurol. 67, 258–260; 2010). Instead, most alterations simply inserted standardized institutional language — unrelated to the proposed study — to the informed-consent document signed by research participants before they enter a trial. The total cost of all that review: more than US\$100,000.

On 3 December, the US National Institutes of Health (NIH) announced a draft policy intended to reduce that redundancy. Open for comment until 29 January, the proposal would require NIH-funded trials that are conducted at more than one site to be approved by a single institutional review board (IRB), which must be willing to shoulder responsibility for all of the sites. The intention is to speed up the approval process for trials that are conducted at multiple facilities. At present, each site may take a crack at reviewing a protocol, often delaying the start of a trial and introducing potential inconsistencies in study protocols and consent forms at different sites.

The NIH's move is the latest in a string of efforts by US regulators to change this institutional practice. In 2006, the US Food and Drug Administration released guidance for clinical trials conducted at multiple sites. In it, the agency stated that this ethical review need not take place at every institution. Instead, each trial could designate an institution to conduct a central review for all participating sites. Four years later, the US Office of Human Research Protections wrote a letter stating its support for that guidance. Despite these assurances, however, it has been difficult to change entrenched institutional practices that have been solidified for more than 40 years.

The NIH's proposal does not prohibit any participating site from conducting its own review, but clearly frowns on the practice — and explicitly pushes the cost of a duplicate review onto the institution.

Inertia is difficult to overcome, particularly at large institutions and with such a valuable resource at stake. Much of this stubbornness is due to an understandable desire by investigators to protect their patients and community. Some local IRB members feel that abdicating their review of research protocols is a violation of their responsibility to that community, and worry that standards will slip if they do not personally review the study.

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As the NIH has said, there is no evidence that multiple ethics reviews enhance protections for human subjects. Centralized review may seem to save time and money, but there is no clear evidence that it protects study subjects any better. Still, the NIH's move to encourage central review is the right one, given the available evidence.

Regulations that favoured local IRB reviews were developed in an era when studies were typically done at a single site. This is no longer the case. As therapies become more tailored to individual genetics, and diseases are subdivided into rarer subtypes, more sites are needed to enrol enough patients to evaluate an intervention.

Around the world, DNA sequencing labs are generating reams of genetic data that could hold the clues to the next medical revolution. Finding those clues quickly and ethically will require studies that combine data from across the globe. Investigators are clamouring for unified informed-consent documents that will allow them to compile genetic information into databases without creating a legal thicket of differing privacy protections. The NIH's move is an important step in that direction, but there is much farther to go. ■

Protect and serve

Nations must keep expanding conservation efforts to avoid a biodiversity crisis.

There are 22,413 species deemed at risk of extinction by the International Union for Conservation of Nature (IUCN). If some ambitious person tried to read out their names — without any breaks for food or water — it would take at least half a day. But that would be just the start. The IUCN has assessed the status of only 76,199 of the 1.7 million species of animals, plants, fungi and protists on Earth that have been described by scientists. And some suggest that at least five times more species still wait to be discovered. Many of these are also threatened, and it would take months to read out all of their names. (Except that they do not, of course, have names.)

There remain vast gaps in knowledge about the planet's biodiversity — and the precarious state of life. Every day, animals and plants go extinct. Nobody knows exactly how many, but estimates range from 500 to 36,000 extinctions per year. A News Feature on page 158 draws together some of the best studies of biodiversity and tries to make such vast numbers fathomable.

Before human populations swelled to the point at which we could denude whole forests and wipe out entire animal populations, extinction rates were at least ten times lower. And the future does not look any brighter. Climate change and the spread of invasive species (often facilitated by humans) will drive extinction rates only higher.

The pace of extinction is leading towards a crisis. If all currently threatened species were to go extinct in a few centuries and that rate continued, the die-offs would soon reach the level of a mass extinction — the kind of biological catastrophe that ended the reign of the dinosaurs and that has happened only five times in Earth's history. The sixth mass extinction could come in a couple of centuries or a few millennia, but it lies somewhere in the future if nations keep to their present course.

There are some hopeful signs. Countries are rapidly expanding the areas they shield from destructive human activities. The United Nations Environment Programme (UNEP) announced last month that countries have set aside 6.1 million square kilometres of ocean and land habitat since 2010, which increases the total protected areas to 15.4% of Earth's land and 3.4% of its oceans. According to UNEP, countries are on track to meet a 2020 goal established under the Convention on Biological Diversity to protect 17% of land areas, although reaching the 10% target for coastal and marine regions will require further efforts. The total areas set aside now equal the size of Africa.

But these efforts are not enough. Many protected zones are ‘paper parks’, where hunting, fishing and habitat destruction continue apace because of lax enforcement. And most parks established so far do not protect the most crucial areas — the ones full of threatened species and habitats. Nations are also investing much less on protection than they were 15 years ago, after adjustments are made for inflation.

In the face of this uncertainty about biodiversity, what should the world do? UNEP estimates that it would take US\$76 billion each year to establish and manage a set of expanded parks that protect important habitats for all wildlife groups. That figure is just as unfathomable as the number of species on the planet. But consider that a blockbuster video game can sell \$500 million in copies in a single day. According to UNEP, the economic benefits of protected areas far outweigh their costs, which could be met through a mixture of conventional sources and innovative funding mechanisms, such as green taxes and payments for the services that ecosystems provide.

As part of this protection effort, nations also need to devote more resources to taking stock of life. The IUCN has set a 2020 goal of assessing 160,000 species, roughly double the current number, which it calculates would cost \$60 million and cover a good representation of most major taxonomic groups and ecosystems. The job of counting and evaluating is not the most exciting science. But it is one of the most fundamental and important tasks that humans can do — to take a measure of life and protect what remains before it disappears. ■

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