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# A Short Guide to Peer-Reviewed Publishing

## Global Health Fellows Program

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## Goal

This guide is designed to help Global Health Fellows and others at USAID to think about opportunities for publishing research, reviews, commentary, and experience from their professional work in peer-reviewed journals. It provides:

- I. A general set of questions to ask about the research materials or professional experience that might be publishable material;
- II. A discussion of options for developing that material into publishable form;
- III. Steps to take in the process of moving from drafts to published articles;
- IV. An annex of journals; and
- V. Guidelines regarding research involving human subjects.



## I. Questions

### *Why publish?*

If USAID staff is to provide technical leadership in the area of global health, publishing is one of the more useful means of demonstrating important ideas, research, and experience. The following quote from Gloria Steele demonstrates that the Bureau for Global Health actively supports publication in addition to other means of demonstrating technical leadership:

"A critical function of technical staff in the Bureau for Global Health is to provide technical leadership. It is essential that our staff demonstrate such leadership and continually develop their technical expertise. One way to show and develop technical leadership is by publishing, especially in peer-reviewed journals. Other ways which I also strongly support include providing input into book chapters and websites, writing technical briefs, and making technical presentations at national and international fora."

*Gloria Steele, Senior Deputy Assistant Administrator, Bureau for Global Health, 2010*

For Global Health Fellows in particular, publishing while working for USAID may also be useful in their post-fellowship careers outside the agency.

### *Why publish in peer-reviewed journals?*

While the peer-review process is not without flaws, publication in peer-reviewed journals is considered the "gold standard." The rigorous vetting process gives peer-reviewed publications more credibility than non-peer-reviewed publications. Articles published in peer-reviewed journals will have been reviewed and evaluated by several experts in the

field. In most cases, the review process is double-blind.<sup>1</sup> That is, the authors of the papers will not know who the reviewers are, and the reviewers are not told who wrote the paper. The anonymous review process enables reviewers to be very frank in their comments.

Although the exact procedures vary from journal to journal, it is common for a manuscript to be reviewed by three independent reviewers. In other words, for a manuscript to get published in a peer-reviewed journal, the author(s) will need to convince both the reviewers and the editor that the paper merits publication.

That being said, it is widely recognized that there are substantial differences in the quality and prestige of different peer-reviewed journals. The more prestigious the journal, the more manuscripts it will receive. This enables prestigious journals to be extremely selective about which manuscripts they accept for publication. Some journals accept as few as 15% of all manuscripts that are submitted. Journals that are not as prestigious tend to receive fewer manuscripts and therefore tend to have a higher acceptance rate.

Nevertheless, publishing in journals that are not peer-reviewed but have wide distribution may also be a useful means of getting out your ideas, research, and experience. An example is *Entre Nous*, a reproductive health journal. Usually these journals have some quality control by editors and have some respect in the international health community.

### ***Do you have the time to prepare a manuscript for publication?***

At USAID, although the focus of work has been on guiding the implementation of international health development work in partnership with the private sector, there is now renewed emphasis on providing leadership in the global health arena. As Senior Deputy Assistant Administrator Gloria Steele notes above, one of the major means of exercising leadership is through publications, which disseminate your ideas and experience out into a broad audience through a respected channel of information. Given heavy workloads in the management of projects, providing technical support to the field, and in coordinating with other donors and agencies, and with few explicit incentives for publications currently reflected in performance reviews, it is important to take your own initiative to develop publishable materials and to find the time to produce quality work. Check with your supervisor (Onsite Managers for Fellows or Point of Contact for contract staff) to see if they are willing to ensure you have the time and to consider publications as part of your performance review. If you are the Technical Advisor on a project, consider participating in writing up evaluations and research for publication. Having USAID staff as a member of a group writing for publication with partners is relatively new territory, so be aware of the partners' sensitivities.

Many professionals (and indeed, many academics) find that they simply have to use their personal time (evenings, weekends, vacations) for working on research and publications.

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<sup>1</sup> There are exceptions to this general rule. For example, the online journal *BioMed Central Public Health* informs reviewers who the author of the manuscript is. However, unlike most journals, they also publish the reviewers comments (and the names of the reviewers), as well as the author's reply to those comments. Because this entire exchange is available to the readers, the review process is extremely transparent. This transparency adds rigor and objectivity to the review.

This investment might be particularly useful for Fellows who are thinking of a more academic or a consulting career after their fellowships end. In any case, you should consider how important or satisfying having something of your own published is relative to your other personal goals and, if it is important, make the time to do it.

### ***What does publishing cost?***

Most journals make money by selling subscriptions and advertisements. Such journals typically do not charge a fee for publishing an article. Some journals may charge a fee if you are publishing research sponsored by a funding agency that explicitly allows payment of publication fees, as is the case with most grants from the National Institutes of Health.

More recently, a new group of web-based “Open Access” journals have emerged. The philosophy of the journals is that everyone should have free access to the content of the journals. The group BioMed Central (BMC) publishes a large number of such journals. One of the major advantages of this approach is that a much wider group of readers will have access to the articles published in the journal. Thus, while subscription fees for many journals tend to restrict access to readers from developing countries, readers all over the world will be able to download articles from Open-Access journals.

Because Open-Access journals do not derive income from subscriptions, they often charge a fee to have a paper published in the journal. For example, as of September 2009, the standard article processing fee for journals published by BioMed Central was \$1,535. (Note that a few BMC journals have a different fee.) Although this fee is hefty, it needs to be considered in the context of the importance of providing wide access to readers in developing countries. If providing access to developing country readers is important to your project donor, then the donor may be willing to authorize use of project funds to pay for article processing fees. Alternatively, it may be possible for Fellows to get authorization to use their professional development funds for this purpose.

### ***Do you have something that is publishable?***

This is a complex question and one that requires thoughtful assessment of the research or professional experience you have. The requirements for publishable research are usually quite different than the requirements for reporting on professional experience. Nevertheless, most journal editors will be concerned with the following issues when making decisions about which manuscripts to accept for publication:

- Is the topic of the manuscript of interest to the readers of the journal?
- Does the manuscript make a significant contribution to the current state of knowledge?
- Is the manuscript (and the data or program experience it is based on) of sufficiently high quality?



## **II. Options for developing your material into publishable form**

### ***Publishable research***

Publishable research requires a clear, well thought-out “research question.” Usually this begins with a review of literature about the topic you are interested in to see what problems are worth researching and how your research might contribute to pushing knowledge beyond what already exists. Often research is best presented as clearly defined hypotheses derived from a combination of theory (what you might logically expect) and evidence from cases. Often USAID projects involve operations research that addresses key issues that have clearly defined research questions.

Another source of research might be data that are collected for monitoring and evaluation of project impact. While the research question for this is not usually tied to existing literature, it focuses on a variety of potential project outputs or outcomes which can often be rephrased in terms of a clear research question. However, a major problem for finding publishable material from monitoring and evaluation data is the failure to collect data from “controls” or similar units (districts, facilities, etc.) which did not receive the project interventions. Most outlets for scientific publication would require control groups in any type of research design.

You should look at the recent literature on the topic on which you are planning to publish to determine the type of analysis that would contribute to that literature. Specific areas to explore include the methodologies of data collection, analysis, and presentation that are expected – especially for scientific journal articles. Each journal will have different expectations for the type of research, methods, and presentation. Some journals accept simple cross tabs and bar charts for some types of analysis while others usually require more sophisticated regression or econometric analysis and tables. You need to adjust your research material to these expectations or find a journal that accepts the methodology that fits your skills, interest, or appropriate data. Scientific journals that publish on subjects for which USAID projects might provide research data include *Social Science and Medicine*; *Health Policy and Planning*; *Bulletin of the World Health Organization*; *American Journal of Public Health*; *Journal of Epidemiology and Community Health*; *AIDS and Behavior*; *Reproductive Health Matters*; and *Reproductive Health*.

### ***Research involving human subjects***

It is extremely important – if your research involves interviewing or clinical information on human subjects – to include in your initial research design appropriate wording and practice that protects those subjects from any unintended harm and gets their informed

consent to participate. Fellows should check with GHFP Project staff because the Public Health Institute (PHI) has its own Institutional Review Board (IRB) for PHI employee-researchers. The PHI IRB is charged with reviewing your protocols and instruments to determine whether to give approval. It is important to get this approval before you start the research and to keep the IRB informed of any changes or lapses in the approved protocols as the research is implemented. All federally funded projects require this approval and most journals require that you have IRB approval to publish this kind of research. (*See annex for more detail.*)

### ***Reviews, commentary, and summaries***

In addition to primary research, there is also wide interest in short articles that review, summarize, or comment on important public health and reproductive health issues with evidence and arguments for improved policies and implementation in areas that USAID officials are working. Often medical journals like *The Lancet* or *British Medical Journal* have special sections on commentary or correspondence that give a venue for publications of this type. These articles usually review several previously published articles or project reports in order to bring attention to recent research or experience about issues such as HIV/AIDS, domestic violence, results of DHS surveys, etc. In addition, reports on conferences or workshops may also be publishable.

### ***Publishable professional experience***

While most opportunities for publications are in the area of scientific research, there is a growing interest in sharing information based on “best practices” that come from experienced professionals who have deep knowledge of their areas of expertise and/or are reporting on projects or program experience that have not had sufficient time to be the subject of a scientific impact evaluation.

In thinking about publishing findings from your professional experience, it is important to think about what is important or unique about your experience. Do you have something to share that would be considered a new “state of the art” or a “best practice” that readers would find interesting? What kinds of lessons do you have to make the professional work of others more effective? What is unique about your own experience? It could be a single experience that illustrates a successful approach to a specific kind of technical or programmatic problem or an accumulation of your experiences in an area that gives you a unique perspective or ability to identify different contexts in which different approaches work.



### III. Steps in the peer-reviewed publishing process

The typical process for publishing in peer-reviewed journals involves the steps described in this section. Please note that the advice given below is primarily for publishing research. Some of the advice is also useful for publishing on professional experience; however, the guidance on

journal websites may be less specific and the rigor of reviews will be less involved than for publishing on methodological issues. (*See websites in Annex.*)

#### ***Determine authorship according to journal guidelines***

Some of your research opportunities may involve other researchers, as is often the case on USAID projects that include contractors. If you are interested in publishing research that others will contribute to or even lead, it is important to discuss authorship and responsibilities early on in the project so that there are clear expectations.

There are no clear standards for authorship. However, a number of journals provide guidance on the minimum criteria for authorship. For example, the *American Journal of Public Health*<sup>2</sup> and *BMC Public Health*<sup>3</sup> require that each author listed on the manuscript has participated significantly in the development of the article to take responsibility for its content and be willing to provide any relevant data upon request. The *American Journal of Public Health* requires each author to certify that they have substantially contributed to each of the following:

- The conception and design of analysis and interpretation of data;
- The drafting or revision of the manuscript, and
- The approval of the final version.

*BMC Public Health* has very similar requirements. People who have contributed to the manuscript, but who do not meet these criteria, should not be listed as authors. Instead, they should be mentioned in the “Acknowledgments” section of the manuscript.

Authorship is a matter of ethics. While it is generally recognized that it would be unethical not to give adequate credit to a contributor, it is equally unethical to give authorship to people who did not make a substantial contribution to the manuscript. A number of journals (e.g., the *American Journal of Public Health*, *BMC Public Health*) require that the manuscript includes a note that clarifies the exact contribution of each of the authors.

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<sup>2</sup> <http://www.ajph.org/misc/ifora.pdf>

<sup>3</sup> <http://www.biomedcentral.com/bmcpublichealth/ifora/>

In addition to deciding who is an author and who is not, one must determine the order in which the authors are listed. Especially in academic circles, the order of authors is often an important indication of responsibility for ideas, methodology, and writing. Often the initiator of the research – the one with the central conceptual ideas and clear role in determining the methodology and responsibility for overall quality – is the first author. Then credit is given for the authors who do most of the writing. There is little problem if the conceptual leader also writes the bulk of the article but if this is not the case, then it is important to define clearly how the order of authorship will be determined. One option, after determining the first author, is to list the co-authors in alphabetical order if all have made similar contributions.

### ***Select the outlet for publication of research studies***

Once you have an initial draft manuscript, your next step is to decide which journal is the most relevant for the type of research or work being reported on and which journal is most likely to accept your research topic and methodology. It is useful to try to submit to the more rigorous peer reviewed journals because citations from these journals are the most respected, are the most often cited in reports and other journals, and gain the most visibility.

For instance, the more rigorous your methodology and the more important the topic, you might consider *Social Science and Medicine*, which tends to have very rigorous standards for publication. *Health Policy and Planning* is also quite demanding, but is oriented toward more practical and policy related issues. (Full disclosure, one of the authors of this piece is on the editorial board of *HPP*).

If you are interested in publishing something that is very timely, you might want to check with the journal to see what their average period between submission and publication is because some journals have a long wait time for publication. (You can check the websites in the Annex of this piece for estimates of periods for each journal.)

Some types of published research, even in peer reviewed scientific journals, are not elaborate full articles reporting on completed research. Your material may merit consideration if it presents a specific research problem or methodology or reports on problems of data collection. Check journal sections that present short reports for examples of this type of published research.

It is generally expected that you will only submit your manuscript to one journal, and only if it is rejected would you submit it to another journal. Most journals require a specific statement to this effect.

### ***Prepare the manuscript on research studies***

Once you have decided to which journal you will submit the manuscript, the authors will need to format the manuscript according to the “guidelines for authors” for the selected journal. It is usually best to review the format requirements of the journal you select and



put your manuscript into that format from the beginning<sup>4</sup>. Pay attention to word or page limitations, double spacing, footnote or end note formats, format and word limits for abstracts, etc. It is easy for reviewers and editors to reject manuscripts because they are not in the acceptable format. You should note that some – but not all – journals will refuse to review papers that exceed the stated word limit. Journals that are picky about this often require that the cover page of the paper include the word count.

Many research manuscripts follow a standard sequence:

- Introduction to why the problem is important – usually with a review of recent literature
- Specific research questions and hypotheses and discussion of their importance and characteristics
- Discussion of the design, the methodology, and the data to be collected
- Presentation of basic findings and results
- Discussion of the meaning and interpretation of the findings, including in relation to what others may have published on the same or similar topics
- Conclusion – often with policy implications
- References/bibliography

Qualitative methodologies or think-pieces often follow different sequencing and logic.

***Clearance procedures for publications by USAID staff. (Check with GHFP project staff if you are a Fellow.)***

1. Get your Office Director's concurrence. You may first want to get your Division Chief's review and concurrence on the manuscript, especially if you want a review before going forward (although in most cases anyone preparing a manuscript for publication, or a commentary or a letter to the editor will likely already have shared it with selected colleagues for review and comment).
2. Only on a case-by-case basis or where your Office Director believes this to be prudent, get your AA or DAA approval.
3. Get LPA (PA) clearance. The point-person in LPA may change so you need to check with the GH Communications Team (Sandra Jordan for PRH, Chris Thomas for HIDN, and Jessica DiRocco for OHA). If the manuscript is outside your current area of work, you need to get the substantive office to clear the manuscript.
4. The manuscript must include the disclaimer that "the views expressed by the author(s) do not necessarily reflect those of USAID." The covering Action Memo

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<sup>4</sup> However, academics often write a draft paper and circulate it with colleagues before even deciding what journal is appropriate – but this slows the process of preparing the manuscript.

that accompanies the manuscript when seeking concurrence to publish should state the title of the manuscript or other type of publication, the authors, where it is being submitted for publication, and that the disclaimer is stated in the manuscript.

For those who want to consult the source document or to keep the basic rules at hand: <http://iapp1.usaid.gov/notices/notDetail.cfm?msgid=17383&currmo=10&curryr=2009&prevnext=no> (Only accessible to those with internal USAID access.)

### ***Who can help you publish?***

There is no formal department or office that provides specific support for publishing. Currently, Jim Shelton ([jshelton@usaid.gov](mailto:jshelton@usaid.gov)) and Jeff Spieler ([jspieler@usaid.gov](mailto:jspieler@usaid.gov)) at the Global Health Bureau have offered to help. Global Health Fellows may also find their university based “mentors” to be helpful and perhaps even serve as collaborators in their research and publishing efforts.

### ***Submit the research manuscript***

The journal website will provide you with the requirements for submission. Usually you will have to send in your manuscript electronically with a cover letter. Most journals will acknowledge receipt of the manuscript.

### ***The journal reviews the manuscript***

The editor(s) of the journal will usually vet the submission to be sure it has at least minimal quality and to select 2-3 peer reviewers to invite to review the manuscript.<sup>5</sup> Many journals have a roster of reviewers for specific topics, but they will also look at your references for clues as to reviewers who have already published in your area.

Journals have different time expectations for reviews but usually give at least a month for each reviewer to send in their reviews. Some journals have a reputation for more rapid turnaround, but others have long periods due to reviewers’ time and to backlog of accepted articles. Some journals are increasingly putting accepted articles on their websites in order to overcome backlogs in print journals. A general rule of thumb for print journals is to allow at least six months to a year from initial submission to publication, depending on how many revisions are needed during the review process.

### ***Receive reviews from the journal***

Upon receipt of the different reviews, the editor will make an initial decision about the manuscript. The reviews will be of varying quality but usually will ask for some form of revision. This is normal and you should not be insulted – it comes with the job of reviewing.

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<sup>5</sup> British journals often use an editorial committee that will pre-review the manuscripts, and only manuscripts that pass this initial pre-review will be sent out for further review.

Typically, the manuscript will be given one of the following ratings:

- Accepted
- Accepted, conditional on minor revisions
  - Even for experienced authors, it is fairly uncommon for a manuscript to be accepted (or accepted, conditional on minor revisions) the first time it is submitted.
- Revise and resubmit
  - In many cases, a manuscript will receive a “revise-and-resubmit.” This implies that the reviewers and editor believe the paper has merit, but that the manuscript may only be publishable after substantial revisions to address the reviewers’ concerns. It is an invitation to revise the manuscript and to resubmit the revised version to the same journal.
- Rejected
  - If a manuscript is rejected outright, this implies that the editor is not interested in receiving a revised version of the manuscript. This does not necessarily imply that the manuscript is weak and not publishable. It may simply indicate that the manuscript is not a good fit for that particular journal, and that it should be submitted to a different journal.

Most journals will provide the authors with a copy of the reviewers’ comments.<sup>6</sup> Because the reviewers’ comments identify the weaknesses of the manuscript, they often clarify how the analysis or manuscript can be improved.

### ***Resubmit the manuscript in response to reviewers’ comments***

#### **Resubmission to the same journal in response to “Revise and Resubmit”**

If the manuscript is re-submitted to the same journal, then it should be accompanied by a cover letter that explains how the revised manuscript has addressed the reviewers’ concerns.

You should take all reviewers’ comments, criticism, and suggestions seriously – the editors usually do, and they make the final decisions. However, you do not have to agree with all reviewer comments. The best strategy is to be respectful but to explain why, in detail, you disagree with the reviewers.

It is usually a good idea to prepare a matrix table with each of the reviewers’ comments and an explanation of what you are doing (or not doing) to respond to the comments. In most cases, the revised manuscript will be sent to the same reviewers. If the reviewers are satisfied with the changes, the manuscript will have a much better chance of acceptance. If the revised version is not accepted, then the author will need to consider whether the manuscript is suitable for submission to a different journal.

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<sup>6</sup> Note that many British-based journals do not provide the reviewers’ comments to the authors. This is a major disadvantage, because the authors cannot receive guidance on how the manuscript can be improved.

You should take care in revising the manuscript – again paying attention to format requirements – and be sure that you take care of any typos and other changes, which become more difficult to change once you get the page proofs.

### **Submission to a different journal in response to “Rejected”**

Your reaction to rejection should be balanced. You may have chosen the inappropriate journal in terms of its audience – too scientific or too general for your piece. You may have chosen a journal that has higher standards for research methodology than you were able to provide. You may have had bad luck in the draw of reviewers and gotten particularly harsh reviews or the reviewers may not have recognized the contribution of the work being presented in the manuscript.

You should consider these factors in choosing where to submit the manuscript again if you choose to do so. It is wise to change the format before submitting to a different journal or they may see that you have already been rejected.

### ***Acceptance, page proofs, and a publication date***

The journal will usually inform you of any final minor revisions required and then accept the manuscript. Once the manuscript has been accepted for publication, the journal will prepare page proofs. The page proofs show what the paper will look like in print. The authors will need to carefully check the page proofs for errors (these could be either your own errors or errors that occurred during the type-setting process) and make sure that the proofs are the best quality possible. It is often useful to have someone else go over the proofs with you carefully to catch any problems. It may also be useful for one person to read the manuscript while the other follows along on the page proofs.

The manuscript will be assigned a publication date. Many journals have a long publication queue. It is not uncommon for a paper that has been accepted to not be published until the following year.

You may also be asked how many “off prints” (or reprints) you want – they are useful if you want to have hard copies to pass out or send to colleagues or to those who helped in the research. Several journals will provide a small number of off-prints (25 to 50) for free, but larger numbers will require payment.

### ***Celebrate and put it on your CV***

After all this effort, it is advisable to make a big deal over finally getting something published. Let people know (Fellows should especially let GHFP know!), and be sure to put it on your CV/resume.

## IV. Annex of journals

(Please note this is an illustrative, not exhaustive, list of journals for your consideration.)



### *Open web-based journals*

- *Public Library of Science:* <http://www.plos.org/>
- *Human Resources for Health:* <http://www.human-resources-health.com/>
- *AIDS Research and Therapy:* <http://www.aidsrestherapy.com/>
- *HIV/AIDS - Research and Palliative Care:* <http://www.dovepress.com/aims-and-scope-hivaid---research-and-palliative-care-d157-j68>
- *Reproductive Health:* <http://www.reproductive-health-journal.com/> The official journal of the [Geneva Foundation for Medical Education and Research](#) (GFMER), a WHO collaborating centre in education and research in human reproduction. *Reproductive Health* is also affiliated with the [International Association for Maternal and Neonatal Health](#) (IAMANEH).

### *HIV/AIDS, reproductive health, epidemiological journals*

- *Journal of Epidemiology and Community Health:* <http://jech.bmj.com/>
- *AIDS and Behavior:* <http://www.springerlink.com/content/1090-7165>
- *AIDS Education and Prevention:* [www.guilford.com/pr/jnai.htm](http://www.guilford.com/pr/jnai.htm)
- *AIDS Research and Therapy:* <http://www.aidsrestherapy.com/>

- *Contraception*: <http://www.contraceptionjournal.org/>
- HIV/AIDS - Research and Palliative Care: <http://www.dovepress.com/aims-and-scope-hivaids---research-and-palliative-care-d157-j68>
- *Reproductive Health Matters*:  
[http://www.elsevier.com/wps/find/journaldescription.cws\\_home/622668/description#description](http://www.elsevier.com/wps/find/journaldescription.cws_home/622668/description#description)
- *Reproductive Health*: <http://www.reproductive-health-journal.com/>

### ***Newsletters, best practices***

- *Center for Global Development*: <http://www.cgdev.org/> Independent research and practical ideas for global prosperity. Publication ‘briefs’ can be found at <http://www.cgdev.org/content/publications/?type=48>
- HIV/AIDS & Sexual and Reproductive Health Integration (Quarterly Newsletter): <http://www.hivandsrh.org/index.php>
- Implementing Best Practices in Reproductive Health Knowledge Gateway: [http://www.ibpinitiative.org/knowledge\\_gateway.php](http://www.ibpinitiative.org/knowledge_gateway.php)

### ***Publication timelines***

- *AIDS Research and Therapy*: Publication process time varies – the website does not provide a time line. Instructions for submitting a manuscript can be found at: <http://www.aidsrestherapy.com/info/instructions/>
- *HIV/AIDS - Research and Palliative Care*: Generally peer review is complete within 2-3 weeks and the editor’s decision within 24 hours of this. It is therefore very rare to have to wait more than 4 weeks for a final decision. Peer review guidelines can be found at: [http://www.dovepress.com/peer\\_review\\_guidelines.php](http://www.dovepress.com/peer_review_guidelines.php).
- *Reproductive Health*: Instructions for submitting a manuscript can be found at: <http://www.reproductive-health-journal.com/manuscript/>
- *Health Policy and Planning*: Instructions for submitting a manuscript can be found at: [http://www.oxfordjournals.org/our\\_journals/heapol/for\\_authors/online\\_submission.html](http://www.oxfordjournals.org/our_journals/heapol/for_authors/online_submission.html)
- *Health Affairs* requires a log-in and password to view submission guidelines: <http://www.healthaffairs.org/>



## **V. Annex – Guidelines regarding research involving human subjects**

### ***Human subjects research conducted by PHI employees:***

If you intend to involve human subjects in your research activities, regardless of your funding source, you must obtain prior approval of your research protocol from the PHI Institutional Review Board (“IRB”). The purpose of the IRB is to protect human subjects from unintended harm; ensure that informed consent is obtained from research participants; and make certain that research is conducted in accordance with ethical principles and federal law.

Under federal regulation, “research” is defined as “a systematic investigation including research development, testing and evaluation, designed to contribute to generalizable knowledge.” The definition of a “human subject” is a “living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.”

Examples of activities that might, depending on particular circumstances, qualify as “research involving human subjects” include the administration of surveys, questionnaires, and interviews; epidemiological research and clinical trials in which data are extracted from public or private records and databases; when drugs or devices are given to volunteers; and ethnographic or observational studies.

It is strongly advised that you consult the PHI IRB as *early* in your research project as is feasible in order to obtain a preliminary determination about the need for full IRB review. The reasons for this are simple: (1) As a PHI employee it is your responsibility to comply with PHI’s human subjects research policies and procedures; (2) the IRB cannot issue “retrospective” approvals; and (3) it is becoming increasingly common for journals to require authors to submit proof of IRB review as a condition of publication.

All relevant information about conducting human subjects research at PHI may be accessed at PHI’s password-protected, internal website, “PHI Online Program Support” under the “Human Subjects” tab. Questions about human subjects research at PHI may be directed to Debora Pinkas, IRB Administrator, at [dpinkas@phi.org](mailto:dpinkas@phi.org).

### ***Human subjects research conducted by non-PHI employees***

If you are not a PHI employee, please ask your sponsoring institution for guidance regarding the institution’s policies and procedures relative to research involving human subjects. For USAID staff, Lee Claypool ([lclaypool@usaid.gov](mailto:lclaypool@usaid.gov)) is the current point person for this.

*Photos courtesy of ehow.com, Mountangelabbey.com and Crestock.com.*