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JATS4R Ethics Statements

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Context

<sec>, @sec-type, <p>, <named-content>, @content-type

Description

For the purpose of this recommendation, ethics statements are understood to provide information on ethical considerations relating to the conduct of the research that a publication is reporting. These include, but are not limited to, ethical considerations for studies involving both animal and human subjects. Some examples are:

- A declaration of compliance with International norms and legislations (such as the Declaration of Helsinki);
- Approvals from local, regional or National review bodies, which may or may not include board/committee names and approval numbers;
- Patient consent declarations, such as written informed consent, consent to publish, and/or parental consent;
- Declarations on handling of confidential data, and anonymization of data.

This recommendation will not deal with competing interests (conflicts of interest, https://jats4r.org/conflict-of-interest-statements), clinical trial registration (https://jats4r.org/clinical-trials), OR data availability statements (https://jats4r.org/data-availability-statements), as these are the object of separate JATS4R recommendations. If you publish documents such as Protocols, CONSORT diagrams, or PRISMA checklists, please treat as supplementary material; these are not considered as part of the ethics statement but you can reference them in the statement as required.

Additional reading

http://www.icmje.org/recommendations/browse/roles-and-responsibilities/protection-of-research-participants.html

Recommendations

DTD versions: 1.0, 1.1, 1.2

1. `<sec>`. The ethics statement SHOULD be contained within a `<sec>`. IF the section is to carry a human-readable heading use `<title>` for this rather than `<label>`.  
   ```markdown
   [Validator result: WARNING: if `<label>` present without `<title>` ]
   ```

2. `@sec-type`. The `@sec-type` attribute MUST be used to identify the section as the Ethics Statement. The value MUST be set to “ethics-statement”.  
   ```markdown
   [Validator result: ERROR: if value contains a mistyped version of ethics-statement (like Ethics-Statement etc.) ]
   ```

3. If you wish to make further distinctions or declarations within the ethics statement, the attribute values (see below) MUST always start with “ethics-” and be followed by the publisher-defined values. They MUST NOT repeat “ethics-statement”.
   
   a) If you want to specify ethics-related information at the sub-<sec> level (i.e. nested <sec>s), use `@sec-type` value of “ethics-” followed by publisher values. See Example 1.  
      ```markdown
      [Validator result: ERROR: if value =“ethics-statement” exists on sec-type (i.e appears more than once in the document); WARNING: if value other than =”ethics-” exists on sec-type nested within parent ethics <sec> ) ]
      ```

   b) If you want to specify ethics-related information at the <p> level or <named-content> level, then use `@content-type` value of “ethics-” followed by publisher values. See Example 2, and 3.  
      ```markdown
      [Validator result: ERROR: if value =“ethics-statement” exists on content-type; WARNING : if value other than =”ethics-” exists on content-type within parent ethics <sec> ) ]
      ```

   c) A suggested list of values could be: ethics-consent-to-publish, ethics-review-body, ethics-approval, ethics-approval-human, ethics-approval-animal.

4. Less preferred (this option does not guarantee machine readability): use `@content-type` attribute within the flow of text (either on <p> or <named-content>). In cases where the publisher has ethics-related text within the flow of the document, they can choose to identify the statement using `@content-type` attribute. The attribute value MUST be “ethics-statement” and/or “ethics-” followed by the publisher-defined values. See Example 6.  
   ```markdown
   [Validator result: ERROR : if value =”ethics-statement” exists on content-type; if parent ethics <sec> exists ]
   ```
Examples

Example 1. Ethics Statements in the <back> element of an article sub-divided into sections with sec-types

<back>
...  
<sec sec-type="ethics-statement">
<title>Ethics Statement</title>
<sec sec-type="ethics-consent-to-publish">
<title>Patient consent for publication</title>
<p>Not required.</p>
</sec>
<sec sec-type="ethics-approval">
<title>Ethics approval</title>
<p>Not required.</p>
</sec>
</back>

Example 2: Ethics Statements in the <body> element of an article subdivided using named-content

<body>
...  
<sec id="s2" sec-type="ethics-statement">
<title>Ethics Statement</title>
<p>All experiments were performed according to
<named-content content-type="ethics-review-body">European Union legislation and with licenses from the Danish Animal Experiments Inspectorate</named-content>. All animals were kept under standard conditions (23°C, 50% humidity, 12-h light/dark cycle) with free access to food and water. The number of animals utilized in the respective experiments was kept to a minimum, and all work was conducted in a manner designed to cause the least harm and suffering to the animals.</p>
</sec>
</body>

Example 3. Ethics Statements in the back element of an article sub-divided, not using sections and different titles

<sec id="s6" sec-type="ethics-statement">
<title>Ethics</title>
<p content-type="ethics-approval-human">Human subjects: Fresh tissue samples were obtained upon informed consent from patients undergoing surgery at the Gynecology Division of the European Institute of Oncology (Milan). Sample collection was performed under the protocol number R789-IEO approved by the Ethics Committee of the European Institute of Oncology.</p>
<p content-type="ethics-approval-animal">Animal experimentation: All animal studies were performed following a protocol approved by the fully authorized animal facility of European Institute of Oncology and by the Italian Ministry of Health (as required by the Italian Law) (IACUCs number 1256/2015) and in accordance to EU directive 2010/63. Mouse tissues were obtained from Karolinska Institutet (Stockholm, Sweden) and IRCCS San Raffaele Scientific Institute (Milan, Italy), in accordance with Institutional Animal Care and Use Committees.</p>
</sec>
Example 4. Ethics Statements in the <back> element of an article sub-divided into sections without attribution at the sub level

<back>
...
<sec sec-type="ethics-statement">
<title>Ethics Statement</title>
<sec>
<title>Patient consent for publication</title>
<p>Not required.</p>
</sec>
<sec>
<title>Ethics approval</title>
<p>Not required.</p>
</sec>
</sec>
</back>

Example 5. Ethics Statement with no subdivision

<sec id="sec2.4" sec-type="ethics-statement">
<title>2.4. Ethical Aspects</title>
<p>The study received ethical approval from the independent ethics committee of University Hospital Marburg (reference number Az. 22/11). Information about the procedure and risks were included in the patient information. Participants in the patient and control groups had to provide written informed consent.</p>
</sec>

Example 6. Least preferred option example

<sec id="sec4-9">
<title>Immunohistochemistry</title>
<p>Fresh tissue samples were obtained upon informed consent from patients undergoing surgery at the Gynecology Division of the European Institute of Oncology (Milan). Sample collection was performed under the protocol n. <named-content content-type="ethics-approval">R789-IEO approved by the Ethics Committee of the European Institute of Oncology</named-content>. The immunohistochemical analysis of L1CAM expression was carried out on a panel of high-grade serous ovarian carcinoma. ...</p>
</sec>