IRB GUIDANCE: Lay Person Summary for IRB Application

CONTENTS

Introduction ................................................................................................................................ 2
Scientific Abstract ................................................................................................................ 2
Lay-Person Summary For IRB Application ................................................................. 2
Checking Reading Grade Level ..................................................................................... 2
Examples ............................................................................................................................... 3
Scientific Abstract ................................................................................................................ 3
Lay-Person Summary ......................................................................................................... 4
Authors ....................................................................................................................................... 4
Review and Approval History ........................................................................................... 5
INTRODUCTION

Several of the SUNY Downstate Health Sciences University IRB applications forms require a lay-person summary which is different from a scientific abstract. This document outlines the key differences between the two. Both scientists and non-scientists review these documents, hence, both should have a good understanding of a project to better evaluate it.

SCIENTIFIC ABSTRACT

A scientific abstract is usually included with your proposal that is submitted to the Central Methodology Review Committee (CMRC), scientific or medical journal for publication, or in an application for funding. It will be written to address other scientists and doctors; therefore it should be written at a graduate reading level. Only obscure terms should be defined. Research methodology should be well outlined and include the various study groups/arms, sample sizes, medications doses, etc. The study goals/aims should be clearly defined. References should be included for all claims made in the abstract.

LAY-PERSON SUMMARY FOR IRB APPLICATION

A lay-person summary is submitted as part of your IRB application. It explains the nature of the study in a manner that any average person can understand, therefore it should be written at the high school reading level. It can be a little higher if all scientific and medical terms are explained. If the disease or condition is well-known in the community such as asthma, it does not require explanation. References are not required.

This is an important component of the application, as it provides a synopsis that is readily understandable to all IRB members. Remember that IRB members consist of community members and non-scientists, as well as scientists and physicians reviewing outside of their area of expertise. The synopsis will also facilitate an efficient review of follow-on submissions (such as amendments and annual renewals).

It is advisable to describe the study in general terms and not focus on the specifics. The reviewers can refer to the protocol or scientific abstract for more detail.

CHECKING READING GRADE LEVEL

Please check the reading level of your lay-person summary using the Flesch–Kincaid Grade Level metric available in Microsoft Word. To turn this feature on, use the following instructions:

- Open Microsoft Word.
- Click “File” and select “Options”
- A new window will pop-up. Select “Proofing” on the left side if this window.
- Then click “Show readability statistics”

Now, when you spell or grammar check a document, you will get readability statistics including the Flesch–Kincaid Grade Level metric. To activate this tool, you can either press F7 or go to Review > Proofing > Editor (may vary by Word version). When Word finishes checking the
spelling and grammar, click on **Total Suggestions**. You must then accept or ignore each suggestion. It will then display readability statistics (Flesch Reading Ease, Flesch-Kincaid Grade Level, and Passive Sentences).

When you see the Flesch-Kincaid Grade Level metric, it usually has a number before and after a decimal point such as 9.3. The number before the decimal point refers to the grade level. The number afterwards refers to the portion of the academic year. Thus, for a value of 9.3 the document is at a 9th grade reading level approximately at the first third of the school year. If the Flesch–Kincaid Grade Level of your abstract is above a 12, it is at an undergraduate or graduate level.

**EXAMPLES**

**SCIENTIFIC ABSTRACT**

This is an example of an abstract written at an undergraduate reading level:

Around 2.8-4.8 in 1,000 children suffer from high-functioning autistic spectrum disorder also known as high-functioning autism (HFA) (Shtayerman, 2007). These children are at an increased risk of co-morbid psychiatric disorders such as mood disorders, anxiety disorders, and suicidal ideation during the transition from teenager to young adult (Gillan & Standen, 2007; Haskins & Silva, 2006; Jennes-Coussens, Magill-Evans, & Koning, 2004; Shtayerman, 2007). This is partially due to lack of services for this particular group. Because they are high-functioning, these individuals have an Intelligence Quotient (IQ) that is normal (70 or above), and are disqualified from receiving services for the mentally disabled that they require (Haskins & Silva, 2006; Hillier, Fish, Cloppert, & Beversdorf, 2007; Minnesota Employment Policy Initiative, 2011; Muller, Schuler, Burton, & Yates, 2003). These psychiatric co-morbidities may also lead to a lack of independence related to issues of job retention, and a lower quality of life. Most of the current policies for this group are directed against discrimination such as the Americans with Disabilities Act. While this allows for job placement, in many instances employers do not make the required accommodations to help these individuals keep their jobs. Article 23 of the Universal Declaration of Human Rights states “[e]veryone has the right to work, to free choice of employment, to just and favourable conditions of work and to protection against unemployment.” For this feasibility study, 100 individuals with high-functioning autistic spectrum disorder will be studied. Factors to be considered on the survey include but are not limited to: the number of accommodations, types of accommodations, quality of life, job satisfaction, and other psychiatric conditions.

References


LAY-PERSON SUMMARY.

This is an example of a summary at a high school grade reading level:

Around 4 in 1,000 children suffer from a mild type of autism (a mental illness), called high-functioning autism (HFA). These children can lead regular lives but might face barriers due to poor social skills. These children are at a higher risk of depression during the change from teenager to young adult. This might be because of a lack of services for this group. Because they are high-functioning, they might score well on certain tests and cannot receive support for the mentally disabled. Having multiple mental illnesses (depression and HFA) may also cause a lack of independence. For example, as young adults, they might have to live with their parents longer because they cannot stay in one job. Most of the current laws for this group are directed against discrimination. While this helps in getting a job, in many cases employers do not make the required work adjustments to help these workers keep their jobs. To understand the current protection against unemployment for these workers, this study will look at 100 surveys from these workers that ask about their workplace needs and if they are being met.

References: N/A

AUTHORS

Laura Henderson
Jannette Jakus
Danielle Lewis
Kevin Nellis
## REVIEW AND APPROVAL HISTORY

Original Issue Date: 05.12.2017  
Supersedes: 05.12.2017  
Revised Date: 05.04.2022  
Effective Date: 05.04.2022

<table>
<thead>
<tr>
<th>Date Reviewed &amp; Approved</th>
<th>Revision Required</th>
<th>Responsible Staff Name and Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>05.12.2017</td>
<td>X</td>
<td>Kevin L. Nellis, MS, CIP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Executive Director, Human Research Protections and Quality Assurance</td>
</tr>
<tr>
<td>05.04.2022</td>
<td>X</td>
<td>Downstate IRB</td>
</tr>
</tbody>
</table>